“GMP, GHP, GLP Practices Relevant to Minor Forest Produce Processing. HACCP & its implementation”

“ Aakansha Management Consultancy”

Journey to food safety

Introduction of Trainer

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- 23 yrs. of experience including Mfg. and FOOD safety management
- Auditor ISO 9001, ISO 22000 , BRC and FSSC
- GMP plus International registered consultant –Netherlands for feed safety
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- WASH auditor-QCI

People have right to expect the food they eat to be safe and suitable for consumption

Food safety

What is food safety ?

Food safety is an important issue to consumers and Food business operators.

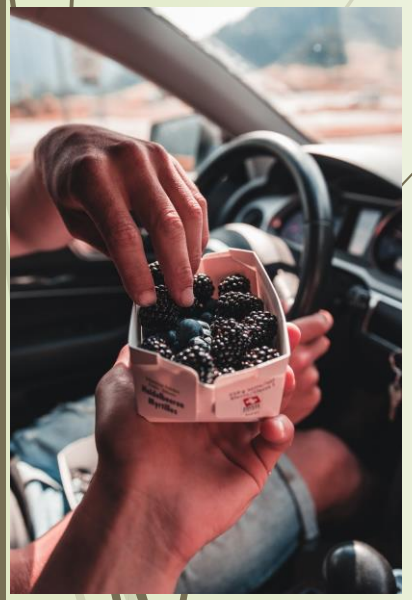
If food become unsafe, it may lead to food born illness, injury and in the worst case scenario it cause death.

Definition

assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use

Making food safe to eat free from disease causing agents (hazards)

Why do we need Food Safety?



Why do we need Food Safety ?

Because eating unsafe food leads to food borne illness.

Food borne illness and foodborne injury are at best unpleasant; at worst, they can be fatal.

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene

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Why do we need Food Safety?

But there are also other consequences.

Outbreaks of foodborne illness can damage trade, brand image and tourism, and lead to loss of economy/earnings, unemployment and litigation.

Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

Why do we need Food Safety?

- International food trade, and foreign travel, are increasing, bringing important social and economic benefits.
- But this also makes the spread of illness around the world easier.
- Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this.
- Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, food borne injury, and food spoilage.
- Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

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Responsibility

Everyone, including primary producers, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to ensure that food is safe and suitable for consumption.

Food Business Operators (FBOs) should be aware of and understand the hazards associated with the food they produce, transport, store and sell, and the measures required to control those hazards relevant to their business, so that food reaching consumers is safe and suitable for use.

Why food becomes unsafe?

A food becomes unsafe when it is attacked by biological, chemical and physical hazards

example

- Spoilage
- Adulteration
- Food poisoning
- Receiving spoiled and contaminated raw material
- Cross contamination
- Food recall
- Food frauds etc.

HACCP

HAZARD ANALYSIS CRITICAL CONTROL POINTS

Hazard analysis and critical control points, or HACCP is a systematic preventive approach to food safety from biological, chemical, physical hazards and more recently radiological hazards in production processes that can cause the finished product to be unsafe and designs measures to reduce these risks to a safe level. In this manner, HACCP attempts to avoid hazards rather than attempting to inspect finished products for the effects of those hazards. The HACCP system can be used at all stages of a food chain, from food production and preparation processes including packaging, distribution, etc

Hazards

What is Hazards?

A hazard is a potential source of harm. Substances, events, or circumstances can constitute hazards when their nature would allow them, even just theoretically, to cause damage to health, life, property, or any other interest of value. The probability of that harm being realized in a specific incident, combined with the magnitude of potential harm, make up its risk, a term often used synonymously in colloquial speech.

Codex definition

Hazard - a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

Food safety Hazards (ISO 22000:2018)

biological, chemical or physical agent in *food* (3.18) with the potential to cause an adverse health effect

Foundation

Before implementation of HACCP – HAZARD ANALYSIS CRITICAL CONTROL POINT -Food safety system

The following are the prerequisite programs to build up the foundation for food safety must be in place

GAP- Good agricultural practices

GMP- Good manufacturing practises

GHP-Good hygiene practices

GSP- Good storage practices

GLP- Good laboratory practices

GMP –Good manufacturing practices

Good Manufacturing Practices (GMP) is a system that ensures that the goods produced by various manufacturing facilities are consistently produced and controlled according to specified quality standards. There are GMP systems for everything from cosmetics to pharmaceutical products to, of course, food.

GMP looks at every aspect of the manufacturing process to guard against potential risks that can prove detrimental to the products being produced. Cross-contamination, mislabeling, and adulteration are just a few of the things GMP aims to prevent.

The FDA regulates the Current Good Manufacturing Practices (CGMP), and therefore requires companies to abide by their specified guidelines. They are considered "Current" because, as new information is discovered, the Good Manufacturing Practices released by the government will change to reflect the new finding(s).

These Practices are made to be flexible, to better allow companies to adjust them to fit their specific needs. However, to meet the GMP and CGMP guidelines, certain areas still have to be met accordingly.

GMP –Good manufacturing practices

WHY GMP IS IMP?

- GMP help ensure the proper design, monitoring, and control of the manufacturing processes and facilities.
- Companies that adhere to these standards help to assure the identity, strength, and quality of their products.
- When implemented, GMP can help to cut down on facility losses and waste and also help to protect the company, consumer, and the environment from harm.

WHAT GOES INTO GOOD MANUFACTURING PRACTICES IN FOOD INDUSTRY MANUFACTURERS?

1. Sanitation and hygiene
2. Suitable facility and locations
3. Equipment's
4. Raw material and storage
5. Personal
6. Validation and qualification
7. Complaint handling
8. Documentation and record keeping
9. Inspection and quality audits

Good hygiene practices

Good Hygiene Practices (GHPs):

Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

Good Hygiene Practices are the set of requirements to prevent contamination of food in order to provide safe food to the consumers. Food borne illnesses can result from contamination due to improper practices like when there is lack of environmental hygiene and poor sanitation. mixed and inappropriate transportation.

WHAT GOES INTO GOOD MANUFACTURING PRACTICES IN FOOD INDUSTRY MANUFACTURERS?

- Primary production
- Environmental hygiene
- Hygiene production of food sources
- Handling , storage and transport
- Cleaning , maintenance and personal hygiene
- Establishment Design and Facilities
- Control of operations
- Maintenance and sanitation
- Personal Hygiene
- Transportation
- Product information and consumer awareness
- Training

Good manufacturing practise and Good hygiene practise

- In order to avoid adverse human health and economic consequences it is absolutely follow good manufacturing practises (GMP) and good hygiene practices(GHP)
- GMP and GHPs are the general principles that lay a firm foundations to ensuring safe food.
- It is a responsibility of FBO to make sure that GMP and GHP are followed correctly.

Codex Alimentarius Commission (CAC)

Codex Alimentarius The Codex Alimentarius Commission develops and adopts food standards that serve as a reference for international food trade.

To implement HACCP in the food processing plant GMP and GHP are the general principals that lay a firm foundation to ensure food safety.

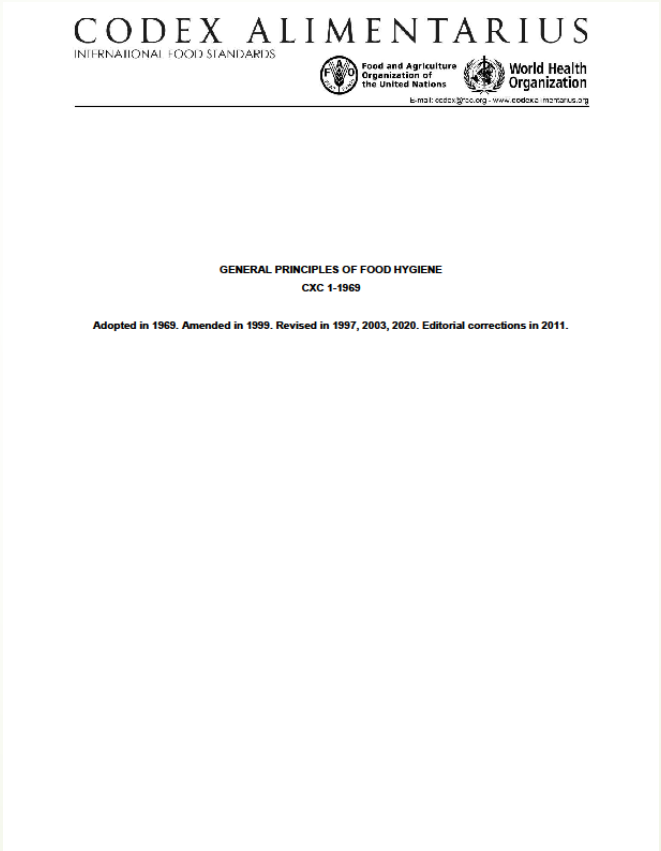
Codex Alimentarius commission has given this course of practices or prps to protect the health of customer and to ensure fare trade practices.

GENERAL PRINCIPLES OF FOOD HYGIENE

- **CXC 1-1969**
- **Adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020. Editorial corrections in 2011.**

Covers GMP and GHP.

PREREQUISITE PROGRAMME(GMP & GHP)



CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations

World Health Organization

e-mail: codex@fao.org - www.codexalimentarius.org

GENERAL PRINCIPLES OF FOOD HYGIENE

CXC 1-1969

Adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020. Editorial corrections in 2011.

PREREQUISITE PROGRAMME(GMP & GHP)

Section 2 :PRIMARY PRODUCTION

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

- avoiding the use of areas where the environment poses a threat to the safety of food;
- controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety,
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

2.1 ENVIRONMENTAL HYGIENE

Potential sources of contamination from the environment should be considered.

In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

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PREREQUISITE PROGRAMME(GMP & GHP)

2.2 HYGIENIC PRODUCTION OF FOOD SOURCES

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

Producers should as far as practicable implement measures to:

- control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- protect food sources from fecal and other contamination (e.g. zoonotic foodborne agents);
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and
- manage waste and store harmful substances appropriately.

PREREQUISITE PROGRAMME(GMP & GHP)

2.3 Handling, Storage and Transport

Procedures should be in place to:

- sort food to remove material which should not be used for human consumption;
- dispose of any rejected material in a hygienic manner; and
- protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

2.4 Cleaning, Maintenance and Personnel Hygiene

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

- cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and
- an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faces).

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PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

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

- contamination is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimize airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic for their intended use;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;
- there is effective protection against pest access and harbourage; and
- there are sufficient and appropriate washroom facilities for personnel.

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities is necessary to enable contaminants to be effectively controlled.

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PREREQUISITE PROGRAMME(GMP & GHP)

3.1 Location and structure

3.1.1 Establishment

Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

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

PREREQUISITE PROGRAMME(GMP & GHP)

3.1.2 Design and layout of food establishment

Should permit adequate maintenance and cleaning

cross-contamination is minimized or prevented.

Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.

PREREQUISITE PROGRAMME(GMP & GHP)

3.1.3 Internal structures and fittings

Should be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions.

following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials that are easy to clean and, where necessary, disinfect;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures (e.g. lighting) should be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens; and
- doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.
- Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions.

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PREREQUISITE PROGRAMME(GMP & GHP)

3.1.4 Temporary/mobile food establishments and vending machines

- Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees.
- Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.

PREREQUISITE PROGRAMME(GMP & GHP)

3.2 Facilities

- **3.2.1 Drainage and waste disposal facilities**
- Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment.
- Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.
- Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food.

PREREQUISITE PROGRAMME(GMP & GHP)

3.2.2 Cleaning facilities

Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.

PREREQUISITE PROGRAMME(GMP & GHP)

3.2.3 Personnel hygiene facilities and toilets

Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food. Such facilities should be suitably located and should not be used for other purposes such as storage of food or items that contact food.

They should include:

- adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water;
- hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and
- suitable changing facilities for personnel, if needed.
- Handwashing basins should not be used for washing food or utensils.

PREREQUISITE PROGRAMME(GMP & GHP)

3.2.4 Temperature

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

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PREREQUISITE PROGRAMME(GMP & GHP)

3.2.5 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- help control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity to ensure the safety and suitability of food (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).
- Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas; the systems should be easy to maintain and clean.

PREREQUISITE PROGRAMME(GMP & GHP)

3.2.6 Lighting

Adequate natural or artificial lighting should be provided to enable the food business to operate in a hygienic manner. Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements

PREREQUISITE PROGRAMME(GMP & GHP)

3.2.7 Storage

Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation of raw and cooked foods or allergenic and non-allergenic food.

Food storage facilities should be designed and constructed to:

- facilitate adequate maintenance and cleaning;
- avoid pest access and harborage;
- enable food to be effectively protected from contamination, including allergen cross-contact, during storage; and
- where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).
- The type of storage facilities required will depend on the nature of the food. Separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

PREREQUISITE PROGRAMME(GMP & GHP)

3.3 Equipment

Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned (other than containers which are single-use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

PREREQUISITE PROGRAMME(GMP & GHP)

3.3.2 Food control and monitoring equipment

Equipment used to cook, heat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to maintain food temperatures effectively.

Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate.

Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristics likely to have an effect on the safety or suitability of food.

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 4: TRAINING AND COMPETENCE

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

Training is fundamentally important to any food hygiene system and the competence of personnel.

Adequate hygiene training, and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.

- **Awareness and Responsibilities**
- **Training Programmes**
- **Instruction and Supervision**
- **Refresher Training**

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 5: ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

To establish effective systems that:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

PREREQUISITE PROGRAMME(GMP & GHP)

5.2 Pest control systems

Pests (e.g. birds, rodents, insects etc.) pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. GHPs should be employed to avoid creating an environment conducive to pests. Good building design, layout, maintenance, and location, along with cleaning, inspection of incoming materials and effective monitoring, can minimize the likelihood of infestation and thereby limit the need for pesticides.

5.2.2 Prevention

5.2.3 Harbourage and infestation

5.2.4 Monitoring and detection

5.2.5 Control of pest infestation .

PREREQUISITE PROGRAMME(GMP & GHP)

5.3 Waste management

- Suitable provision should be made for the removal and storage of waste. Waste should, as far as possible, be collected and stored in covered containers and should not be allowed to accumulate and overflow in food handling, food storage, and other working areas or the adjoining environment in a manner that compromises food safety and suitability. Personnel responsible for waste removal (including hazardous waste) should be properly trained so they do not become a source of cross-contamination.
- Waste storage areas should be easily identifiable, be kept appropriately clean, and be resistant to pest infestation. They should also be located away from processing areas.

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 6: PERSONAL HYGIENE

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

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

Food businesses should establish policies and procedures for personal hygiene. FBOs should ensure all personnel are aware of the importance of good personal hygiene and understand and comply with practices that ensure food safety and suitability.

PREREQUISITE PROGRAMME(GMP & GHP)

6.1 Health Status

- Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.
- It may be appropriate for personnel to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.

6.2 Illness and Injuries

Some symptoms of illnesses that should be reported to management so that the need for possible exclusion from food handling and/or medical examination can be considered include:

- jaundice;
- diarrhoea;
- vomiting;
- Fever
- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.); and
- discharges from the ear, eye or nose.

Personnel with cuts and wounds should, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof plasters and, where appropriate, gloves. Appropriate measures should be applied to ensure plasters do not become a source of contamination (e.g. plasters of contrasting colour compared to the food and/or detectable using a metal detector or x-ray detector).

PREREQUISITE PROGRAMME(GMP & GHP)

6.3 Personal Cleanliness

- Personnel should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by personnel through adequate hand washing and, where necessary, the wearing of gloves. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination.
- Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety. In particular they should wash hands:
  - at the start of food handling activities;
  - when returning to work after breaks;
  - immediately after using the toilet; and
- after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items.
- In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

PREREQUISITE PROGRAMME(GMP & GHP)

6.4 Personal Behaviour

When engaged in food handling activities personnel should refrain from behaviour which could result in contamination of food, for example:

- smoking or vaping;
- spitting;
- chewing, eating, or drinking;
- touching the mouth, nose or other places of possible contamination; and
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items such as false nails/eye lashes should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

PREREQUISITE PROGRAMME(GMP & GHP)

6.5 Visitors and other persons from outside the establishment

Visitors to food businesses, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel. Visitors should be guided through a hygiene policy of the business prior to visits and encouraged to report any type of illness/injury that may pose cross-contamination issues

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 7: CONTROL OF OPERATION

To produce food that is safe and suitable for human consumption by: formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;

designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business.

If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption.

PREREQUISITE PROGRAMME(GMP & GHP)

7.1 Description of products and processes

- Product description
- Process description
- Consideration of the effectiveness of GHPs
- Monitoring and corrective action
- Verification

PREREQUISITE PROGRAMME(GMP & GHP)

7.2 Key aspects of GHPs

- **7.2.1 Time and temperature control**
- **7.2.2 Specific process steps**
- **7.2.3 Microbiological, physical, chemical and allergen specifications**
- **7.2.4 Microbiological contamination**
- **7.2.5 Physical contamination**
- **7.2.6 Chemical contamination**
- **7.2.7 Allergen Management**
- **7.2.8 Incoming Materials**
- **7.2.9 Packaging**

PREREQUISITE PROGRAMME(GMP & GHP)

7.3 *Water*

7.4 Documentation and Records

7.5 Recall Procedures - removal from the market of unsafe food

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 8: PRODUCT INFORMATION AND CONSUMER AWARENESS

Appropriate information about food should ensure that:

- adequate and accessible information is available to the next FBO in the food chain or the consumer to enable them to handle, store, process, prepare and display the product safely and correctly;
- consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and removed/returned if necessary.

Consumers should be given enough information on food hygiene to enable them to:

- be aware of the importance of reading and understanding the label;
- make informed choices appropriate to the individual, including about allergens; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using food correctly.

PREREQUISITE PROGRAMME(GMP & GHP)

8.1 Lot Identification and Traceability

- Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.
- A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006), especially to enable the recall of the products, where necessary.

8.2 Product Information

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

8.3 Product Labelling

- Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

8.4 Consumer Education

- Consumer education program should cover general food hygiene. Such programs should enable consumers to understand the importance of any product label information and following any instructions accompanying products, and to make informed choices. In particular, consumers should be informed of the relationship between time/temperature control, cross contamination and foodborne illness, and of the presence of allergens. Consumers should also be informed of the *WHO 5 Keys to Safer Food* and educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding cross contamination) to ensure that their food is safe and suitable for consumption.

PREREQUISITE PROGRAMME(GMP & GHP)

SECTION 9: TRANSPORTATION

Food may become contaminated or may not reach its destination in a suitable condition for consumption, unless effective hygiene practices are taken prior to and during transport, even where adequate hygiene practices have been taken earlier in the food chain.

During transportation, measures should be taken where necessary to:

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

HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.

HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing.

Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

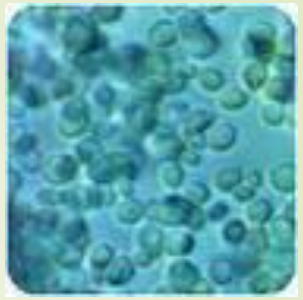
HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

HACCP principles can be considered throughout the food chain from primary production to final consumption (FARM- FORK), and their implementation should be guided by scientific evidence of risks to human health.

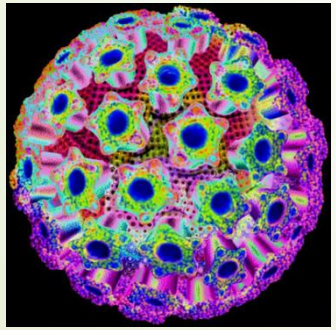
As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released.

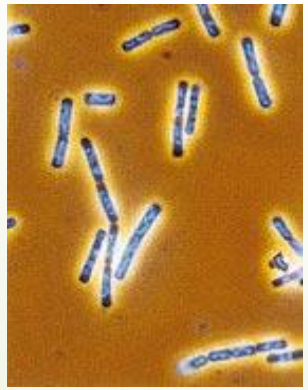
In addition, the application of HACCP systems can aid review by competent authorities and promote international trade by increasing confidence in food safety.

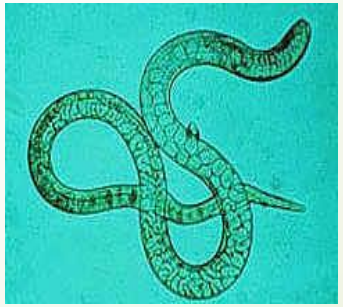
Biological hazards

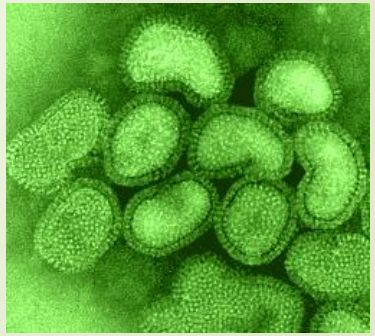


- Biological hazards can cause illness and include:
  - Bacteria: *E.coli, Salmonella, Listeria, Campylobacter, Shigella*
  - Viruses: cold viruses, Hepatitis A, Norwalk virus
  - Parasites: *Giardia, Cryptosporidium, Trichinella*, tapeworms
  - Yeasts and moulds
  - Any toxin produced by microbiological organisms is also a biological hazard





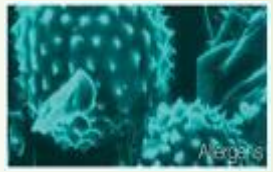


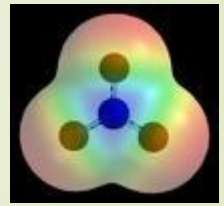


Chemical hazards

Chemical hazards can cause injury or poisoning and include:

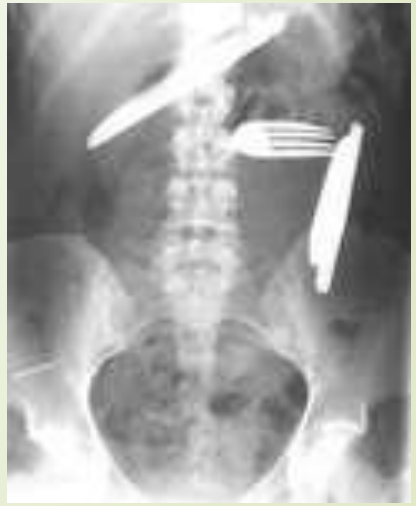
- Naturally occurring substances (e.g. allergens, plant specific toxins)
- Excessive, intentionally added chemicals: antibiotics, pesticides, herbicides, fungicides, nitrates
- Accidentally added chemicals: cleaning chemicals, paint, pest control chemicals



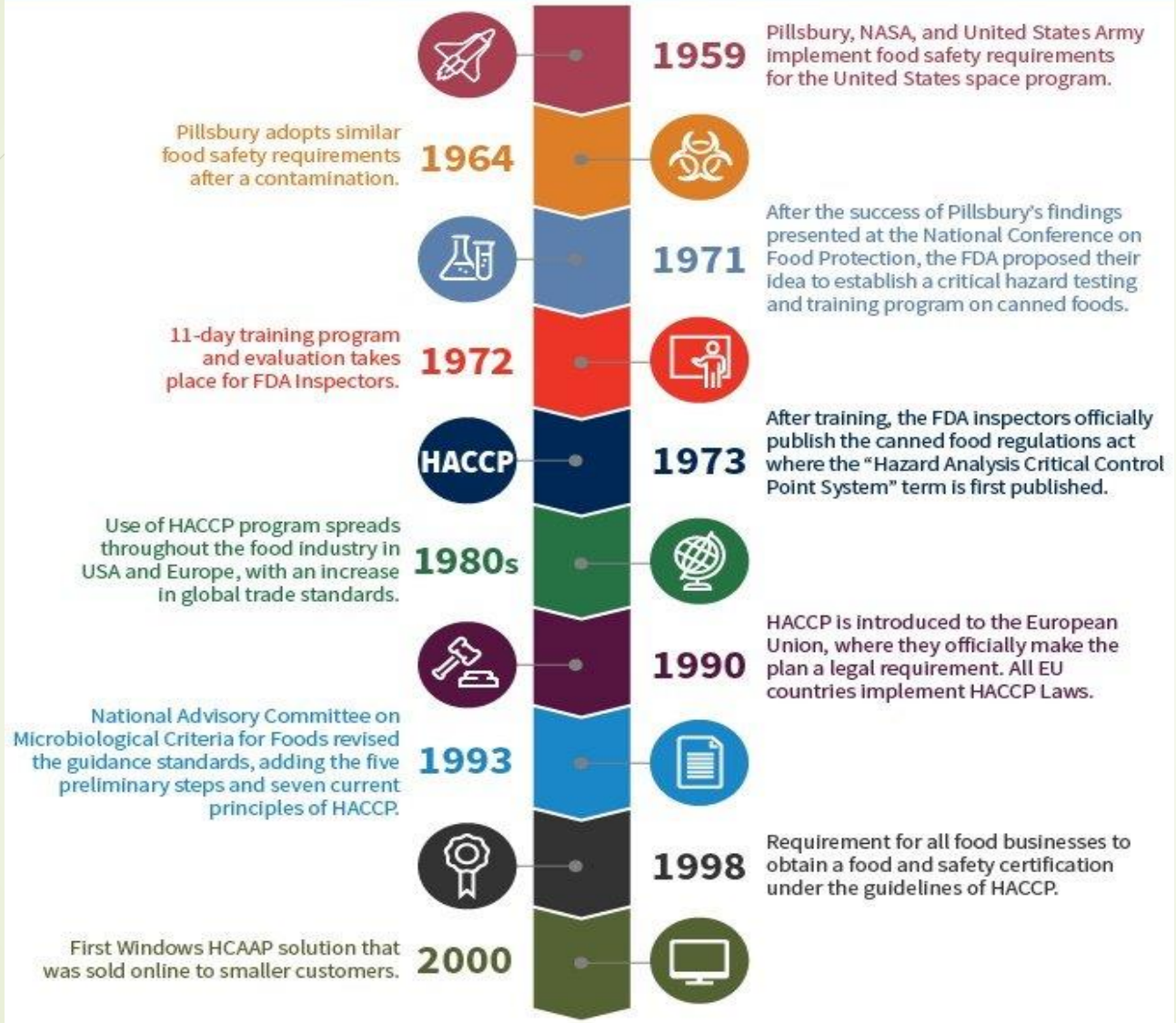


Physical hazards

- Physical hazards are foreign objects that can cause injury:
  - Glass
  - Metal grindings, screws, nuts, bolts
  - Stones, pebbles
  - Needles
  - Hard plastic
  - Bones



THE HISTORY OF HACCP



HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system is designed, validated and implemented in accordance with the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis and identify control measures.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish validated critical limits.

PRINCIPLE 4

Establish a system to monitor control of CCPs.

HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

PRINCIPLE 5

Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.

PRINCIPLE 6

Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

Application of HACCP

Prior to apply HACCP principles , FBO ensures that all prerequisite programs such GMP, GHP ,GSP and GLP should be in place.

Legal requirements should meet

Five Pre steps

- **Assemble HACCP Team and Identify Scope (Step 1)**
- **Describe product (Step 2)**
- **Identify intended use and users (Step 3)**
- **Construct flow diagram (Step 4)**
- **On-site confirmation of flow diagram (Step 5)**

HACCP- HAZARD ANALYSIS CRITICAL CONTROL POINT

- List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)
- Determine the Critical Control Points (Step 7/ Principle 2)
- Establish validated critical limits for each CCP (Step 8/ Principle 3)
- Establish a Monitoring System for Each CCP (Step 9/ Principle 4)
- Establish corrective actions (Step 10/ Principle 5)
- Validation of the HACCP Plan and Verification Procedures (Step 11/ Principle 6)
- Establish Documentation and Record Keeping (Step 12/ Principle 7)

Good Laboratory Practices

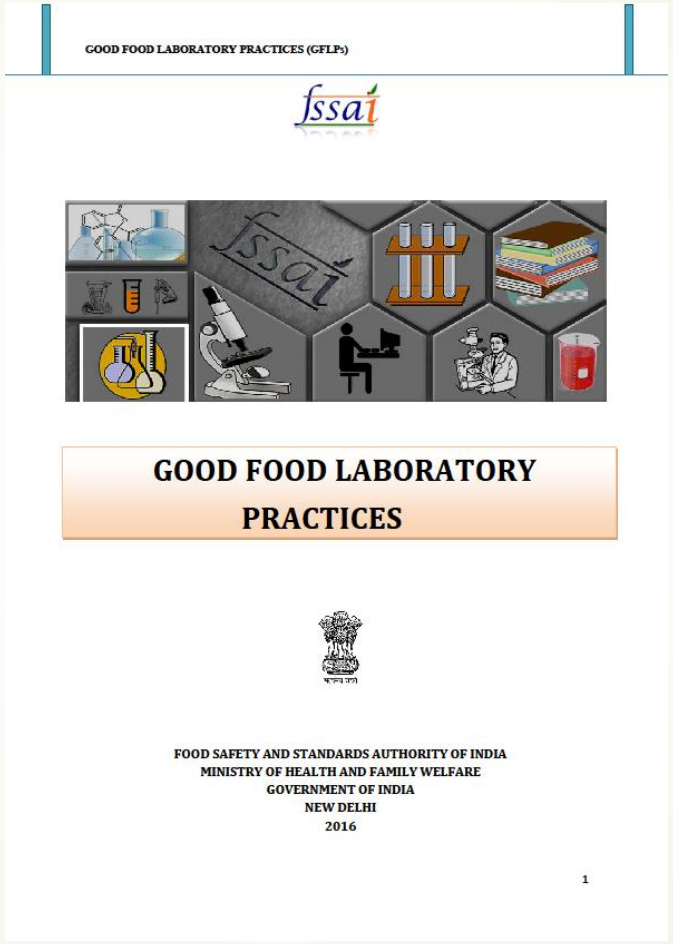
Good laboratory practice or good laboratory practices are accepted methods to carry out activities or operations in a laboratory. The authorities and laboratory organizations say that these practices help ensure safety. They also have a positive influence on the quality of the result. For pharmaceutical companies, for example, GLP compliance is extremely important.

According to the European Commission:

"The principles of Good Laboratory Practice (GLP) promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices."

GLP is the part of quality assurance that ensures the organisations consistently produce and control produce to high quality standards

Good Laboratory Practices



Thank you!

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CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

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World Health Organization

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GENERAL PRINCIPLES OF FOOD HYGIENE

CXC 1-1969

Adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020. Editorial corrections in 2011.

INTRODUCTION

People have the right to expect the food that they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury can be severe or fatal or have a negative impact on human health over the longer term. Furthermore, outbreaks of foodborne illness can damage trade and tourism. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence.

International food trade and the flow of travellers are increasing, bringing important social and economic benefits. However, this also makes the spread of illness around the world easier. Eating habits have undergone major changes in many countries and new food production, preparation, storage, and distribution techniques have developed to reflect this. Effective food hygiene practices, therefore, are vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including primary producers, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to ensure that food is safe and suitable for consumption. Food Business Operators (FBOs) should be aware of and understand the hazards associated with the food they produce, transport, store and sell, and the measures required to control those hazards relevant to their business, so that food reaching consumers is safe and suitable for use.

This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the stage in the food chain, the nature of the product, the relevant contaminants, and whether the relevant contaminants adversely affect safety, suitability or both, these principles will enable food businesses to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities. While it is the FBOs' responsibility to provide safe food, for some FBOs this may be as simple as ensuring that the WHO 5 keys to Safer Food are adequately implemented. The 5 keys are: 'keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperatures and use safe water and raw materials.

FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety.

The sufficiency of the implemented GHP to address food safety could be determined through conducting a hazard analysis and determining how to control identified hazards. However, not all FBOs have the expertise to do this. If the FBO is not able to conduct a hazard analysis, the FBO may rely on information on appropriate food safety practices from external sources such as that provided by competent authorities, academia or other competent bodies (e.g. trade associations or professional societies) that has been based on the identification of relevant hazards and controls. For example, requirements in regulations for production of safe food are based on hazard analysis often conducted by competent authorities. Similarly, guidance documents from trade associations and other organizations that describe food safety procedures are based on hazard analyses conducted by experts knowledgeable about the hazards and controls needed to ensure the safety of specific types of products. When external generic guidance is used the FBO should make sure that the guidance corresponds with the activities of the establishment and ensure all relevant hazards are controlled.

All GHPs are important but some GHPs have a greater impact on food safety. Thus, for some GHPs, based on safety concerns with the food, greater attention may be needed to provide safe food. For example, the cleaning of equipment and surfaces which come into contact with ready-to-eat food should warrant greater attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. Greater attention may include a higher frequency of application, of monitoring and of verification.

In some circumstances, the implementation of GHPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process, technological advances (e.g. extending shelf-life through modified atmosphere packaging) or end use of the product (e.g. products destined for a special dietary purpose). In such cases, when there are significant hazards identified through hazard analysis as not being controlled by GHPs, they should be addressed in the HACCP plan.

Chapter One of this document describes GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. Chapter Two describes HACCP. HACCP principles can be applied throughout the food chain from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health. The table in Annex 1 provides a comparison of control measures applied as GHPs and those applied at Critical Control Points (CCPs) with examples.

OBJECTIVES

The General Principles of Food Hygiene: Good Hygiene Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) System aim to:

- provide principles and guidance on the application of GHPs applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide guidance on the application of HACCP principles;
- clarify the relationship between GHPs and HACCP; and
- provide the basis on which sector and product-specific codes of practice can be established.

SCOPE

This document provides a framework of general principles for producing safe and suitable food for consumption by outlining necessary hygiene and food safety controls to be implemented in production (including primary production), processing, manufacturing, preparation, packaging, storage, distribution, retail, food service operation and transport of food, and where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General

The document is intended for use by FBOs (including primary producers, importers, manufacturers/processors, food warehouse/logistics operators, food service operators, retailers and traders) and competent authorities, as appropriate. It provides basic information to meet the needs of food businesses, irrespective of the nature of product and size of food business, in the context of food trade. However, it should be noted that it is not possible for the document to provide specific guidance for all situations and specific types of food businesses and the nature and extent of food safety risks associated with individual circumstances.

There will be situations where some of the specific recommendations contained in this document are not applicable. The fundamental question for each food business operator in every case is “what is necessary and appropriate to ensure the safety and suitability of food for consumption?”

The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In deciding whether a measure is necessary or appropriate, an evaluation of the likelihood and severity of the hazard toward establishing the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the measures in this document to be flexibly and sensibly applied with a regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food chain operations and practices and varying degrees of risk to public health involved in producing and handling food.

Roles of Competent Authorities, Food Business Operators, and Consumers

Competent authorities are responsible for deciding how these general principles are best applied through legislation, regulation or guidance to:

- protect consumers from illness, injury, or death caused by consumption of food;
- ensure FBOs implement an effective control system so that food is safe and suitable for consumption;
- maintain confidence in domestically and internationally traded food; and
- provide information that effectively communicates the principles of food hygiene to food business operators and consumers.

FBOs should apply the hygienic practices and food safety principles set out in this document to:

- develop, implement and verify processes that provide food that is safe and suitable for its intended use;
- ensure personnel are competent as appropriate to their job activities;
- build a positive food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food safety practices;
- contribute to maintaining confidence in domestically and internationally traded food; and
- ensure that consumers have clear and easily understood information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing food correctly.

Consumers should play their role by following relevant guidance and instructions for food handling, preparation, and storage and applying appropriate food hygiene measures.

GENERAL PRINCIPLES

(i) Food safety and suitability should be controlled using a science-based preventive approach, for example a food hygiene system. GHPs should ensure that food is produced and handled in an environment that minimizes the presence of contaminants.

(ii) Properly applied prerequisite programmes, which include GHPs, should provide the foundation for an effective HACCP system.

(iii) Each FBO should be aware of the hazards associated with the raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled, as appropriate to the food business.

(iv) Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. When the application of GHPs alone is not sufficient, a combination of GHPs and additional control measures at CCPs should be applied.

(v) Control measures that are essential to achieve an acceptable level of food safety, should be scientifically validated[1].

(vi) The application of control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate to the nature of the food product and the size of the food business.

(vii) Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment, new scientific knowledge) associated with the food business.

(viii) Appropriate communication about the food and food process should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain.

Management Commitment to Food Safety

Fundamental to the successful functioning of any food hygiene system is the establishment and maintenance of a positive food safety culture acknowledging the importance of human behaviour in providing safe and suitable food. The following elements are important in cultivating a positive food safety culture:

- commitment of the management and all personnel to the production and handling of safe food;
- leadership to set the right direction and to engage all personnel in food safety practices;
- awareness of the importance of food hygiene by all personnel in the food business;
- open and clear communication among all personnel in the food business, including communication of deviations and expectations; and
- the availability of sufficient resources to ensure the effective functioning of the food hygiene system.

Management should ensure the effectiveness of the food hygiene systems in place by:

- ensuring that roles, responsibilities, and authorities are clearly communicated in the food business;
- maintaining the integrity of the food hygiene system when changes are planned and implemented;
- verifying that controls are carried out and working and that documentation is up to date;
- ensuring that the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements; and
- encouraging continual improvement, where appropriate, taking into account developments in science, technology and best practice.

[1] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)

DEFINITIONS

For the purposes of this document the following definitions apply:

Acceptable level: A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

Allergen cross-contact: the unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient.

Cleaning: The removal of soil, food residues, dirt, grease or other objectionable matter.

Competent Authority: The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement.

Contaminant: Any biological, chemical or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

Contamination: The introduction or occurrence of a contaminant in the food or food environment.

Control:

- when used as a noun: The state wherein correct procedures are being followed and any established criteria are being met.
- when used a verb: To take all necessary actions to ensure and maintain compliance with established criteria and procedures.

Control measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

Corrective action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation.

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.

Critical limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food.

Deviation: Failure to meet a critical limit or to follow a GHP procedure.

Disinfection: Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability.

Flow diagram: A systematic representation of the sequence of steps used in the production or manufacture of food.

Food business operator (FBO): The entity responsible for operating a business at any step in the food chain.

Food Handler: Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and that is expected, therefore, to comply with food hygiene requirements.

Food hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Food hygiene system: Prerequisite programmes, supplemented with control measures at CCPs, as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use.

Food safety: Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability: Assurance that food is acceptable for human consumption according to its intended use.

Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

HACCP Plan: Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

Hazard: A biological, chemical or physical agent in food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

Primary Production: Those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat.

Prerequisite programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.

Significant hazard: A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

CHAPTER ONE

GOOD HYGIENE PRACTICES

SECTION 1: INTRODUCTION AND CONTROL OF FOOD HAZARDS

The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling hazards in food products.

Knowledge of the food and its production process is essential for the effective implementation of GHPs. This Chapter provides guidance for effective implementation of GHPs, including appropriate location, layout, design, construction and maintenance of premises and facilities, and should be applied in conjunction with sector and product-specific codes.

GHPs manage many sources of food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing, and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display.

As previously noted, all FBOs should be aware of and understand hazards associated with their businesses, and the control measures required to manage these hazards, as appropriate. FBOs should consider (using external resources as needed) whether the application of GHPs alone is sufficient to manage some or all of the hazards associated with the operation through control of their sources, e.g.

- Control of water quality – minimizes the presence of many potential hazards (e.g. biological, chemical, physical);
- Control of faecal contamination – minimizes the potential for contamination with many foodborne pathogens such as *Salmonella*, *Campylobacter*, *Yersinia*, pathogenic strains of *E.coli*;
- Control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne; and
- Control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.

After consideration of the conditions and activities in the business, it may be determined that GHPs alone may be sufficient to manage the hazards. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important for food safety (e.g. increased stringency of cleaning of a mincer for producing minced meat for raw or lightly cooked consumption compared to equipment used for producing meat to be cooked prior to consumption; increased monitoring and/or verification of disinfection of food contact surfaces).

Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. In the case in which significant hazards are identified that need to be controlled after the implementation of GHPs, it will be necessary to develop and implement a HACCP system (see Chapter 2).

SECTION 2: PRIMARY PRODUCTION

OBJECTIVES :

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

- an assessment of the suitability of water used where it may pose a hazard, for example, crop irrigation, rinsing activities, etc.

− avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contaminated sites);

− controlling contaminants, pests and diseases of animals and plants, to the extent practicable, to minimize the threat to food safety (e.g. appropriate use of pesticides and veterinary drugs);

− adopting practices and measures to ensure food is produced under appropriately hygienic conditions (e.g. cleaning and maintaining harvest equipment, rinsing, hygienic milking practices).

RATIONALE:

To reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at all stages of the food chain.

The types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, by applying prerequisite programmes such as Good Agricultural Practices (GAPs) and/or GHPs, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g. at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops. Not all provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.

2.1 Environmental control

Potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of contaminants would lead to an unacceptable level of such contaminants in food, e.g. using polluted areas[2], locating near facilities emitting toxic or offensive odours which could taint foodstuffs or near sources of contaminated water such as discharge of waste water from industrial production or runoff from agricultural land with high faecal material or chemical residues, unless there is a measure to reduce or prevent the contamination of food.

[2] *Code of Practice Concerning Source Directed Measures to Reduce Contamination of Food with Chemicals* (CXC 49-2001)

2.2 Hygienic Production

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

Producers should as far as practicable implement measures to:

- control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- protect food sources from faecal and other contamination (e.g. zoonotic foodborne agents);
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and
- manage waste and store harmful substances appropriately.

2.3 Handling, Storage and Transport

Procedures should be in place to:

- sort food to remove material which should not be used for human consumption;
- dispose of any rejected material in a hygienic manner; and
- protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

2.4 Cleaning, Maintenance and Personnel Hygiene

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

- cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and
- an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces).

SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

OBJECTIVES:

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

- contamination is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimize airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic for their intended use;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;
- there is effective protection against pest access and harbourage; and
- there are sufficient and appropriate washroom facilities for personnel.

RATIONALE:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities is necessary to enable contaminants to be effectively controlled.

3.1 Location and structure

3.1.1 Location of establishment

Food establishments should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of an establishment, including temporary/mobile establishments, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which are reasonably likely to contaminate food;
- areas subject to flooding;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

3.1.2 Design and layout of food establishment

The design and layout of food establishments should permit adequate maintenance and cleaning. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, should be such that cross-contamination is minimized or prevented.

Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.

3.1.3 Internal structures and fittings

Structures within food establishments should be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. In particular, the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials that are easy to clean and, where necessary, disinfect;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures (e.g. lighting) should be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens; and
- doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.

Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions.

3.1.4 Temporary/mobile food establishments and vending machines

Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees.

Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.

3.2 Facilities

3.2.1 Drainage and waste disposal facilities

Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment.

Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food.

3.2.2 Cleaning facilities

Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.

3.2.3 Personnel hygiene facilities and toilets

Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food. Such facilities should be suitably located and should not be used for other purposes such as storage of food or items that contact food. They should include:

- adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water;
- hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and
- suitable changing facilities for personnel, if needed.

Handwashing basins should not be used for washing food or utensils.

3.2.4 Temperature

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

3.2.5 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- help control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity to ensure the safety and suitability of food (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

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

3.2.6 Lighting

Adequate natural or artificial lighting should be provided to enable the food business to operate in a hygienic manner. Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.

3.2.7 Storage

Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation of raw and cooked foods or allergenic and non-allergenic food.

Food storage facilities should be designed and constructed to:

- facilitate adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination, including allergen cross-contact, during storage; and
- where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

3.3 Equipment

3.3.1 *General*

Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned (other than containers which are single-use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

3.3.2 Food control and monitoring equipment

Equipment used to cook, heat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to maintain food temperatures effectively.

Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate.

Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristics likely to have an effect on the safety or suitability of food.

SECTION 4: TRAINING AND COMPETENCE

OBJECTIVE:

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

RATIONALE:

Training is fundamentally important to any food hygiene system and the competence of personnel.

Adequate hygiene training, and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.

4.1 Awareness and Responsibilities

Food hygiene training is fundamentally important to the food business. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Personnel should have the knowledge and skills necessary to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.

4.2 Training Programmes

Elements to take into account in determining the extent of training required include:

- the nature of hazards associated with the food, e.g. its ability to sustain growth of pathogenic or spoilage microorganisms, the existence of potential physical contaminants or known allergens;
- the manner in which the food is produced, processed, handled and packed, including the likelihood of contamination;
- the extent and nature of processing or further preparation before consumption of the food;
- the conditions under which the food will be stored;
- the expected length of time before consumption of the food; and
- the use and maintenance of instruments and equipment associated with food.

Training programmes should also consider the knowledge and skill levels of the personnel being trained. Topics to be considered for training programmes could include the following as appropriate to a person's duties:

- the principles of food hygiene applicable to the food business;
- the measures relevant to the food business that are used to prevent contaminants in food;
- the importance of good personal hygiene, including proper hand washing and wearing, when needed, appropriate clothing, for food safety;
- the good hygiene practices applicable to the food business.
- appropriate actions to take when food hygiene problems are observed.

In addition, for retail and food service operations, whether personnel have direct customer interaction is a factor in training, since it may be necessary to convey certain information about products (such as allergens) to customers.

4.3 Instruction and Supervision

The type of instruction and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers, supervisors and/or operators/workers should have sufficient knowledge of food hygiene principles and practices to be able to identify deviations and take necessary action as appropriate to their duties.

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and verification to ensure that procedures are being carried out effectively. Personnel tasked to perform any activities used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks on the safety and suitability of the food.

4.4 Refresher Training

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers and personnel associated with the food business, such as maintenance staff, remain aware of all procedures necessary to maintain the safety and suitability of food. Records should be kept of training activities.

SECTION 5: ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

OBJECTIVES:

To establish effective systems that:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

RATIONALE:

To facilitate the continuing effective control of food contaminants, pests, and other agents likely to compromise food safety and suitability.

5.1 Maintenance and Cleaning

5.1.1 General

Establishments and equipment should be maintained in an appropriate condition to:

- facilitate all cleaning and disinfection procedures;
- function as intended; and
- prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper.

Cleaning should remove food residues and dirt which may be a source of contamination, including allergens. The cleaning methods and materials necessary will depend on the nature of the food business, the food type and the surface to be cleaned. Disinfection may be necessary after cleaning, especially for food contact surfaces.

Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety and suitability. Cleaning products suitable for food contact surfaces should be used in food preparation and storage areas.

Cleaning and disinfection chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions and contact times, and stored, where necessary, separated from food, in clearly identified containers to avoid contamination of food.

Separate cleaning equipment and utensils, suitably designated, should be used for different hygiene zones e.g. food and non-food contact surfaces.

Cleaning equipment should be stored in an appropriate place and in such a manner to prevent contamination. Cleaning equipment should be kept clean, maintained and replaced periodically so as not to become a source for cross-contamination of surfaces or food.

5.1.2 Cleaning and disinfection methods and procedures

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, and vacuum cleaning (or other methods that avoid the use of water), and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water increases the likelihood of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food, e.g. spray from pressure washing can spread contamination from dirty areas, such as floors and drains, over a wide area and contaminate food contact surfaces or exposed food.

Wet cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying an appropriate detergent solution to loosen soil; and
- rinsing with water (hot water where appropriate) to remove loosened material and residues of detergent.

Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate that, on a scientific basis, rinsing is not required. Concentrations and application time of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions for optimal effectiveness. If cleaning is not done effectively to remove soil to permit the disinfectant to contact microorganisms or if sub-lethal concentrations of the disinfectant are used, the microorganisms may persist.

Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean. Where appropriate, programmes should be drawn up in consultation with relevant experts.

Written cleaning and disinfection procedures should be used, where appropriate. They should specify:

- areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected;
- responsibility for particular tasks;
- method and frequency of cleaning and, where appropriate, disinfection; and
- monitoring and verification activities.

5.1.3 Monitoring of Effectiveness

Application of cleaning and disinfection procedures should be monitored for effectiveness and periodically verified by means such as visual inspections and audits to ensure the procedures have been applied properly. The type of monitoring will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensure the cleaning and disinfection programme is being implemented as designed and verify its effectiveness.

Microorganisms can sometimes become tolerant to disinfecting agents over time. Cleaning and disinfection procedures should follow the manufacturers' instructions. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of different types of microorganisms (e.g. bacteria and fungi).

While effectiveness of cleaning and disinfecting agents and instructions for use are validated by their manufacturers, measures should be taken for sampling and testing the environment and food contact surfaces (e.g. protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning and disinfection procedures, including the correct disinfectant concentration, to achieve the necessary results and to make sure protocols are being followed. Cleaning and disinfection and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

5.2 Pest control systems

5.2.1 *General*

Pests (e.g. birds, rodents, insects etc.) pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. GHPs should be employed to avoid creating an environment conducive to pests. Good building design, layout, maintenance, and location, along with cleaning, inspection of incoming materials and effective monitoring, can minimize the likelihood of infestation and thereby limit the need for pesticides.

5.2.2 Prevention

Establishments should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be covered. Roll up doors should close tightly against the floor. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of food processing establishments.

5.2.3 Harbourage and infestation

The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and preferably away from walls. Areas both inside and outside food premises should be kept clean and free of waste. Where appropriate, refuse should be stored in covered, pest-proof containers. Any potential harbourage, such as old and unused equipment, should be removed.

Landscaping surrounding a food establishment should be designed to minimize attracting and harbouring pests.

5.2.4 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps (e.g. insect light traps, bait stations) should be designed and located so as to prevent potential contamination of raw materials, products or facilities. Even if monitoring and detection are outsourced, FBOs should review monitoring reports and, if necessary, ensure they or their designated pest control operators take corrective action (e.g. eradication of pests, elimination of harbourage sites or invasion routes).

5.2.5 Control of pest infestation

Pest infestations should be addressed immediately by a qualified person or company and appropriate corrective action taken. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. The cause of infestation should be identified, and corrective action taken to prevent a problem from reoccurring. Records should be kept of infestation, monitoring and eradication.

5.3 Waste management

5.3.1 General

Suitable provision should be made for the removal and storage of waste. Waste should, as far as possible, be collected and stored in covered containers and should not be allowed to accumulate and overflow in food handling, food storage, and other working areas or the adjoining environment in a manner that compromises food safety and suitability. Personnel responsible for waste removal (including hazardous waste) should be properly trained so they do not become a source of cross-contamination.

Waste storage areas should be easily identifiable, be kept appropriately clean, and be resistant to pest infestation. They should also be located away from processing areas.

SECTION 6: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

RATIONALE:

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

Food businesses should establish policies and procedures for personal hygiene. FBOs should ensure all personnel are aware of the importance of good personal hygiene and understand and comply with practices that ensure food safety and suitability.

6.1 Health Status

Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

It may be appropriate for personnel to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.

6.2 Illness and Injuries

Some symptoms of illnesses that should be reported to management so that the need for possible exclusion from food handling and/or medical examination can be considered include:

- jaundice;
- diarrhoea;
- vomiting;
- fever;

- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.); and
- discharges from the ear, eye or nose.

Personnel with cuts and wounds should, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof plasters and, where appropriate, gloves. Appropriate measures should be applied to ensure plasters do not become a source of contamination (e.g. plasters of contrasting colour compared to the food and/or detectable using a metal detector or x-ray detector).

6.3 Personal Cleanliness

Personnel should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by personnel through adequate hand washing and, where necessary, the wearing of gloves. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination.

Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety. In particular they should wash hands:

- at the start of food handling activities;
- when returning to work after breaks;
- immediately after using the toilet; and
- after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items.

In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

6.4 Personal Behaviour

When engaged in food handling activities personnel should refrain from behaviour which could result in contamination of food, for example:

- smoking or vaping;
- spitting;
- chewing, eating, or drinking;
- touching the mouth, nose or other places of possible contamination; and
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items such as false nails/eye lashes should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

6.5 Visitors and other persons from outside the establishment

Visitors to food businesses, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel. Visitors should be guided through a hygiene policy of the business prior to visits and encouraged to report any type of illness/injury that may pose cross-contamination issues.

SECTION 7: CONTROL OF OPERATION

OBJECTIVES:

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

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
- designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business.

RATIONALE:

If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption.

Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

7.1 Description of products and processes

After consideration of the conditions and activities of the food business it may be necessary to pay greater attention to some GHPs that are particularly important for food safety. In this case, the following provisions could be considered.

7.1.1 Product description

An FBO that is producing, storing or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner that does not compromise the awareness of hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity (a_w)), process steps and/or intended purpose.

The description could include, as appropriate:

- the intended use of the food, e.g. whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example raw seafood to be cooked;
- products intended for specific vulnerable consumer groups e.g. infant formula or food for special medical purposes;
- any relevant specifications e.g. ingredient composition, aw, pH, type of preservation method used (if any), or important characteristics associated with the food, such as any allergens present;
- any relevant limits established for the food by the competent authority or, in the absence thereof, set by the FBO;
- instructions provided for further use, for example keep frozen until cooking, cook to a specified temperature for a specified length of time, product shelf-life (use-by date);
- storage of product (e.g. refrigerated/frozen/shelf stable) and transport conditions required; and
- food packaging material used.

7.1.2 Process description

The FBO should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram, which shows the sequence and interaction of all processing steps in the operation, including where raw materials, ingredients and intermediate products enter the flow and where intermediate products, by-products and waste are released or removed. The flow diagram could be used for a number of similar food products that are produced using similar production or processing steps, to ensure all steps are captured. The steps should be confirmed as accurate by an on-site review of the operation or process. For example, for restaurants the flow diagram could be based on the general activities from the receipt of ingredients/raw material, storage (refrigerated, frozen, room temperature), preparation before use (washing, defrosting), and cooking or preparation of food.

7.1.3 Consideration of the effectiveness of GHPs

Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of *Listeria* spp. on its meat contact surfaces, or a conveyor belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2).

7.1.4 Monitoring and corrective action

The FBO should monitor the hygienic procedures and practices as relevant to the business and as applicable to the hazard being controlled. Procedures could include defining methods of monitoring (including defining responsible personnel, frequency and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.

When monitoring results indicate a deviation, the FBO should undertake corrective action. Corrective action should consist of the following actions, as appropriate:

- bringing the process back into control by, for example, altering temperature or timing, or concentration of disinfectant;
- isolating any affected product and evaluating its safety and/or suitability;
- determining proper disposition of affected product that is not acceptable to market;
- identifying the cause that resulted in the deviation; and
- taking steps to prevent reoccurrence.

Records of corrective actions should be retained.

7.1.5 Verification

The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is occurring, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate:

- review of GHP procedures, monitoring, corrective actions and records;
- review when any changes occur to the product, process and other operations associated with the business; and
- assessment of the efficacy of cleaning.

Records of GHP verification activities should be kept, where appropriate.

7.2 Key aspects of GHPs

Some key aspects of GHPs such as those described in Sections 7.2.1. and 7.2.2, could be considered as control measures applied at CCPs in the HACCP system.

7.2.1 Time and temperature control

Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food.

Time and temperature control systems should take into account:

- the nature of the food, e.g. its a_w, pH, and likely initial level and types of microorganisms, such as pathogenic and spoilage microflora;
- the impact on the microorganisms, e.g. time in growth/dangerous temperature zone;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be validated, and as appropriate, monitored and recorded. Temperature monitoring and recording devices should be checked for accuracy and calibrated at regular intervals or as needed.

7.2.2 Specific process steps

There are many individual processing steps for specific foods which contribute to the production of safe and suitable food products. These vary depending on the product and can include key steps such as cooking, chilling, freezing, drying and packaging.

The composition of a food can be important in preventing microbial growth and toxin production, e.g. in its formulation by adding preservatives, including acids, salts, food additives or other compounds. When formulation is used to control foodborne pathogens (e.g. adjusting the pH or a_w to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly and that the controlling parameters are monitored.

7.2.3 Microbiological[3], physical, chemical and allergen specifications

Where microbiological, physical, chemical and allergen specifications are used for food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, sampling parameters, analytical methods, acceptable limits and monitoring procedures. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.

7.2.4 Microbiological contamination

Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, e.g.:

- by direct contact or indirectly by food handlers;
- by contact with surfaces;
- from cleaning equipment;
- by splashing; or
- by airborne particles.

Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection.

Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a potentially high microbiological load such as meat, poultry, and fish have been handled or processed.

In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard covering, footwear, and to wash their hands and where necessary sanitize them.

7.2.5 Physical contamination

Systems should be in place throughout the food chain to prevent contamination of foods by extraneous materials, such as personnel belongings, especially any hard or sharp object(s), e.g. jewellery, glass, metal shards, bone(s), plastic, wood fragments, that could cause injury or present a choking hazard. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection of equipment, should be undertaken. Detection or screening devices which are appropriately calibrated should be used where necessary (e.g. metal detectors, x-ray detectors). Procedures should be in place for personnel to follow in the case of breakages (e.g. breakage of glass or plastic containers).

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[3] Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21- 1997).

7.2.6 Chemical contamination

Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives and food processing aids that may be harmful if used improperly should be controlled so they are only used as intended.

7.2.7 Allergen Management[4]

Systems should be in place to take into account the allergenic nature of some foods, as appropriate to the food business. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens. This management system should include controls put in place to prevent the presence of allergens in foods where they are not labelled. Controls to prevent cross-contact from foods containing allergens to other foods should be implemented, e.g. separation either physically or by time (with effective cleaning between foods with different allergen profiles). Food should be protected from unintended allergen cross-contact by cleaning and line change-over practice and/or product sequencing. Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed. Where necessary food handlers should receive specific training on allergen awareness and associated food manufacturing/processing practices and preventive measures to reduce the risk to allergic consumers.

7.2.8 Incoming Materials

Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to specifications, and their compliance with food safety and suitability specifications should be verified where necessary. Supplier quality assurance activities, such as audits, may be appropriate for some ingredients. Raw materials or other ingredients should, where appropriate, be inspected (e.g. visual examination for packages damaged during transportation, use-by-date and declared allergens, or temperature measurement for refrigerated and frozen foods) for appropriate action before processing. Where appropriate, laboratory tests could be conducted to check food safety and suitability of raw materials or ingredients. These tests may be conducted by a supplier that provides a Certificate of Analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or processing where appropriate. Stocks of raw materials and other ingredients should be subject to effective stock rotation. Documentation of key information for incoming materials (e.g. supplier details, date of receipt, quantity etc.) should be maintained.

7.2.9 Packaging

Packaging design and materials should be safe and suitable for food use, provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used should not contain toxic contaminants and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Any reusable packaging should be suitably durable, easy to clean and, where necessary, to disinfect.

7.3 *Water*

Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach[5]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g. some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.

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[4] See the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020)

[5] Microbiological Risk Assessment Series 33: Safety and Quality of Water Used in Food Production and Processing

7.4 Documentation and Records

Appropriate records for the food business operation should be retained for a period that exceeds the shelf-life of the product or as determined by the competent authority.

7.5 Recall Procedures - removal from the market of unsafe food

FBOs should ensure effective procedures are in place to respond to failures in the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective identification, and removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. Reporting to the relevant competent authority should be required and public warnings considered where product may have reached consumers and when return of product to the FBO or removal from the market is appropriate. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials.

Provision should be made for removed or returned products to be held under secure conditions until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to reduce the hazard to acceptable levels, where permitted by the competent authority. The cause and extent of a recall and the corrective actions taken should be retained by the FBO as documented information.

SECTION 8: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Appropriate information about food should ensure that:

- adequate and accessible information is available to the next FBO in the food chain or the consumer to enable them to handle, store, process, prepare and display the product safely and correctly;
- consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and removed/returned if necessary.

Consumers should be given enough information on food hygiene to enable them to:

- be aware of the importance of reading and understanding the label;
- make informed choices appropriate to the individual, including about allergens; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using food correctly.

RATIONALE:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been implemented earlier in the food chain. Insufficient product information about the allergens in food can also result in illness or potentially death for allergic consumers.

8.1 Lot Identification and Traceability

Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006), especially to enable the recall of the products, where necessary.

8.2 Product Information

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

8.3 Product Labelling

Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

8.4 Consumer Education

Consumer education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product label information and following any instructions accompanying products, and to make informed choices. In particular, consumers should be informed of the relationship between time/temperature control, cross contamination and foodborne illness, and of the presence of allergens. Consumers should also be informed of the *WHO 5 Keys to Safer Food* and educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding cross contamination) to ensure that their food is safe and suitable for consumption.

SECTION 9: TRANSPORTATION

OBJECTIVES:

During transportation, measures should be taken where necessary to:

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

RATIONALE:

Food may become contaminated or may not reach its destination in a suitable condition for consumption, unless effective hygiene practices are taken prior to and during transport, even where adequate hygiene practices have been taken earlier in the food chain.

9.1 General

Food should be adequately protected during transport[6]. The type of conveyances or containers required depends on the nature of the food and the most appropriate conditions under which it should be transported.

9.2 Requirements

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected and dried;
- permit effective separation of different foods or foods from non-food items that could cause contamination where necessary during transport;
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsafe or unsuitable for consumption; and
- allow any necessary temperature, humidity and other environmental conditions to be checked.

9.3 Use and Maintenance

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances for bulk food transport should be designated and marked for food use and used only for that purpose, unless controls are taken to ensure that the safety and suitability of the food are not compromised.

Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection, and drying should take place between loads.

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[6] *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001)

CHAPTER TWO

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

INTRODUCTION

The first section of this Chapter sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second section provides general guidance for the application of the HACCP system and the third section describes its application in 12 successive steps (Diagram 1), while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food business operation. The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation should be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes (e.g. Good Agricultural Practices (GAPs), etc.). It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (e.g. consultants) or adapt a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site circumstances. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid review by competent authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the commitment and involvement of management and personnel and the knowledge and/or training in its application for the particular type of food business. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation and may include, for example, expertise in primary production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application.

SECTION 1: PRINCIPLES OF THE HACCP SYSTEM

The HACCP system is designed, validated and implemented in accordance with the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis and identify control measures.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish validated critical limits.

PRINCIPLE 4

Establish a system to monitor control of CCPs.

PRINCIPLE 5

Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.

PRINCIPLE 6

Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

SECTION 2: GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

2.1 Introduction

Prior to application of a HACCP system by any FBO in the food chain, that FBO should have in place prerequisite programmes, including GHPs established in accordance with Chapter One of this document, the appropriate product and sector-specific Codex Codes of Practice, and in accordance with relevant food safety requirements set by competent authorities. Prerequisite programmes should be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs.

For all types of food businesses, management awareness and commitment to food safety are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and personnel having the appropriate HACCP training and competency. Therefore, ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

A HACCP system identifies and enhances control of significant hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). By specifying critical limits for control measures at CCPs and corrective actions when limits are not met, and by producing records that are reviewed before product release, HACCP provides consistent and verifiable control beyond that achieved by GHPs.

A HACCP approach should be customized to each food business. Hazards, control measures at CCPs and their critical limits, CCP monitoring, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified in a Codex Code of Practice or other appropriate guidelines might not be the only ones identified for a specific application or might be of a different nature.

The HACCP system should be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food business. Periodic review should also be conducted when the application of the HACCP principles has resulted in a determination that no CCPs are needed, in order to assess whether the need for CCPs has changed.

2.2 Flexibility for small and/or less developed food businesses[7]

The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual food businesses. This is particularly relevant in small and/or less developed food businesses. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses are available and encouraged. Some approaches may provide ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this chapter. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. Applying such flexibility e.g. recording only monitoring results when there is a deviation instead of every monitoring result to reduce unnecessary burden of record keeping for certain types of FBOs, is not intended to impact negatively on the efficacy of the HACCP system and should not endanger food safety.

Small and/or less developed food businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP system. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. A comprehensive explanation of the basis for the HACCP plan should be provided to the FBO. The FBO is ultimately responsible for elaboration and implementation of the HACCP system and the production of safe food.

The efficacy of any HACCP system will nevertheless rely on management and personnel having the

[7] *FAO/WHO Guidance to governments on the application of HACCP in small and/or less-developed food businesses.*

appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

SECTION 3: APPLICATION

3.1 Assemble HACCP Team and Identify Scope (Step 1)

The FBO should ensure that the appropriate knowledge and expertise are available for the development of an effective HACCP system. This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan.

Where relevant expertise is not available in house, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement a HACCP System in house. A generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes. The scope should describe which food products and processes are covered.

3.2 Describe product (Step 2)

A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. a_w, pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.

3.3 Identify intended use and users (Step 3)

Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer; the description may be influenced by external information, e.g. from the competent authority or other sources on ways in which consumers are known to use the product other than those intended by the FBO. In specific cases (e.g. hospitals), vulnerable groups of the population may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.

3.4 Construct flow diagram (Step 4)

A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of ingredients and food contact materials, water and air if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following:

- the sequence and interaction of the steps in the operation;
- where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- any outsourced processes;
- where applicable reworking and recycling take place;
- where end products, intermediate products, waste and by-products are released or removed.

3.5 On-site confirmation of flow diagram (Step 5)

Steps should be taken to confirm the processing activities against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

3.6 List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)

Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided in Diagram 2. The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.

The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that have to be addressed in the HACCP plan).

In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered:

- hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data);
- the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control;
- the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control[8];
- identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information;
- the nature of the facility and the equipment used in making the food product;
- survival or multiplication of pathogenic microorganisms;
- production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal);
- the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and,
- conditions leading to the above.

The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)

In some cases, it may be acceptable for a simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (biological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the specific hazards of concern. There can be drawbacks to such an approach, as the controls can differ for hazards within a group, e.g. controls for pathogenic spore-formers versus vegetative cells of microbial pathogens. Generic HACCP-based tools and guidance documents provided by external sources, for example, by industry or competent authorities, are designed to assist with this step and mitigate concerns about different controls needed for hazards within a group.

Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes* or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, e.g. at critical control points.

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[8] FBOs may take advantage of risk assessments and risk management matrices established by a competent authority or by international expert groups such as JEMRA.

Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment. More than one hazard may be controlled by a specified control measure. For example, a heat treatment can control both *Salmonella* and *E. coli* O157:H7 when they are present as hazards in the food.

3.7 Determine the Critical Control Points (Step 7/ Principle 2)

The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree. A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.

To identify a CCP, whether using a decision tree or other approach, the following should be considered:

- Assess whether the control measure can be used at the process step being analysed:
    - If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard.
    - If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.
- Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs.

The CCPs identified could be summarized in tabular format e.g. the HACCP worksheet presented in diagram 3, as well as highlighted at the appropriate step on the flow diagram.

If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

Establish validated critical limits for each CCP (Step 8/ Principle 3)

Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, a_w, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced.

Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]. Validation of critical limits may include conducting studies (e.g. microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).

[9] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

3.9 Establish a Monitoring System for Each CCP (Step 9/ Principle 4)

Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards a deviation at a CCP. The adjustments should be taken before a deviation occurs.

Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation (e.g. a drop in temperature or a broken sieve, rapid drop in temperature during pasteurization, or a gradual increase in temperature in cold storage). Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.

The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

All records and documents associated with monitoring CCPs should be signed or initialled by the person performing the monitoring and should also report the results and timing of the performed activity.

3.10 Establish corrective actions (Step 10/ Principle 5)

Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation.

The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition.

External experts may be needed to conduct evaluations regarding the safe use of products when a deviation occurs. It may be determined that the product could be reprocessed (e.g. pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (e.g. contamination with *Staphylococcus* enterotoxin). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

3.11 Validation of the HACCP Plan and Verification Procedures (Step 11/ Principle 6)

3.11.1 *Validation of the HACCP Plan*

Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded.

Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources[10].

[10] *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

Where HACCP guidance developed by external experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.

During the initial implementation of the HACCP system and after verification procedures have been established, evidence should be obtained in operation to demonstrate that control can be achieved consistently under production conditions.

Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary a revalidation of the HACCP plan.

3.11.2 *Verification Procedures*

After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:

- reviewing monitoring records to confirm that CCPs are kept under control;
- reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation;
- calibrating or checking the accuracy of instruments used for monitoring and/or verification;
- observing that control measures are being conducted in accordance with the HACCP plan;
- sampling and testing, e.g. for microorganisms[11] (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety;
- sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and
- reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.

3.12 Establish Documentation and Record Keeping (Step 12/ Principle 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.

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[11] *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food* (CXG 21-1997).

Examples of documentation include:

- HACCP team composition;
- hazard analysis and the scientific support for the hazards included or excluded from the plan;
- CCP determination;
- critical limit determination and the scientific support for the limits set;
- validation of control measures; and
- modifications made to the HACCP plan.

Examples of records include:

- CCP monitoring activities;
- deviations and associated corrective actions; and
- verification procedures performed.

A simple record-keeping system can be effective and easily communicated to personnel. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices, and checklists to record, for example, product temperatures. Where appropriate, records can also be maintained electronically.

3.13 Training

Training of personnel in food businesses, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel in charge of each Critical Control Point. Training programmes should be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.

Cooperation between food business operations, trade groups, consumer organisations, and competent authorities is vitally important. Opportunities should be provided for the joint training of food business operators and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Annex 1 - Comparison of control measures with examples.

	Control measures applied as GHPs	Control measures applied at CCPs
Scope	General conditions and activities for maintaining hygiene, including creating the environment (inside and outside the food business) so as to ensure production of safe and suitable food. Generally, not specific to any hazard but results in reduction of likelihood of hazards occurring. Occasionally a GHP activity may target a specific hazard and this may be a GHP that requires greater attention (e.g. cleaning and disinfection of food contact surfaces for control of *Listeria monocytogenes* in a ready-to-eat food processing environment).	Specific to production process steps and a product or group of products and necessary to prevent eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis.
When identified?	After consideration of the conditions and activities necessary to support the production of safe and suitable food.	After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where a deviation would result in the production of a potentially unsafe food.
Validation of the control measures	Where necessary, and generally not carried out by FBOs themselves (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008). Validation data provided by competent authorities, published scientific literature, information provided by manufacturers of equipment/ food processing technology etc. is adequate e.g. cleaning compounds/products/equipment should be validated by the manufacturer and it is generally sufficient for the FBO to use cleaning compounds/products/equipment according to manufacturers' instructions. The FBO should be able to demonstrate it can follow manufacturers' instructions.	Validation should be carried out (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008).

Criteria	GHPs may be observable (e.g. visual checks, appearance) or measurable (e.g. ATP tests of equipment cleaning, concentration of disinfectant), and deviations may require an evaluation of the impact on safety of the product (e.g. whether the cleaning of complex equipment such as meat slicers is adequate).	Critical limits at CCPs which separate acceptability from unacceptability of the food: • measurable (e.g. time, temperature, pH, a_w), or • observable (e.g. visual checks of conveyor belt speed or pump settings, ice covering product).
Monitoring	When appropriate and necessary, to ensure procedures and practices are applied properly. Frequency dependent on the impact on the product's safety and suitability.	Necessary to ensure critical limit is met: • Continuously during production or • if not continuous, at appropriate frequency that ensures to the extent possible the critical limit has been met.
Corrective actions when deviation has occurred	• For procedures and practices: Necessary • For products: Usually not necessary. Corrective action should be considered on a case- by-case basis, as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting (where needed) or post maintenance equipment checks indicating missing machinery parts, may result in action on product.	• For products: Necessary pre-determined actions. • For procedures and practices: Necessary corrective actions to restore control and prevent reoccurrence. • Specific written corrective actions should be developed for each CCP in the HACCP plan in order to effectively respond to deviations when they occur. • The corrective actions should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers.
Verification	When appropriate and necessary, usually scheduled (e.g. visual observation that equipment is clean before use).	Necessary: Scheduled verification of implementation of control measures, e.g. through record review, sampling and testing, calibration of measuring equipment, internal audit.
Record keeping (e.g. monitoring records)	When appropriate and necessary, to allow the FBO to assess whether GHPs are operating as intended.	Necessary to allow the FBO to demonstrate ongoing control of significant hazards.
Documentation (e.g. documented procedures)	When appropriate and necessary to ensure GHPs are properly implemented.	Necessary to ensure the HACCP system is properly implemented.

Diagram 1 – Logic Sequence for Application of HACCP

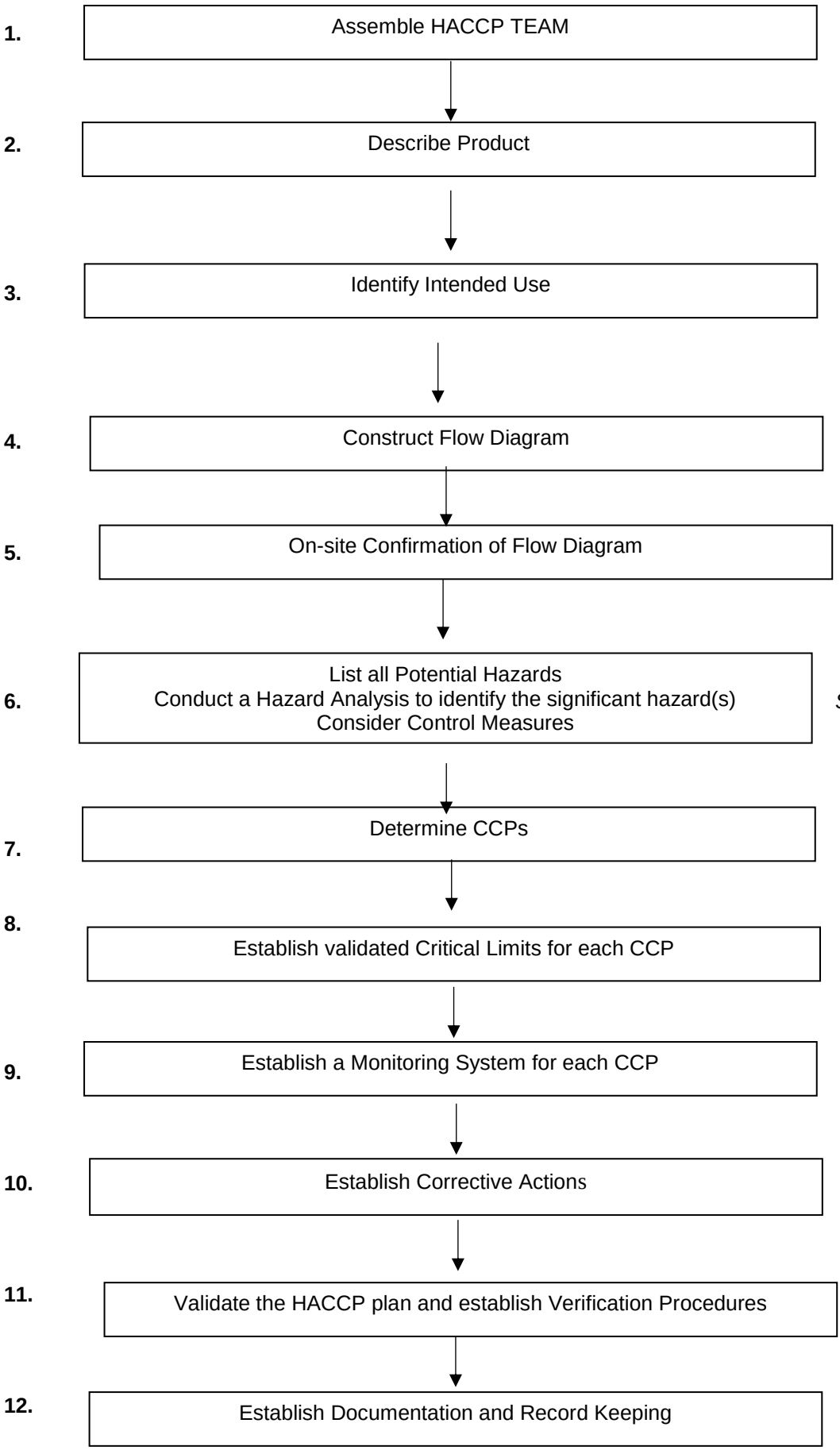


Diagram 2 – Example of Hazard Analysis Worksheet

(1) Step*	(2) Identify <u>potential</u> hazards introduced, controlled or enhanced at this step B = biological C = chemical P = physical		(3) Does this potential hazard need to be addressed in the HACCP plan? Yes	(3) No	(4) Justify your decision for column 3	(5) What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level?
	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					

*A hazard analysis should be conducted on each ingredient used in the food; this is often done at a “receiving” step for the ingredient. Another approach is to do a separate hazard analysis on ingredients and one on the processing steps.

Diagram 3 – Example of a HACCP Worksheet

Critical Control Points (CCPs)	Significant Hazard(s)	Critical Limits	Monitoring				Corrective Actions	Verification Activities	Records
			What	How	When (Frequency)	Who			

GOOD FOOD LABORATORY PRACTICES

सत्यमेव जयते

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI
2016

GOOD FOOD LABORATORY PRACTICES (GFLPs)

TABLE OF CONTENTS

1.0 SCOPE:

1.1 These Guidelines specify the general requirements for the competence to carry out systematic sampling of food samples, conduct chemical, microbiological tests and testing of packaging materials to ascertain the quality of food. It covers the tests performed using standard methods, non-standard methods, and laboratory-developed methods.

1.2 These Guidelines are applicable to all organizations performing tests to ascertain the quality of food material including packaging material. These include, for example, first-, second- and third-party laboratories, and laboratories where testing forms part of inspection and product certification.

These Guidelines are applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification/guidance of the text and examples. They do not contain requirements and do not form an integral part of these Guidelines.

1.4 These Guidelines are for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used as the basis for certification of laboratories.

NOTE 1 The term 'management system' in these Guidelines means the quality, administrative and technical systems that govern the operations of a laboratory.

NOTE 2 Certification of a management system is sometimes also called registration.

1.5 Compliance with regulatory, calibration of equipment/glassware and safety requirements on the operation of laboratories is not covered by these Guidelines. These Guidelines are over and above ISO/IEC 17025:2005 framed specially for those testing laboratories engaged in sampling, conducting chemical and/ or microbiology tests and testing of packaging materials to ascertain the quality of food. Laboratories seeking accreditation as per ISO/IEC 17025:2005 should comply with the requirements of ISO/IEC 17025:2005.

2.0 STRUCTURE OF FOOD LAB:

2.1 Personnel:

Personnel need to clearly understand the nature of the foods they are testing and reasons for testing when undertaking contract review and method selection.

2.2 The Management Structure:

An up-to-date chart showing the organisational structure and lines of responsibility of the laboratory is an important feature of the quality assurance programme and should appear in the Quality Assurance Manual. When the laboratory is part of a larger organisation it may also be desirable to have a chart showing the management and operational relationships which control the input of work requested and the output of results from the laboratory, the overall picture of the laboratory and the resources available for it. The general structure of staff is shown in Figure 2.1.

The office of Head of Laboratory (other titles such as "Chief" or "Director" are often used) may include a Deputy if the laboratory staff is sufficiently large. Usually, however, the duties of the Head, in his or her absence, are assumed by a senior supervisor of the analytical staff. The analytical and support staffs are discussed below in Sections 2.5 and 2.6, respectively. The administrative staffs includes all administrative assistance such as a secretary, typing and filing clerks, a management assistant and a librarian (if the laboratory library is of a size to need one). Basically the administrative staffs are those persons generally involved in "office" or "paperwork" functions. These staffs are very important to the smooth operation of a laboratory. It is false economy to understaff the administrative group because their work often must then be done in part by the analytical or support staff.

Figure 2.1 The staffing structure of a typical food testing laboratory is as follows:

Head of Laboratory			
Officer –in-Charge (**Chemistry Section**)	Officer –in- charge (**Microbiological Section**)	Officer –in-charge (**Biotech. Section**)	Officer –in-charge **(Administrative Section)**
Team Leaders Technical Staff/Analyst Supporting Staff	Team Leaders Technical Staff/Analyst Supporting Staff	Team Leaders Technical Staff/Analyst Supporting Staff	Secretarial Staff Supporting Staff

2.2 Head of the Laboratory:

Although the duties of the head of the laboratory are many, some may be delegated and others undertaken by other parts of the food control administration. The laboratory Head may have to give evidence in court or write documents used in court, in which case he must have a thorough understanding of food and related law and court procedure. There will also be involvement in committee work and relations with other organizations. The laboratory Head is usually the spokesman for the laboratory in many instances.

Note: In case of FSSAI labs, the Head must prepare work plans with the food safety officers (FSO) and overall food control authorities. Sampling plans agreed with the FSO should aim at areas of concern and major abuses.

2.3 Supervisors:

The supervisor is the on-site manager of the laboratory. Having supervisors assigned to specific units or areas of work permits the Head to more effectively plan for execution the total workload of the laboratory.

Supervisors can be expected to do analytical work in addition to their supervisory duties. However, if their group exceeds five professional analysts, it is best not to require additional analytical work except for occasional problem solving and trouble-shooting. A reasonable maximum number of analysts for one person to supervise is 10 to 12. This can be more if nonprofessional support staff is added.

A supervisor's duties can include the following:

1. Assisting the Head in overall laboratory work planning and planning the work of the group supervised.
2. Receiving and assigning samples for analysis, within the group.
3. Answering questions and assisting in solving analytical problems posed by individual analysts.
4. Reviewing the reports of completed work and making appropriate recommendations.
5. Ensuring that the group has the necessary supplies and equipment to do the work.
6. Ensuring that proper laboratory safety and housekeeping practices are followed by the group.
7. Recommending to the Head new instruments or equipment needed, and training needs of individual analysts.
8. Recommending appropriate disciplinary action when needed to enforce laboratory rules or regulations.
9. Supposed to manage the entire laboratory in the absence of the Head.

Supervisors should train one or more analysts in their group to serve as backups, to supervise the group in the supervisor's absence. The back-ups should be given some formal classroom training in supervision in addition to on-the job experience.

2.4 Team Leaders:

Another important, and often overlooked, position is Team Leader. A team leader is a senior analyst who has been assigned a small group, usually not more than 4, to do a specific task or type of analysis. The leader has no supervisory functions as such, but is the coordinator of the group's activities and is the contact point for the supervisor.

Team leaders are most useful when a large number of a repetitive type of analysis is to be done in a specified period of time. This could be a specific analytical survey or an emergency public health problem requiring screening analysis. The leader usually works along with the group in addition to the coordinative function. Such experience is often useful to determine if the assigned leader has potential as a future supervisor.

2.5 Analytical Staff:

The basic job of the analytical staff is to analyze the samples received and to issue a report. They may also be required to appear in court as fact or expert witnesses to give evidence in relation to a report. They may also be called onto offer advice to industry and trade, to assist in improvement of food quality, or advice on conformity with standards or other legal requirements. This can involve the laboratory staff in factory visits and even requests to carry out experimental work. Whether or not the laboratory undertakes such work will be a matter of organizational policy. The decision will depend on a number of factors, including the availability of alternative facilities, the nature of individual ownership, etc. The integrity of the analyst is paramount, and superiors must be informed of any conflict of interest that arises. As in the case of food inspectors, it is proper for the analysts to have no vested interest in regulated industries. This requirement is mandatory in many countries.

2.6 Support Staff

The support staffs of a laboratory is those persons working in and for the laboratory who are not conducting analyses or are not involved in administrative duties. Some examples of duties include:

1. Glassware washing.
2. Cleaning and housekeeping maintenance.
3. Disposal of sample reserves (when no longer required).
4. Pest control.

5. Heavy lifting and moving.

Support staffs typically have little or no educational qualifications beyond the ability to read and write. However, they must be willing and able to learn not only their duties, but also laboratory safety procedures. It is most important that sufficient persons are hired as support. The work they do must be done by someone and this is usually an analyst or technician when there is insufficient support staff. There is no fixed module for numbers of support workers, but 15-20% of the number of analytical staff is often sufficient.

3.0 INFRASTRUCTURE AND ACCOMMODATION AND RELATED REQUIREMENTS:

3.1 General Principles:

Facilities must allow the laboratory's work to proceed both effectively and safely.

Laboratory design should reflect the general features of the work programme anticipated in the long-term (10-20 years) rather than the specific pattern of current work.

3.2 Design of the Laboratory:

Even though the final design of the laboratory is made by architects and engineers, the analytical staff should be involved in some of the decisions that will ultimately affect their working environment and conditions. The food control laboratory have several functions such as chemical analysis of foods for proximate composition, trace metals, additives, GM testing, nutrients and toxicants, some basic food microbiology analysis and product organoleptic evaluation .

3.3 General Considerations:

Laboratory layout should be devised with efficiency in mind. For example, the distances staff have to walk for the different steps of the analytical processes they undertake should be as short as possible, though bearing in mind that some procedures may have to be segregated from others for analytical and/or safety reasons.

There is often a 5 year period from the decision in principle to build a new laboratory to when it is accepted and operational. Also there will usually be an expectation that it will not require major alteration for a further 10 years. Given that the work load may change in this time span there are real disadvantages in designing a laboratory just to reflect the detail of the currently anticipated work load. Even within a given work volume,

events may demand that the relative emphasis given to the different types of analyses may change. Additionally, advances in instrumentation and analytical methodology may alter the space and environmental requirements for a particular analysis. There is an argument for designing a laboratory in terms of "generic" activities and "specialised" activities.

Generic activities can be categorized as "wet chemistry" which will require extensive provision of fixed benches with water, power, sinks, fume cupboards, reagent shelves, glassware cleaning and storage, as compared to "instrument rooms" where less extensive servicing (though with additional piped gas supplies and perhaps stabilised power supplies) and flexible arrangements of movable tables/benches may be adequate.

Specialised rooms may be required for "clean air" work (e.g. on some environmental contaminants) or for work with substances which need to be handled with special care either for safety or for cross-contamination reasons, e.g. radioactive materials and some particularly toxic substances or for storage and dispensing of standards of pure compounds which are being analysed at trace levels elsewhere in the laboratory. A specialised room for large-scale and/or dusty sample preparation activities, e.g. grinding, blending, mixing, stirring will be invaluable, particularly if work is envisaged on heterogeneous analytes (e.g. aflatoxins in nuts or figs where primary samples of 30 kg are sometimes needed). With this approach the important design parameters are those concerned with correctly identifying the needs for specialised activities and with estimating the relative needs for the generic activities of "wet chemistry", "instrument room" and - for that matter - "food microbiology" if, as is often the case, that is to be carried out in the same premises.

Offices are needed for management and for clerical staff. There must be toilet and washing facilities for all staff. Eating, drinking, and smoking are always discouraged, and should be prohibited, in the laboratory proper. It is the responsibility of management to provide an appropriate alternative area for these activities. A separate staff room, however small, deserves consideration since it not only provides a greater degree of safety to laboratory personnel but also helps to ensure sample integrity. To provide for a prompt exit in the event of fire or other emergency, at least two entrances/exits must be provided for each laboratory whenever possible.

3.4 The Chemical Laboratory:

From a quality assurance standpoint, the design features which are important are those which can lead to erroneous results or to "lost" work, leading to missed deadlines and cost overruns. Erroneous results can arise from test materials becoming contaminated (e.g. by dust) or by cross-contamination from another sample or from a standard. Whilst good working practices will usually control most situations satisfactorily, a design

which provides complete segregation of trace analyses from highly concentrated formulations and from pure substances used in preparing analytical standards is virtually essential: the segregation must apply to all facilities for washing/cleaning equipment, washing and storage of glassware, use of protective clothing and even transfer of notebooks and records.

Design features which avoid dust, whether from environmental sources or from other samples are highly desirable from the quality assurance standpoint. Dust contamination of test materials is essentially sporadic and uneven; as such it is likely it will often be missed by the normal quality control checks. Design should aim for dust avoidance by using glass-fronted reagent shelves, keeping work-tops clear of unnecessary "static" items, regular cleaning of work surfaces with absorbent cloths, floor and furniture designed so that they can be cleaned with vacuum cleaners with suitable exhaust filters or absorbent mops. Designs which involve cleaning by the traditional "duster and brush" approach which simply spread contamination more widely should be avoided. Ventilation intakes and fume cupboard exhausts must be sited carefully so as to avoid re-circulation of laboratory air and the associated risk of contamination of test materials and hazard to laboratory staff.

3.4.1 Equipment and Instruments:

The complexity of equipping a laboratory and the consequent delay in production of useful results should not be underestimated. In the early stages, the requirements for equipment may seem large and complex but once the laboratory is established, the running costs are relatively low. It is sometimes not appreciated by the non-technical administrator that an analysis may require 10 or 20 individual items and that if even one is not available the analysis cannot be carried out. On the other hand, many items are common to different analyses so that, once the many hundreds of items required in a food control laboratory have been provided, there comes a point at which productivity can rise sharply and investment decrease. The logistical problems of maintenance, repair and replacement of equipment are also considerable. Adequate provision must be made for obtaining spares and replacement parts and for their storage. It is false economy if staff are being paid but cannot do an important part of their work due to a lack of relatively inexpensive equipment. Some of the instruments and equipment needed for chemical analysis by a modern food control laboratory are: (for purposes of this listing, 'instruments' are measuring devices and 'equipment' are processing devices. Apparatus made primarily of glass are not included).

Some of the instruments and equipment needed for chemical analysis by a modern food control laboratory are: (for purposes of this listing, 'instruments' are measuring devices and 'equipment' are processing devices. Apparatus made primarily of glass are not included).repeated.

Instruments:

1. Analytical Balance
2. pH meter
3. Spectrophotometer, UV-visible, double-beam
4. Spectrophotometer, atomic absorption
5. High Performance Liquid Chromatograph (with UV and differential refractive index detectors)
6. Gas Chromatograph (with flame ionization and electron capture detectors)

Equipment:

1. Blender
2. Grinder
3. Pulverizing hammer mill
4. Air oven, forced draft
5. Vacuum oven, with pump
6. Muffle furnace
7. Centrifuge
8. Refrigerator
9. Freezer
10. Heaters and hot plates
11. Steam and water baths
12. Water distillation still or deionizer

All of the above equipments and instruments are moveable, although the larger or more sensitive units are generally not moved, once placed. The major items of fixed equipment constructed in place are the fume hoods. The extensive use of solvents, ashing and noxious chemicals in food analysis, requires more fume hoods than other types of laboratory work. In fact, to experienced food analysts, there never seem to be enough hoods, even in a well-equipped laboratory. Fume hoods may be purchased pre-fabricated with outlets for services. The material of construction is most important, especially if the hood has to withstand acid fumes in general and perchloric acid in particular. The supplier must be given full details of the use to which the fume hood will be put. Hoods can be constructed out of local materials such as wood, preferably hard woods, coated with epoxy resins. Such should never be used for acid digestions, but only for solvent extraction work.

3.4.3 Utilities:

Electricity must either be a stable supply, or the voltage must be stabilized by either one large stabilizer for the whole laboratory, or by a unit for each of the instruments

requiring it. The lab should have sufficient number of electrical sockets. There must be several cold water taps per bench to allow for rinsing, condensers, etc., but hot water can be restricted to those sinks where apparatus is washed. In a larger laboratory a distribution system for distilled or deionized water would be advantageous. Fume hoods should have adequate provision for water taps, compressed air valves, electrical sockets etc.

Special methods, such as trace analysis, usually require distillation from glass apparatus of water initially partially purified by distillation or deionization. The initial purification produces water very low in salts, but if the original supply contains organic matter this may not be removed, and traces of resin material may be present. A steady supply of compressed air is required for an atomic absorption spectrophotometer (AAS) and is very useful to have available at the bench. A compressor is suitable for use with the instrument but if used for other purposes at the same time it must be capable of supplying those needs without affecting the AAS supply. Apart from the inaccuracy that will result from a change in the flame characteristics, sudden failure of the air may result in a flashback, which is expensive if the mixing chamber is destroyed, and could be dangerous. However, it must be emphasized that manufacturers design this part of the instrument to be as safe as possible under flashback conditions. Therefore, in many ways it is probably better to have a separate air supply to the AAS. This instrument also has to be provided with a ventilation hood to remove gases formed during operation, particularly if nitrous oxide is used as the fumes are very toxic.

Utility services require a large space but need to be concealed for aesthetic reasons, yet require an easy access for repair purposes. To satisfy these conflicting demands, the main runs may be in voids above false ceilings and in floor ducts. Secondary services are then run to outlet points on benches taken from floor level along the wall behind benches in voids especially incorporated in the design of the bench fittings. Frequent access points are provided for maintenance purposes.

Drain pipes should be of high density polythene or copolymer polypropylene with screwed joints. These show good resistance to most organic and inorganic chemicals. The drainage lines may be embedded in the flooring. As it is not acceptable to discharge laboratory wastes directly into the sewerage system, all waste from laboratory sinks and other waste fittings should be led first into dilution pots (about 5 litre capacity) before being released into the main sewers. Buildings can be designed to include a large dilution tank where all laboratory sink waste is directed before entering the sewerage system.

4. ENVIRONMENT CONDITIONS, SAFETY AND RELATED REQUIREMENTS:

4.1 Environmental Control:

Adequate control of temperature, humidity and dust is important to staff comfort, instrumental performance and safe working (e.g. with flammable solvents). If they are to perform properly optical instruments often require stable temperature conditions. Electronic equipment may have prescribed operating ranges for environmental temperature and humidity. Computers may need to be protected from strong magnetic fields from other equipment; any staff or visitors with heart pace-makers must avoid such fields. Cooling water, either from mains supplies or localised refrigeration may be necessary for the proper functioning of some equipment. Test materials, reagents, standards may need to be stored under controlled conditions. Some substances are affected by sunlight or fluorescent lights and must be protected from it. Delicate balances and optical instruments may need to be protected from vibration (e.g. from blenders, shakers and centrifuges) or may even need stabilised supports. All these needs have to be identified and documented so that proper procedures for monitoring them and taking necessary action can be included in the quality assurance system.

Records will be needed which show that: samples are received, stored, handled and analysed under environmental conditions that will not adversely affect analyses; temperature, humidity and light controls are adequate in sensitive areas to protect samples, extracts from them, personnel and equipment; the results of environmental sampling in laboratory areas are recorded; these should include records of air-flow rates across fume cupboard apertures.

4.2 Housekeeping Control:

As with any other aspect of the laboratory's activities, the responsibility for housekeeping activities must be clearly defined. Cleaning staff and laboratory staff must each have clear instructions as to their respective duties in relation to:

1. cleaning of floors, vertical surfaces (e.g. cupboards, walls, windows and doors),
2. horizontal surfaces (e.g. work surfaces, shelves), equipment, interiors of refrigerators, freezers, fume cupboards, controlled environment stores
3. control of the contents of refrigerators, freezers, fume cupboards, controlled environment stores
4. checking the performance of air-conditioning and dust extraction equipment and fume-cupboards
5. pest control

The quality assurance programme will include work schedules, records of observations and of action required/taken covering housekeeping activities of this nature.

4.3 Safety Features:

The building and laboratory design should include a number of safety features including:

1. The fire areas of corridors should be formed of concrete blocks.
2. Services should include a shower sprinkler system near each doorway so that a worker can take an immediate shower, clothes and all, in the case of accidental general contact with corrosive or poisonous liquids or fire.
3. There should be built-in eye wash fountains or at least portable eyewash stations (obtainable from most chemical supply firms).
4. The traffic flow, the egress pattern and the proportions of the laboratory are all safety considerations. It must always be possible to leave the laboratory safely irrespective of the initial site of a fire. Serious thought must be given to the number and location of fire extinguishers and stand pipe systems, and to the availability of sprinkler systems.
5. Laboratories should be well-lit so that the operator does not have to peer too closely over potentially hazardous material in order to see what he is doing. There should be ample working space and bench tops and other surfaces should be kept clear of all material except that in current use.
6. Benches are best without shelves, only services, these being operated from the front so that the operator does not have to stretch across the bench. It is still common to see reagents on shelving at the back of benches (or above the centre of double-width benches) but it is probably safer if such reagents can be kept on side - shelve or in trays which are brought to the bench as required.
7. Flooring needs to be of a non – slip material, resistant to acids and solvents, but not so hard as to be tiring to stand on for a few hours at a time. No material is entirely satisfactory. Well-laid linoleum and a filled epoxy resin on top of concrete are among the best available. It is advisable not to polish laboratory floors.
8. Pollutants generated within the laboratory must be removed safely, quickly and efficiently. In particular, toxic or noxious gases must be removed expeditiously through a duct system that does not exhaust near the building air conditioning intake.
9. The building must be planned for security. Restriction of access is of considerable importance because of the extremely valuable and sensitive equipment used in the laboratory work as well as to protect the integrity of official samples.
10. It is very advisable to have an efficient fire and smoke detection system with appropriate alarms. Common fire detection equipment is usually either rate-of-temperature-rise or fixed-temperature detector using a substance of known

melting point. There are advantages (and disadvantages) to each type of detector and the laboratory Head should select the one he feels best fits his laboratory.

Designing a laboratory to afford protection against every kind of hazard should be aimed at, but, the level of safety for the most general applications and to provide supplementary systems in areas of higher hazard has to be achieved.

A safe solvent storage area is ideally separate from the laboratory building in a stand-alone structure. It can be a small building of one room and some possible design features are: (reasons are given in parenthesis)

1. Construction of cement blocks or bricks. (Only non-flammable materials surround the solvents.)
2. For a stand-alone building, double walls with insulation between. The exterior wall can be material other than block or brick. (Provides insulation from the sun and makes air conditioning more effective.)
3. An epoxy film to cover the entire floor plus 10 cm up the base of the walls. (Any solvent spillage will pool and evaporate, rather than soak through the floors or walls.)
4. A copper pipe (about 25 mm) inside the room, which goes through the floor and is embedded about 2 m in earth. (A ground pipe to bleed off any static electricity charges - which often build up when solvents are poured).All metal objects in the room are to be attached to the pipe using heavy guage single strand copper wire. Also, attach a short wire with an alligator clip. (This grounds all metal. The clip is used to ground any metal cans used for solvent transfer.)
5. Storage shelves of metal and connected by wire to each other and the grounding pipe.
6. Air conditioning is external, with the entrance duct at the top of one corner of the room and the exit duct at the base of the opposite corner.(The room must be cooled as many solvents will boil at hot outside temperatures. The air entrance on top and exit on the bottom diagonally across the room, will cool the room and will also serve to sweep and remove any solvent fumes on the floor - solvent fumes are generally heavier than air and will pool on the floor.)
7. The door is of metal and fire-rated for at least one hour, with a positive closure. It must seal well when closed. The door sill is at least 10cm high. (Fire doors are metal sheathed around cement. The closure, the sea land the high sill all act to prevent escape of solvent, either floor spillage or fumes.)
8. Air conditioner exits duct with a fire baffle (to prevent flashback) and ducted to exit in the outside air at building roof height. (Fumeshave a better chance of being carried away by breezes and someone smoking nearby will not present a fire risk.)
9. An extinguisher system, which should be carbon dioxide or Freon type and not water sprinklers.

5.0 PERSONNEL RELATED REQUIREMENTS:

1. The personnel should be technically competent to perform their duties as allotted to them whether operating on specific equipments/ performing tests /evaluating results/signing the reports.

2. Qualification for doing specific tasks shall be judged on the basis of their education, training, specific experience and demonstrated skill.

3. Regular and refresher training should be organized to keep the personnel update in their domain of activity.

4. Specific job description for each personnel should be defined with their role and responsibility.

5. Personnel should wear proper uniform and protective clothing's, etc as required depending upon the test method.

6. While doing test no phone calls/ cell calls should be attended to avoid any type hazards and carelessness while performing the test.

7. Normally blank determination along with the known-standards must be carried out in duplicate/ replicate to check the accuracy of the results obtained and human error etc.

8. All the analysis records must be documented either through hardcopy or through soft copy to demonstrate that the tests are really been carried out.

9. Random checking of the result should be done inter-laboratory and intra-laboratory to check the proficiency of the personnel.

10. In case of hazardous analysis, special precautions as provided in the methods should be taken for self and surroundings.

11. While opening and closing the laboratory room, safety precaution should be taken care of depending upon the nature of the laboratory, equipment and test method. Special care should be taken for microbiological lab. Instructions in this regard must be displayed in the lab.

12. In case of contractual appointment, technical competency of the personnel should be judged and they should be put on job only after they are trained and their competency in the respective field is established.

13. Alternative arrangement of personnel should exist in case one is not available but not at the cost of their technical competency.

14. Personnel should be medically fit depending upon the test method he is deployed to avoid any hazards.

15. Special precaution should be taken by the personnel during break time to ensure that tests are carried out as per prescribed method and no relaxation is given in the test method.

16. Calculation should be rechecked on random basis by the supervisor.

17. Daily wages should not be put to job.

18. The personnel at the time of working in the laboratory should be alert and concentrate on their work only.

19. Supervisory officer should randomly watch the analysis activity and guide from time to time to increase the competency of analyst.

20. Eating habits should be avoided in the laboratory.

21. First Aid box should be available in the lab. along with emergency Telephone no. of hospital/doctors/contact person.

22. During odd times person should avoid working lonely.

23. Fuming chamber must be used for test requiring ash, protein determination, evaporation of solvents etc.

24. While pouring down acids etc in the basin, water taps should be kept on slowly.

25. Electrical equipments should be handled with great care.

26. Poisonous and hazardous chemicals must be kept under safe custody.

27. Manual sucking from mouth of liquid should be done with bulb type pipette.

28. Competency of the personnel should be judged regularly by giving unknown samples.

29. No external or internal pressure should be put on analyst.

30. Output should not be linked with quantum of work. More emphasis should be on quality output or results.

6.0 TEST METHODS:

1. The laboratory shall use only official methods depending on the requirement of the test, its sensitivity and nature of the commodity which is being tested and quality/safety factors to be determined.

2. In case of non-official method, validation of the methods as per set norms is a must and their range of detection/quantification, L.O.D./L.O.Q. limitations etc. must be established.

3. Selection of method is very important depending upon the requirement of the test and customer requirement.

4. Estimation of uncertainty of measurement should be available for each method in context of the food commodity and test to be done.

5. External calibration of the equipment is a must annually or depending upon its use. However in case of any equipment being used very frequently, internal calibration facility should be available and done regularly with a record thereof.

6. Glass apparatus should be calibrated.

7. In case of standard chemicals required in testing, whose purity can alter the result should be certified reference material with proper traceability.

8. In case of recovery and PPM level extraction from a food commodity, percentage recovery must be established for each food and the contaminant/constituent which have to be determined and the calculation should take care of such recovery.

9. Sometimes official methods do not prescribe the interfering material in the test method, limitations ,its sensitivity, range of detection and qualification, capability of the equipments being used, due to change of the sophisticated equipment as prescribed in the method for a particular model/ technology. Hence it is necessary to establish the suitability of such methods for their particular test and equipment, etc before giving the results. Obviously the method needs to be validated internally for its particular use using particular equipment.

10. Standard solution/CRM Solution should be stored at required temperature and condition and its strength should be checked regularly and record thereof should be maintained.

11. Calculation should be done and rounded off while reporting the results to the required level of standard.

12. SOP as far as possible should be available for test method along with the protocol.

13. Method should be available while performing any test to follow exactly the test method prescribed. No short cuts should be followed and tests should not be done on a memory basis alone.

14. Purity of the solvents, water being used and other chemicals should be checked regularly and a record thereof should be maintained.

15. In case of any controversy or marginal results, only reference methods should be used.

16. In case of micro biological analysis standard culture must be available to establish the confirmation of the microbes. SWAB testing must be done for inoculation room and media preparation room regularly to ensure that it is not contaminated.

17. The results should be recorded commensurating with the calibration of the glass apparatus etc e.g. in case of a burette, the result should be reported only to the displayed capabilities of the burette.

18. Special precaution should be taken for pipetting and ejecting the solution from the pipette. The solution should not be blown by air through mouth.

19. All the apparatuses specially glass should be contamination free and should be cleaned and rinsed thoroughly before use. No chemicals should be used after its expiry or otherwise if it looks like deteriorated or decomposed.

7.0 EQUIPMENTS:

1. All the equipments being used should be under permanent control of the laboratory and should be capable of in context of the test method.

2. The equipment must be calibrated depending upon the requirements by an outside accredited lab and/or internally as the case may be.

3. In case the sophisticated instruments are shifted from one place to another the same should be re-calibrated.

4. Depending upon the uses, the equipments should be internally calibrated either daily or at a periodically interval as the case may be.

5. Instruction manual, operation manual and other details of the equipments like calibration, due date of calibration, safety precaution, etc must be available at the side of the equipment.

6. Each equipment should be uniquely identifiable.

7. The equipment should be placed and test must be performed under a proper environmental condition as prescribed. Normally the room should be dust-free, air conditioned with controlled humidity. Special condition needs to be followed in case of equipment being used in case of micro biological analysis like Air handling unit, etc.

8. Each sophisticated equipment should have IQ, OQ and PQ Certificate from the manufacturer.

9. LOD/LOQ/ Range of detection/ range of quantification must be established for each equipment in context of the test method, nature of the food commodity, constituent to be determined. The reason being that normally in official methods, the model of the equipment being used along with its accessories becomes old whereas due to technological advancement a model of the equipments are upgraded along with accessories and software, hence the LOD, LOQ, etc must be established and should be checked as claimed by the manufacturer which may not commensurate with the limits given in the official methods. SOP must be available for operation.

10. Equipments not working should be placed under a tag " out of order"

11. Software being used in the equipment must be validated and a record thereof should be available.

12. Maintenance plan of the equipment should be available and should be done under annual maintenance contract.

13. Equipments should not be subjected to overloading or mishandling which could give erroneous results.

14. In case the equipment send outside the laboratory for repair, etc. proper procedure of packing and transportation as prescribed by the manufacturer should be followed.

15. Intermediate checks of the equipments must be done through known and certified standards regularly. The equipment should be handled by technically competent and trained personnel only. Such personnel should be trained on routine maintenance and minor repair of the equipments.

16. Proper procedure as prescribed by the manufacturer should be followed for cleaning of the equipments and its accessories before and after use.

17. The SOP for safe handling, transportation, storage, use and plant maintenance of the equipments must be available to ensure proper functioning and to prevent deterioration /contamination.

18. Do and don'ts regarding important instruction should be available along with side of the equipments and should be visible all the time.

19. Due care should be taken to ensure constant voltage supply of electricity as required for the equipment to avoid fluctuation and thus variation in results.

20. After return of the equipment from repair, the same procedure should be followed as that for new equipment to ensure that the results rendered by the equipments are as per capability of the equipment. In such cases the instruments needs to be recalibrated before put to use.

21. Equipments where gases are being used, the purity of the gas should be as per requirement of the equipment/test method.

22. Gas cylinders should be put outside the laboratory room at a well secured and approachable place.

23. Temperature and humidity of the room where the equipments are placed must be recorded daily. In case of micro biological laboratory, special precaution should be taken as per requirement of the test method for environmental conditions especially in case of isolation and determination of pathogens.

24. In case of a mobile food testing laboratory a separate SOP should be available and the equipments used in such laboratory should be technologically sturdy to

avoid variation in results. Calibration of such equipments needs to be done very frequently preferable daily before being put to use.

25. Software being used in the equipment should be capable of achieving the accuracy required and should be complied with the specification related to the test method.

26. Software should be upgraded and validated from time to time.

27. Obsolete equipments giving erroneous results in context of the requirement of the test method should not be put to use.

28. The equipment should be placed on a vibration free platform.

29. Daily cleaning of the equipment should be done by trained personnel as per SOP

30. Proper safety precautions should be taken for equipments running round the clock in the absence of the personnel.

8.0 CERTIFIED REFERENCE MATERIALS / STANDARDS AND REFERENCE CULTURES:

Testing, validation/calibration, standardization & reference materials are inter-related due to dependent on each other. Without proper reference materials, it is not possible to make up any idealized and reliable measurement system. As per the lab quality assurance procedure reference materials are required for all types of testing and validation/calibration. These are widely used for validation/calibration of an apparatus and testing procedure, assessing the true value.

The reference materials are generally used for, to develop and validate accurate method of analysis ensuring traceable measurement results at the working level, to calibrate measurement system and to demonstrate the accuracy of results, assure the long term adequacy and integrity of measurement quality assurance programme and monitor the lab performance, use in inter laboratory comparison and proficiency testing programme.

The laboratory shall ensure to maintain the reference standards, which are certified by the competent body having traceability to a national/international system like NIST etc. The certificate provided by the supplier/manufacturer shall be maintained in the laboratory for records.

The reference standards having high purity, critical characteristics and require to store in special condition and hence its, to be stored in appropriate special condition as per the requirements. The substances are to be kept in sealed vial and shall be stored in dry place, away from heat, sunlight & moisture.

The reference material of various parameters such as metals, pesticides, antibiotics, volumetric standards etc. may be received from standard brand like Sigma, Aldrich, Fluka, Riedel-de-Haen, Dr. Ehrenstrofer Gmbh, Merck, Supelco etc. in regular intervals accompanying with certificates with proper label. The certificates shall include the name of the standard, the purity, uncertainty at a stated level of confidence, expiry/ validity/ shelf life, QC release, chemical formula / structure, assay/potency level of confidence / chromatogram, storage condition etc. The same shall be verified for the label, certificate & condition during receiving of the standards.

The reference standard solutions are required for sample analysis, quantification and QC checks. The laboratory shall be prepared the standard solution as needed like stock / primary, intermediate & working solution and wherever applicable the purity shall be considered during preparation. The standard solutions shall be kept in screw capped glass vials, standard volumetric flasks/stoppered conical flask (transparent/amber coloured) in air-conditioned room / refrigerate /deep freezer depending upon storage condition & requirements.

The standards shall be prepared from bulk reference standard materials received from the market as A grade material. The selection criteria for the bulk material intended to accept as working standard in assay and purity of substances. For accepting the material to be taken as working standard the molecule must be subjected to chemical characterization. First the standard stock solution to be prepared from which different working standard is made. The preparation of standards is generally carried out in regular interval as per the requirement / laboratory protocol and the records of those are to be maintained and labelled with concentration & date of preparation.

The preparation of working standard is generally carried out during analysis/ whenever necessary and records of these are to be maintained.

The intermediate checks of the standards shall be checked in regular interval to ensure the performance, stability & integrity of the standards and records of those are maintained with Quality Control Chart / Levey-Jennings Chart etc.

The shelf life / expiration date declared by the reference standards providing organization is generally applied to unopened condition that have to store at recommended temperature. Hence it is the responsibility of the laboratory to maintain the critical characterization, performance, stability & integrity of the standards through

proper handling, storage etc & same shall be ensured by the intermediate checks in regular interval / as per the laboratory protocol.

For some reference standards the shelf life / expiration date may not declared by the reference standards providing organization, in those cases the following shelf life may be considered when the standards are stored un opened at recommended temperature

1. Room temperature items, which are not temperature sensitive and usually are stabled for five years from the date of receipt.
2. Refrigerated items usually are stabled for two years from the date of receipt.
3. Freezer items usually are stabled for one year from the date of receipt

However it is the primary responsibilities of the laboratory to ensure the performance, stability & integrity of the standards through intermediate checks in regular interval / as per the laboratory protocol.

Reagent solution/standard solutions shall be prepared in established manner, for preparation of reagents the testing personnel refers to be relevant reference. After their preparation, those are to be stored in appropriate storage condition i.e. protected from light, tightly stoppered, refrigerated etc. Wherever, it is recommended reagents are to be prepared freshly. All the reagents/solutions bottles shall be properly labelled with name, date of preparation, concentration etc.

All reference standards shall be kept under responsible person to maintain proper storage, transport, security, integrity, mishandling etc and the relevant records are also to be maintained. The utmost care & protection shall be taken during handling & preparation of standards to avoid cross contamination & health hazard.

The reference culture/microbial pure cultures are used establishing acceptable performance of media, performance of the kits, validation of methods and assessing/evaluating the laboratory performance. The reference microbial strains are directly collected by laboratory from recognized national or international collection (ATCC, MTCC, NCIM etc) with traceability. Generally the reference strains are received in lyophilized stage or deep-frozen stage. If the reference strain has been thawed they shall not be refrozen.

The reference microbial stains are used for Quality control; internal quality control and performance of culture media in terms of productivity, selectivity, performance evaluation and interpretation of result. The reference cultures are received either on slant form or in lyophilized forms in vials.

On receipt the reference cultures, requires to revive in the laboratory. The active cultures shall be sub-cultured on to recommended medium and incubated at temperature specified. For lyophilized culture the outer surface of the vials is

disinfected, wrapped with thick cotton wool and neck of the culture vials is broken. The contents transfer into 3 to 5 ml of recommended broth medium and mixed properly. The suspension is to streak on the recommended agar plate and incubates at specified temperature. Reference cultures to be checked for its purity, homogeneity, and typical morphology. Subsequently they have to check for characteristic reaction in selective medium and biochemical reactions. Whenever necessary, serological test as per analytical procedure is also to be carried out to check the pure culture.

Sub-culturing from original stock in regular intervals as working culture for routine use and records to be maintained. The intermediate checks on the purity and biochemical characterization also to be checked. All the working cultures are properly locate with name, date etc. & to be kept under proper storage condition.

All reference standards / pure culture stains are to be kept under responsible person to maintain proper storage, transport, security, integrity, mishandling etc and the relevant records are also to be maintained. The utmost care & protection shall be taken during handling of microbial pure cultures for to avoid cross contamination & health hazard. The laboratory has to maintain procedures / instruction for all.

[Sources of reference materials are at Annexure 8.1]

9. CALIBRATION AND PERFORMANCE ASSESSMENT RELATED REQUIREMENTS:

For accurate test results, lab shall be ensured that the equipments which are suitable for intended purpose and capable of providing valid results, such instruments would be regularly inspected, checked & calibrated accordingly. So laboratory should establish a schedule for the calibration and performance verification of equipments/instruments, which will be direct influence on the test results.

The calibrations to be done by in-house (internal)/external agencies/competent body having traceability to a national / international standard (NABL accredited lab) depending upon the type of equipment / instruments.

Laboratory management has to first segregate and classify the instrument, require external and internal calibration. The interval / frequency of calibration has to decide by the laboratory considering the equipment/instruments type, uses, experience and need base, previous performance of the equipment etc.

Regarding external calibration laboratory has to collect the information from the calibration agencies / laboratories to ascertain the facility / capability to fulfil the laboratory requirements, status of accreditation, charges etc and based on the same the competent calibration agencies / laboratories can offer for the calibration job. The calibration for the instruments like balance etc is recommended to perform on site and

others may be sent to workshop/workplace. The laboratory shall ensure calibration status / performance status of the instruments / equipments goes outside of the laboratory control after return / put into service.

It is the laboratory responsibility to verify / check the calibration certificate in terms of the lab requirements, traceability to the primary standard, ensure the capability / calibration range, uncertainty, due date of next calibration (if require) etc and laboratory has to evaluate the services. All records are to be maintained.

The sophisticated instruments such as GC / GC-MS, HPLC/ LC MS MS, AAS/ AES, ICP-MS/ OES, UV-VIS Spectrophotometer etc. are recommended to check the performance verification & operational qualification (OQPV) al least once in a year / depending upon criticality of the uses of the instruments through the service providers / OEM. It is the responsibility of the laboratory to verify / calibrate the instruments to ensure the performance in regular basis / before put into use / analysis by use reference standards etc.

The equipments like thermometer, pressure gauge, humidity meter, laboratory may calibrate through external calibration agencies with proper traceability in regular intervals / as per the lab protocol and the laboratory may use the same equipments as standards for verification.

Where the certain criteria e.g. temperature, humidity etc has a direct effect in the result of the test, the measuring device should be appropriate in quality to achieve the perfect accuracy and those devices should be calibrated (internally/externally) traceable to national/international standards.

In case of incubators, water baths, ovens, furnace etc. the stability of temperature, uniformity of temperature distribution and time required to achieve the equilibrium are to establish initially by experienced personnel. The documented monitoring system of operating temperature is also be maintained.

Other equipments/instruments like conductivity meter, pH meter, refractometer and other similar devices are to be verified in regular interval and prior to use with reference standard.

Laboratory also ensures that the performance of the lab autoclave is also capable to meet the specified time and temperature, pressure. Devices used for controlling/monitoring of operating cycles are verified as well as calibrated. Laboratory is also ensuring to maintain records of autoclave operation including temperature/pressure and time for every cycle. In addition to monitoring the effectiveness of the autoclave operation during its cycle also be checked by use of chemical/biological indicator for monitoring sterilization/decontamination purpose when a load has been processed.

The weight and balance are also to be calibrated traceably at regular interval / as per the lab protocol. The performance of the weighing balance to be checked in regular interval / every time before use.

The volumetric equipment such as dispenser/diluters, pipettes, volumetric flasks etc. used in lab are to be checked to ensure the performance of the equipment. The equipments shall be checked for the accuracy of the delivered volume against the set volume and the precision of the repeat deliveries also be measured. Laboratory shall obtain the certified specific tolerance supplies from manufacturer/companies and calibrate through external agencies with traceability. The laboratory may also follow internal verification and intermediate checks on accuracy. The lab also ensures to provide a dedicated balance as reference to carry out the in-house calibration verification of glass wares etc.

The status of calibration (internal / external) of all the equipments/instruments including frequency of calibration, date of last calibration, due date of next calibration, plan and procedures shall be maintained by the laboratory

10. PURCHASE OF CONSUMABLES/ EQUIPMENTS :

The laboratory should be maintained a proper system on purchase service & supplies of all media, chemical, reagents & other requirements/appliance, consumables to avoid undesirable, unconfirmed supplies of them and also ensure there should not be any effect on the of test analysis / result.

Requirements like name of the chemicals, appliances, glassware's, consumables, brand name, quantity, Management, rate contract/ comparative quotation, quantity available in stock shall be well documented by the laboratory.

Purchase shall be made in a systematic manner through a proper purchase / laboratory protocol considering different aspect like quarter/half year/annual requirements, pattern of previous consuming, approximate cost etc. Regarding purchase of equipments / instruments laboratory shall be need based considering the laboratory requirements, indented for use, accuracy / sensitivity, sophistication / latest version, future plan / work load etc.

On arrival of all the purchase materials, the laboratory shall be received & verified with reference to the order placed and the relevant criteria like quantity, brand, code, certificate of analysis, date of expiry , guarantee / warranty, condition of the items on arrival etc. The necessary entries / documents shall be maintained.

All instructions related to the purchase like storage, handling, inventory, responsibility etc shall be maintained & documented by the laboratory and followed in a systematic way.

The items/ supplies will effect on test result and the laboratory shall be evaluated the same to ensure the quality. Records are also to be maintained.

It is the responsibility of the laboratory to verify the certificates, reports etc related to services opt by the laboratory from the calibration agencies, equipment / instrument manufacturer / service providers etc..

Laboratory shall evaluate the performance of the supplier & service providers in regular intervals and approved list supplier & service providers with all details shall be maintained.

The laboratory must be maintained procedures / instruction & documents / records for all.

11. SAMPLING & SAMPLE HANDLING:

Sampling for testing or analysis is a process of taking a representative portion from a material or product to test (e.g. by physical measurements, chemical analysis, microbiological examination), typically for the purposes of identification, quality control, or regulatory assessment. The sampling is a significant role in testing activities as it reflects the ultimate test results.

It is not mandatory that all the laboratories shall be involved in sampling activities. However the laboratory involves in sampling shall maintain at least the following

The laboratory policy & declaration on sampling.

The laboratory should have authorized personnel / sampler with adequate knowledge, training etc on sampling.

The laboratory shall maintain the sampling plan & procedure in respects of the products / materials that shall include selection, withdrawn & preparation of samples during sampling. The same shall be based on appropriate statistical method / regulatory guidelines / references.

Work instruction shall be maintained for the personnel involve in sampling activities.

The laboratory should have all facilities like tools, equipments / instruments etc requires for various sampling.
The laboratory shall maintain the relevant data & operation related to sampling, procedure use, location, date / time of sampling, identification of sampler, other specific requirements like environmental conditions, transportation, statistics the sampling procedures are based upon etc and documents shall be maintained.

All incoming samples shall receive through the receiving section maintained and supervised by laboratory responsible person. On receiving section the laboratory responsible personnel initially checked the relevant overall criteria like sample identity/labelling, mode of transportation, condition of the sample including packaging, sample quantity, verification of fees (whenever necessary), parameter to be tested etc against the customer declaration / requirements. Any abnormalities / deviation / doubts from the normal condition, suitability of the sample for tests etc , the same shall be clarified from the customer / laboratory responsible personnel before accepting the samples for registration / testing. In case microbiological test samples, the same shall be received in the sterilized container/sample box etc. The laboratory documentation system shall includes all relevant information such as customer details, date of receipt, condition of the sample on receipt, sample quantity, transportation , parameters to be tested ,observation/remark (if any) etc.

The laboratory shall maintain a system on traceability of all accepted samples and the same shall be maintained throughout the retention of the sample in the laboratory without any confusion.

The laboratory must have all infrastructures, facilities for storage and preserve the samples depending on the physical, chemical and microbiological properties to maintain the sample integrity, security, avoid loss / damage, deterioration etc. The laboratory must have proper documented system on retention & disposal of the tested / remnant / reference samples. The retained samples may also use for retesting and the internal quality assurance purpose. Wherever necessary the specific storage like deep freezer, refrigerator etc shall be provided and during storage the environmental conditions shall be maintained, monitored & documented.

The laboratory must have documented system, procedures, instructions & facilities for conditioning and preparation of sample according to the standard method or laboratory protocol to maintain the homogeneity, avoid loss / damage of the test sample.

The laboratory should ensure to maintain a proper documented system procedure for handling of test items including sample receiving, storage, transportation, retention / disposal, integrity, avoid and prevent loss/damage of the test samples.

11.1 General Principles:

The identity, homogeneity and integrity of the materials being handled by the laboratory must be ensured throughout the time they are under the control of the laboratory e.g. from sample receipt to data report and authorized disposal of the surplus material.

The analytical data report must reflect the composition of the received material as a whole.

11.2 General:

Sampling is a defined procedure whereby a part of the substance material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis) the sample may not be representative but is determined by availability.

The sampling procedure should describe the selection, sampling plan, withdrawal or preparation of sample from a substance, material or product to yield the required information. If the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with appropriate sampling data and shall be included in all documents containing test and /or calibration results.

The laboratory shall have the procedure for recording relevant data and operations relating to sampling that forms part of the testing and calibrations that is undertaken. These records shall include the sampling procedure used, the Identification of the sampler, environmental conditions (if relevant) and diagrams and other equivalent means to identify the sampling location as necessary.

11.3 Samples may be conveniently classified under two broad divisions:

I. Formal samples – These are samples taken to determine if the food complies with national or local laws or regulations and
II. Informal Samples – These are samples taken for the purpose of monitoring or as part of survey work.

Formal follow-up samples can be taken if informal samples receive adverse laboratory reports. Formal or informal sample are also taken under others such as follow-up to a consumer complaint.

11.4 Sample Collection:

Work scheduling is greatly facilitated by arranging a sampling programme for routine monitoring with the inspectorate. As part of a general food control programme there is need to:

1. Regularly inspect foods at different stages in the manufacture and distribution chains, using planned surveillance programme.

2. carry out general surveys of the quality of the food supply through random sampling and analysis.
3. monitor certain specific problem areas with regards to food safety – specific potential risks, e.g. level of metallic contaminants pesticide residues, mycotoxins etc.
4. inspect foods for export, for certification of quality (if needed)
5. inspect food import. This is best done on all imported consignments by formal sampling carried out systematically in a manner representative of the lot.
6. formal sampling should also be done on locally produced food products based on the food inspector's observations or because a random or investigatory samples under the regular programme was unsatisfactory or the product is one that requires thorough surveillance. Analysis of formal or informal samples is also necessary in an emergency such as an outbreak of food poisoning.

11.5 Quantity of Samples to be collected, product wise is shown at Annex 11.1

(Ref. Annex II of FSSAI Manual on General Guidelines on Sampling)

11.6 Sample Receipt and Assignment:

Receipt and identification of a sample have to be clear and unambiguous for the quality assurance to be maintained. The laboratory register of test materials should be of a type where papers are numbered and cannot be removed. Entries on computer-based registers must be protected against deletion and /or alteration. A back-up copy must be produced and stored separately from the original.

When a sample is received for analysis, there must be a system to track the sample throughout its initial stage, analysis and later reserve storage. This is usually embodied in a record-keeping system, which is keyed to a unique identification number assigned to the sample at the time of sampling. This number can be sequential (i.e., 00001 to 9999) or can be devised to give information (i.e., 024-95-07) the 24th sample taken in 1995 under sampling programme No7) The record must show the movement of a sample, its receipt, assignment to a laboratory person for analysis, return to the sample and eventual dispersal. One of the administrative staff should be given this record – keeping function and closely supervised by the laboratory Head. It is preferable to use a card system rather than a logbook as cards are more flexibly handled. There are certain items of information, which should be on each card:

1. Sample number
2. Product name
3. Date Sampled

4. Date received at the laboratory
5. Type of sample (Survey, Complaints etc.)
6. Method of storage (dry, refrigeration, freezing etc.)
7. Storage location (coded for easy finding)
8. Date assigned for analysis
9. To whom assigned (the analyst should initial to show receipt)
10. Date retuned (from analysis)
11. From whom returned (maybe different from the original analyst)
12. Reserve storage method and location
13. Final disposal of samples, method and date.

Example of a typical sample record is given at Annex 11.2 (ref. Appendix 5.1 of FAO 14/14)

11.7 Control and Storage:

The storage of test materials is of major importance if the analytical data produced is to reflect and be traceable to the original sample. Deterioration of test materials invalidates any results. Therefore; test materials must be stored so as to ensure their integrity, safety, legality and stability. The laboratory must guard against deterioration, contamination and loss of identity. Special care will be needed where trace analysis is involved in order to ensure that extraneous materials do not contaminate the test materials and equipment.

There are three basic forms of storage - room temperature (dry room), refrigeration and freezing. The QA programme should specify the conditions to be used (Annex 11.3 - reference Appendix 5.3 of FAO 14/14). There are also problems associated with the type of container in which food can be stored. Foods that contain fats and oils should not be stored in copper or metallic vessels and foods that easily desiccate such as fruits need to be stored in ways, which avoid loss of water.

Perishable, unfrozen food must be maintained at 0C – 4C and frozen food kept preferably at -18 C or below. All perishable items should be examined within 36 hrs. Of collection .Perishable samples that have been examined within 36 hrs after being sampled should be frozen, canned. Dry non-perishable foods maybe stored at room temperature before analysis.

The test material could also be dried and stored pending analysis, if analysis will not be affected by drying.

Special conditions apply to test materials, which are to undergo microbiological examination as well as chemical analysis. If a test material is to be stored frozen and a

number of separate analyses are to be performed, it is preferable to sub-sample before freezing.

All test materials when stored must be properly and indelibly labelled so that identification is not lost .The most effective method of labelling maybe to place the label in its own plastic bag, inside the test material container, but separated from the food by a suitable layer.

The sample is then stored until it can be matched with a suitable test note containing all the above information and any other relevant information required for analysis and interpretation of the results. The test note should preferably be of the type that incorporates enough space for the test results and observations. The sample and the test note should (when matched if they arrive at different times) be clearly and indelibly marked with a registration number and passed to the analyst. From this point onwards, the analyst will identify everything pertaining to that sample with the laboratory number.

11.8 The Analytical Sample (Test Portion):

Before removing the test portion (s) for analysis, the analyst must be certain that all records are in order, integrity has been maintained containers are intact and sealed (if any) ,unbroken.

Any ambiguity in the analytical requirement must be resolved, e.g. with canned pickle in oil, is the analysis to be done on the pickle, oil or the whole contents of the can.

For analysis, the analyst first removes a test portion. If the test material comprises more than one item (fruit, vegetable etc.) the test portion should contain material from each item – usually achieved by comminuting a number of items and removing a portion. After the test portion has been removed, the remaining test material is returned to the storage.

11.9: Referral of the Test Material:

On occasions it may be necessary to pass a test material to another laboratory for some specialized analysis or because of some analytical facility not being available with the laboratory or because of overload of work. Unless the other laboratory is a part of the same QA programme or the two laboratories are accredited by the same (or equivalent schemes), this referral would mean that the test portion sent for that analysis ceases to be quality assured by the parent laboratory. This should be made clear in the analysis report to the customer.

11.10 Test Material Disposal:

Sample disposal is relatively a simple matter. The only problem arrives when there is a hazard involved in the destruction or the sample remains must have specific treatment e.g. a sample of groundnut heavily contaminated with alfatoxin. Any residual material if valuable such as flavouring concentrate maybe required to be returned to the originator. The register should therefore have a column in it for details of when, how and where the test material was disposed.

11.11 Documentation for QA Programme:

1. Register for sample receipt: Test material identification
2. Flow chart of the sample submitted for laboratory examination
3. Storage conditions for food test materials

12.0 QUALITY ASSURANCE MEASURES:

12.1 General Principles:

The QA programme for a laboratory covers all the policies and activities, which can affect the quality of its output.

12.2 Definition and Scope:

A QA programme maybe defined as a mechanism used to ensure that the data are fully reliable, suitable for the intended purpose, presented on time and at an acceptable cost. It is a formal, planned activity whose purpose is to provide assurance that the quality control programme is actually affected and is designed to fit the needs of the laboratory.

The scope of the quality assurance system has to be developed in such a way that there is confidence that whenever data are reported

1. the identity and integrity has not been compromised
2. the analysis has been conducted by member of the staff who is competent for the task
3. the equipments and the methods are appropriate and are working properly
4. the laboratory can demonstrate its current capability to produce valid data.

The format adopted in meeting these requirements may vary from laboratory to laboratory.

Each laboratory (or group of laboratories) meets different requirements, operates within a different organizational environment, experiences different constraints and should have a QA programme, which takes account of these factors.

There are certain factors, which are common

1. The use of validated methods
2. The use of standard operating procedure (SOP) in the laboratory
3. Calibration and traceability of measurement (including use of certified reference material)
4. External assessment of performance

While facilities exist for accreditation of laboratories for particular types of work, it is usual to find requirements for these features within this scope of accreditation process along with the requirements for topics which may include organization and management, laboratory accommodation and environment, equipment maintenance, handling of test materials, test methods and quality control procedures (and method performance characteristics), staff training and performance, security, records and reports, sub-contracting of work , outside support services , handling of complaints , quality audit and system review.

12.3 Preparation:

QA Programme is concerned with everything that goes on in the laboratory, which may affect “Quality”. Each member of the staff involved in the QA programme must be

1. clear about what they are expected to do
2. know how to do it and
3. be able to show that they had done it properly

Documentation is a major feature of QA programme. Formulation of a QA programme should contain three essential components

a) Prevention, which requires an orderly programme of planning and positive actions before or during analysis to ensure that all analytical systems are performing appropriately, easy calibration and maintenance of instruments use of reference materials and training.

b) Assessment, a form of control that includes periodic checks on the analyst performance e.g. analysis of check samples and validation of methodology.

c) Correction, an action taken to determine cause (s) of quality defects and to re-establish proper functioning of analytical operations e.g. trouble

shooting to correct malfunctioning equipment, re-evaluation of methodology and re-training.

12.4 External Proficiency Testing:

Proficiency testing is the part of QA programme, which looks at the accuracy (correctness') of the results actually being reported by the laboratory on real test materials. An independent external assessment of the correctness of the typical result provides an impartial test of analytical quality: this is done by proficiency testing scheme, i.e. methods of checking laboratory testing performance by means of inter laboratory tests. This includes comparison of a laboratory's results at intervals with those of other laboratories. Procedures used when analyzing test materials for such a scheme are those normally used by the laboratory.

The proficiency testing is likely to grow in importance because of regional and international developments which require laboratory data to be mutually acceptable between nations for many regulatory purposes .A harmonized protocol for the proficiency testing of the chemical laboratories has been prepared by joint ISO /AOAC International/IUPAC Working Group (November 1992, ISO /REMCO, N263). This identifies and explains the major features recommended for proficiency testing scheme. The major features of the protocol are listed in Annex 12.3 (Ref. Appendix 10.1 of FAO Manual14/14)

12.5 Internal Quality Control Checks:

Blank Analysis:

Blanks are to included in analytical methods .A blank is characterized as a sample included in the analytical processes, which has all the properties of the actual sample except that it does not contain the substance of interests.

Duplicate Analysis:

Duplicate sample analysis is the analysis of the same sample twice in order to determine the precision of the analysis.

Spike Analysis:

A sample is split into two sub samples in the laboratory. One is analyzed according to the specified procedure. The other is treated by adding a known amount and concentration of the indicator being measured, running this specified procedures. This should increase the concentration in the spiked sample relative to the unsp sample, by a predictable amount. Usually 10 percent of the sample are split and spiked. They are used to test the accuracy of the laboratory method.

12.6 External Performance Evaluation:

In order to verify that a laboratory possesses the capability to provide accurate and reliable test data in its day to day operations and to maintain high standards of performance, a competent, disinterested third party is necessary to evaluate laboratories based on personnel, physical facility, instrumentation and quality assurance / quality control programme, and the laboratory's performance. For this purpose, an organization should participate in inter laboratory comparisons of the proficiency testing programs.

12.7 QA Manual:

Each laboratory with a QA programme should have a manual that documents the operations of the laboratory. A typical manual might consist of the following:

a. Title page with signatures of all approving officials and date of issue (Annex 12.1)-Ref: Appendix 2.2 of FAO manual 14/14
b. Table of contents
c. Organizational structure and exactly where the laboratory fits into this structure
d. Objective of the quality assurance programme
e. Essential elements of the QA Programme (Annex 12.2)-Ref Appendix 2.1 of FAO manual 14/14.
f. Documentation forms
g. Performance and frequency of Audit
h. Corrective and follow-up action

A Statement of the QA Policy both general and specific is needed in the QA Manual; the objective of the laboratory should be clearly defined. The principal objective of the laboratory, for example, is to produce reliable results

12.8 Implementation:

Actual implementation of the QA programme is a co-operative effort of the management, and member of QA unit, section leaders and analyst. Management decides the amount of resources to be allocated to the QA Programme. This decision determines the nature and the size of the QA unit. In formulating the QA Programme, this unit receives technical input from the analyst. Once formulated by the QA Unit and approved by the management the QA programme is ready for introduction.

Analysts are responsible for day-to-day maintenance of the programme. The QA Unit periodically monitors this adherence and makes its report and recommendations to the management, which then decides on the action to be taken so as to achieve compliance with the programme.

12.9 Revision of the QA Manual:

The QA Manual must be designed so that the change is easily accommodated. It is essential that organizational pattern emerge, workload shifts and methodology develops. The QA Manual can react rapidly to these changes in the work of the laboratory.

12.10 Documentation Required or the QA Programme:

- Laboratory elements to be considered in the QA Manual
- QA Manual cover and contents pages (Annexe 12.1)
- A statement of QA Policy

13.0 LABORATORY RECORDS:

13.1 General Principles:

All the information that has any particular relevance to the materials and the analysis performed on them must be documented in a systematic fashion at any point in its passage though the laboratory. Records must allow a test material to be traced back to its arrival and any information that arrive with it.

Records should be such that if the need for reanalysis arises, it could be done under the same conditions and in the same way as before. Records must be retained and protected from misuse, loss or deterioration for an agreed time.

13.2 Sample Collection Records:

Responsibility for sample collection generally falls outside the food-control laboratory; hence it is not covered here.

13.3 The Analysts Worksheets:

The analyst worksheet provides a written account of the laboratory analytical results. Certain requirements apply to all worksheets.

1. All the basic information must be recorded directly on the worksheet before analysis has begun.
2. As soon as the worksheet is obtained it should be initialled.
3. All entries should be clearly legible and made in permanent ink.

4. No entries should be erased or over -written if an incorrect entry is made. The analyst should draw a line through the incorrect entry; write above it the correct figure or word and then date and initial the corrected entry.
5. Data should not be discarded without explanation.
6. The exact analytical method should be referenced clearly and completely. If the method has not been published or is not covered by SOP it should be written in full on the worksheet or as an attachment to the worksheet.
7. If the analysis has been made in duplicate or triplicate etc. the result of each analysis as well as the summary of all result must be recorded.
8. If more than one analyst is involved in analysis the worksheet must indicate which analyst broke this seal and which analyst performed each segment of the analysis.
9. Any continuation sheets that accompany the analyst worksheets should be numbered in a consecutive series e.g. 1 of 8, 2of 8, 8 of 8 pages. An example of ex analyst worksheet is shown at Annex 13.1(Ref: Appendix 11.1 of FAO manual 14/14)
10. Worksheets are check for accuracy, completeness and compatibility with other documents by the supervisor or the designated representative.
11. The date on which the analyst submitted the worksheet to the supervisor is indicated.
12. The exact method used is referenced. Any modification to the referenced method is stated and the reason for the modification is given.
13. All calculations are clearly shown with the proper number of significant figures used.
14. The use of controls and their results are specified.

13.4 Analyst relies increasingly on instruments, which produce a hard copy record of the instrumental readings. Taking chromatographic charts as an example, this must be clearly labelled (test material number, analyst, date and any other necessary identifiers) and stored in a logical sequence. Chromatograms of Standards, recoveries and sample extracts must be cross- referenced to each other and to the responsible analyst laboratory notebook to allow for easy checking of results. The full chromatographic conditions employed must be stated on the chromatogram or must be readily obtainable from the analyst's notebook.

14 LABORATORY REPORTS:

14.1 General :

The laboratory report is a condensed version of the data appearing in worksheets and laboratory notebooks. It must contain all the information normally necessary for the customer to utilize the result it contains

14.2 The **format of laboratory report** typically include the following

- Name, Address of the Laboratory
- Name, Address of the customer
- Certificate/Report Number
- Page Identification (Page X of Y)
- Sample received details (Dates, Names of deliverable, receiver)
- Unambiguous identification of sample / test material (Description, Laboratory Number etc.)
- Analysis conducted, Methods, Procedures any deviation from standard practices.
- Preparation of test material, taking of test portions
- Results
- Uncertainty of measurements
- Comments on significant of findings (if expected by the customer)
- Date of report
- Authorizing signature

14.3 Retention of Laboratory Record:

The sequence of records should form a continuity of documentation to produce a clear, accurate and in-disputable history of the test material with all aspects of documentation in agreement.

All sample registers worksheets, reports and associated documents must be retained for a period, which is determined by the management in consultation with the customers and is documented.

Storage of such material should follow the normal rules of archiving in terms of indexation, traceability, security, appropriate levels of protection against fraud and tampering, from fire, flood etc. Backup copies must be held of any records stored as electronic signal on magnetic media. This should be renewed at appropriate intervals.

Dates and signature of individuals who withdraw and return documents in storage must be recorded.

14.4 Documentation for QA programme:

- Analyst worksheet
- Laboratory report
- Procedures for checking of results
- Procedures for authorization for report
- Period for retention of documents
- Procedures for archiving and disposal of documents.

Annexure 8.1

A. Sources for Biological Reference Material:

1. Within India reference strain can be obtained from IMTECH, Chandigarh (www.imtech.res.in);
2. National Chemical Laboratory, Pune (www.ncl-india.org);
3. Christian Medical College, Vellore (www.cmch-vellore.edu);
4. Central Research Institute, Kasauli, HP (http://mohfw.nic.in);
5. National Institute of Communicable Diseases, Delhi (www.nicd.ac.za)

[Ref: - NABL 102]

B. Sources for Chemical Reference Material:

NIST – Trace Certified Reference Materials (CRMs) may be used

C. Sources for Physical Reference Material:

National Physical Laboratory, Delhi (www.nplindia.org)

ONLINE TRAINING PROGRAMME
on
Minor Forest Produce Processing

ORGANISED BY :

Indian Institute of Food Processing Technology (IIFPT)

Packaging of Minor Forest Products

BIDHAN DAS

DEPUTY DIRECTOR & REGIONAL HEAD

INDIAN INSTITUTE OF PACKAGING,

KOLKATA CENTRE

INDIAN INSTITUTE OF PACKAGING
(Head Office) :MUMBAI

Shanghvi & Associates | Indian Institute of Packaging, Mumbai | architect madhoop kumar

BACKGROUND

- REGISTERED AS A SOCIETY AS PER SOCIETIES REGISTRATION ACT, 1860.
- AN AUTONOMOUS BODY IN THE FIELD OF PACKAGING AND WORKING UNDER THE ADMINISTRATIVE CONTROL OF MINISTRY OF COMMERCE & INDUSTRY, GOVT. OF INDIA.
- ESTABLISHED IN 1966 WITH ITS HEADQUARTERS & PRINCIPAL LABORATORIES IN MUMBAI.
- 1st REGIONAL CENTRE WAS OPENED AT CHENNAI IN 1971.
- 2nd REGIONAL CENTRE WAS OPENED AT KOLKATA IN 1973.
- 3rd REGIONAL CENTRE CAME AT DELHI IN 1986.
- 4th REGIONAL CENTRE WAS OPENED AT HYDERABAD IN 2006.
- 5TH REGIONAL CENTRE WAS OPENED AT AHMEDABAD, GUJRAT IN 2017.
- 5th REGIONAL CENTRE FOUNDATION STONE LAID AT BANGALORE IN 2013 AND THE CONSTRUCTION IS ON PROGRESS.
- 6th REGIONAL CENTRE WILL BE SET UP AT GUWAHATI. RE-ALLOTMENT LETTER OF THE LAND IS TO BE RECEIVED FROM GOVT. OF ASSAM.
- 7th REGIONAL CENTRE WILL BE SET UP AT KAKINADA, AP. ALLOTMENT LETTER OF THE LAND IS YET TO BE RECEIVED.
- 8TH REGIONAL CENTRE IS BEING ESTABLISHED IN VARANASI, UP

BRANCH OFFICES

OBJECTIVES

- **TO PROMOTE THE EXPORT MARKET BY WAY OF INNOVATIVE PACKAGE DESIGN AND DEVELOPMENT.**

- **TO PROMOTE THE EXPORT OF PACKAGING MATERIALS AND MACHINERIES BY WAY OF PARTICIPATION IN OVERSEAS EXHIBITION AND ALSO ORGANISING NATIONAL AND INTERNATIONAL EXHIBITIONS IN INDIA.**

- **TO INCREASE THE STRENGTH OF TECHNICAL MANPOWER THROUGH PACKAGING EDUCATION IN INDIA.**

- **TO PROMOTE PACKAGING INDUSTRY THROUGH TECHNICAL SERVICES IN INDIA.**

- **TO UPGRADE THE OVERALL STANDARDS OF PACKAGING AT NATIONAL LEVEL.**

TWO MAJOR ACTIVITIES

- **TRAINING & EDUCATION.**
- **RESEARCH AND DEVELOPMENT**
  - **TESTING & CERTIFICATION OF PACKAGING MATERIALS & PACKAGES.**
  - **TECHNICAL CONSULTANCY ON PACKAGE DESIGN & DEVELOPMENT.**
  - **APPLIED RESEARCH & SHELF LIFE STUDIES OF FOOD, PHARMACEUTICAL & COSMETIC PRODUCTS**
- **NATIONAL AND INTERNATIONAL EXHIBITIONS I.E "INDPACK" & "INDIAPACK"**
- **ORGANISING NATIONAL PACKAGING AWARDS I.E "INDIASTAR" & "PACMACHNE" FOR EXCELLENCE IN PACKAGING**

ACTIVITIES

TRAINING & EDUCATION

- TWO YEARS POST GRADUATE DIPLOMA IN PACKAGING (PGDP)
- 18 MONTHS DISTANCE EDUCATION PROGRAMME (DEP)
- 3 MONTHS ANNUAL INTENSIVE TRAINING CERTIFICATE PROGRAMME (ITC)
- SHORT TERM TRAINING PROGRAMMES AS PER REQUIREMENTS OF INDUSTRIES.
- INTERNATIONAL TRAINING PROGRAMMES FOR WPO,APF, INDO - AFRICA FORUM SUMMIT, GOVT OF SRI-LANKA, BANGLADESH ETC
- NATIONAL AND INTERNATIONAL CONFERENCES.

TESTING AND CERTIFICATION

- AUTHORISED BY DG SHIPPING & DGCA,GOVT OF INDIA AS COMPETANT AUTHORITY FOR TESTING OF BULK PACKAGES FOR CARRIAGE OF DANGEROUS GOODS FOR EXPORT AND ALSO TO ISSUE UN CERTIFICATE AS A MANDATORY REQUIREMENT
- ACCREDITATED TO NABL AND BIS TO ISSUE TEST REPORTS.

ACTIVITIES

CONSULTANCY SERVICES

- FORMULATION OF TECHNICAL SPECIFICATIONS OF PACKAGES FOR EXPORT OF FRESH AND VEGETABLES, SPICES, TEA, MARINE PRODUCTS - FOR APEDA, MPEDA, SPICES BOARD,TEA BOARD ETC RESPECTIVELY.
- TECHNICAL AUDIT OF PACKAGING SYSTEMS TO HIGHLIGHT THE SHORTCOMINGS AND TO SUGGEST SUITABLE MEASURES TO THE INDUSTRIES.

RESEARCH AND DEVELOPMENT

- DEVELOPMENT OF ALTERNATIVE TYPE OF PACKAGING MATERIALS BASED ON JUTE,COIR AND OTHERS IN ASSOCIATION WITH IJIRA,COIR BOARD ETC.
- DEVELOPMENT OF SUITABLE PACKAGE TO ENHANCE THE SHELF-LIFE OF TENDER COCONUT WATER WITH IIT,MUMBAI , SPONSORED BY MOFPI.
- DEVELOPMENT OF MODIFIED PACKAGING SYSTEM FOR THE EXPORT OF CHILLED MEAT PRODUCTS, SPONSORED BY APEDA.

PROPOSED PLAN

- **TO GET THE RECOGNITION AS " INSTITUTE OF NATIONAL IMPORTANCE" AS PER ACT OF PARLIAMENT.**
- **TO COMMENCE DEGREE COURSE I.E FOUR YEARS B.TECH IN PACKAGING TECHNOLOGY & MANAGEMENT BY 2017-18**
- **TO COMMENCE 2 YEARS M.TECH PROGRAMME IN FIVE DISCIPLINES :**
  - **FOOD PACKAGING**
  - **PHARMACEUTICAL & COSMETICS PACKAGING**
  - **INDUSTRIAL PACKAGING**
  - **PACKAGING OF CHEMICALS & ALLIED PRODUCTS**
  - **PACKAGE PRINTING & GRAPHICS.**
- **ELIGIBILITY FOR B.TECH (12 STANDARDS THRO JEE)**
- **ELIGIBILITY FOR M.TECH (THRO GATE / ENTRANCE)**
  - **B.TECH IN FOOD TECHNOLOGY,PRINTING TECHNOLOGY, POLYMER SCIENCE, MECHANICAL, ELECTRICAL, ELECTRONICS etc.**

PACKAGING INDUSTRY

- **RAW MATERIAL MANUFACTURERS**
- **PACKAGING MATRIALS CONVERTERS**
- **PACKAGING USERS INDUSTRY**

Packaging Materials

1)Scientific Packaging Materials

2) Traditional Packaging Materials

ANCILLARY PACKAGING MATERIALS

- CAPS & CLOSURES
- LABELS
- BOPP SELF ADHESIVE TAPES
- STRETCH & CLING FILMS
- STRAPS, CLIPS & HOOKS
- BUBBLE FIMLS, THERMOCOLE & FOAM
- CUSHIONING MATERILAS

TRADITIONAL PACKAGING MATERIALS

- **EARTHEN POT**
- **BAMBOO BASKET / CANE BASKET**
- **LEAVES**
- **WOODEN BARREL / BOX**
- **JUTE BAGS**

TRADITIONAL PACKAGING MATERIALS

Traditional Packaging

Scientific Packaging

TRADITIONAL PACKAGING MATERIALS

TRADITIONAL PACKAGING MATERIALS

TRADITIONAL PACKAGING MATERIALS

TRADITIONAL PACKAGING MATERIALS

SCIENTIFIC PACKAGING MATERIALS

SCIENTIFIC PACKAGING MATERIALS

SCIENTIFIC PACKAGING MATERIALS

SCIENTIFIC PACKAGING MATERIALS

- **Paper**
- **Glass**
- **Metal**
- **Plastic**

Forest Produce (FP)

- Section 2(4) of the Indian Forest Act 1927 defines only "forest-produce" and this term connotes to those products whether found in, or brought from a forest such as
- timber, charcoal, caoutchouc, catechu, wood-oil, resin, natural varnish, bark, lac, mahua flowers, mahua seeds, kuth and myrabolams,
- trees and leaves, flowers and fruits, and all other parts or produce of trees,
- plants not being trees (including grass, creepers, reeds and moss), and all parts or produce of such plants,
- wild animals and skins, tusks, horns, bones, silk, cocoons, honey and wax, and all other parts or produce of animals, and
- peat, surface soil, rock and minerals (including lime-stone, laterite, mineral oils), and all products of mines or quarries;

Minor Forest Produce (MFP)

- Minor Forest Produce (MFP) is a subset of forest produce and got a definition only in 2007 when the Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006, was enacted. Section 2(i) of the said Act defines a Minor Forest Produce (MFP) as all non-timber forest produce of plant origin and includes bamboo, brushwood, stumps, canes, Tusser, cocoon, honey, waxes, Lac, tendu/kendu leaves, medicinal plants and herbs, roots, tuber and the like.
- Thus, the definition of "minor forest produce" includes bamboo and cane, thereby changing the categorization of bamboo and cane as "trees" under the Indian Forest Act 1927.

MSP for Minor Forest Produce

- Minor forest produce includes **non-timber items** such as **bamboo** and **other grasses**, **edible or useful roots, seeds, fruits, flowers and plants.**

- A number of people from **Scheduled Tribes** and other **forest-dwelling** communities depend on the **collection** and **sale** of such items for their **livelihood**.

Recommended style of CFB for PACKAGING of Pineapples

PHOTOGRAPH NO. 7
PINEAPPLES PLACED IN
MICRO- PERFORATED POUCH

PHOTOGRAPH NO. 8
PINEAPPLES PLACED IN FOAM GUARD

Recommended style of CFB for PACKAGING of Pineapples

PHOTOGRAPH NO. 9
PINEAPPLES PLACED VERTICALLY IN MICRO- PERFORATED POUCH

PHOTOGRAPH NO. 10
PINEAPPLES PLACED VERTICALLY IN FOAM GUARD

Recommended style of CFB for PACKAGING of Pineapples

PHOTOGRAPH NO. 11
PINEAPPLES PLACED HORIZONTALLY IN MICRO- PERFORATED POUCH

PHOTOGRAPH NO. 12
PINEAPPLES PLACED HORIZONTALLY IN FOAM GUARD

EPE FOAM JACKET

Minor Forest Products

- Minor forest products include all products obtainable from the forests other than wood and thus comprise products of vegetable and animal origin.
- Some of the important forest products of minor nature are follows:-

✓ Plant Products:- grasses, bamboos, oils, gums, spices, tannins and resins etc.

✓ Animal Products:- honey, lac, wax, Ivory, horns, hides etc

Packaging of Honey

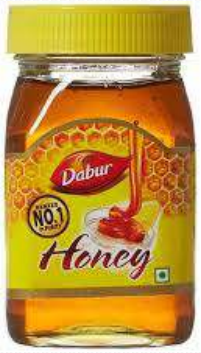
Physical and Chemical Properties :-

- At room temperature, honey is a **supercooled liquid**, in which the glucose precipitates into solid granules.
- This forms a **semisolid** solution of precipitated glucose crystals in a solution of fructose and other ingredients.
- The **density** of honey typically ranges between **1.38 and 1.45** kg/l at 20 °C
- Honey has the ability to absorb moisture directly from the air, a phenomenon called **hygroscopy.**
- The average **pH** of honey is 3.9, but can range from **3.4 to 6.1**
- Honey from different plant source contains **volatile organic compounds** (VOCs) which play a primary role in determining **honey flavors and aromas**.

Packaging of Honey

GLASS PACKAGING :-

- Excellent moisture & gas barrier properties to protect the honey from external environments.
- Hygienic and suitable for sterilization
- Non reactive & transparent
- Good protection power



Issues:-

- It is relatively heavy
- Glass is fragile so easily broken
- Release alkali to aqueous preparation

PLASTICS CONTAINERS FOR HONEY

- Generally PET or HDPE or PP containers are used for packaging of honey.

PET (Polyethylene Terephthalate)

✓ lightweight , transparent

✓ More impact resistant

✓ Helps protect food or liquids inside the packaging.

HDPE (High-Density Polyethylene)

- Low cost
- Moisture resistance
- Good chemical resistance
- Food grades available
- Good Stackability
- Available in different shapes

Issues:-

- Poor weathering resistance
- Flammable
- Sensitive to stress cracking
- Difficult to bond

PP (Polypropylene)

- Flexible, Low Friction
- Heat resistant
- Acid resistance and cheap
- Highly resistance to corrosion
- High tensile strength
- Good ESCR
- Integral – Hinging properties

Issues:-

- It is susceptible to UV degradation
- poor bonding properties

Packaging of Spices- Cardamom, chilies etc.

Characteristic of Spices :-

- Spices are **aromatic substances** of vegetable origin, derived from plant parts - leaves, bark, fruit, flower, stem, root, seeds
- They contain **volatile oils** which **impart aroma and flavour** to the product.
- They are used as **condiments and seasonings** and form an essential part of food preparations as they add flavour, taste and appearance.
- They have **good anti-oxidant and preservative** properties.
- They are also used for medicinal purposes

SPOILAGE FACTORS / CHARACTERISTICS

1) MOISTURE CONTENT

Spices, specially powders are hygroscopic in nature and pick-up moisture from the atmosphere resulting in sogginess and caking or lumping of the powder. Moisture pick up also results in loss of free-flowing nature of the spice powder.

2) LOSS OF AROMA/FLAVOUR

Spices contain volatile oils which impart aroma/flavour to the product. Loss in volatile oil content or oxidation of some aromatic components results in aroma and flavour loss.

3) DISCOLOURATION

- Some spices like green cardamom, red chilies, turmeric, saffron contains natural pigments.
- On exposure to light there is loss of colour and deterioration.

4) INSECT INFFESTATION

Spices are prone to spoilage due to insect attack.
This can be accelerated due to high humidity, heat and oxygen.

5) MICROBIAL SPOILAGE

- Due to high humidity of about 70% and above moisture absorption takes place. Beyond a certain level of moisture content, microbial growth occurs resulting in spoilage.

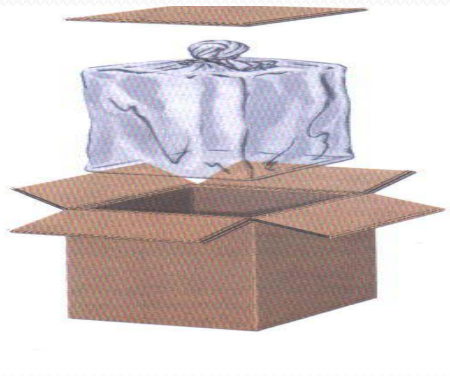
BULK/ INSTITUTIONAL PACK FOR WHOLE & GROUND SPICES

Traditional Pack

Jute sack/bag, Wooden box, Tin Container

New Trend/Alternate

Plastic woven sacks, bag-in box, paper bag, Plastic pouch



CONSUMER PACK- WHOLE SPICES

TRADITIONAL

Pouch of Mono Film

NEW TRENDS / ALTERNATES

Laminated Printed Pouch, Lined Carton, Pouch in Carton

CONSUMER PACK- GROUND SPICES

TRADITIONAL

Pouch of Mono Film, Tin plate Container, Glass Bottle

NEW TRENDS / ALTERNATES

Laminated Printed Pouch, Lined Carton Composite Container, Plastic Container

Packaging of Ginger

Properties of Ginger

- High moisture content
- Irregular shapes and sizes
- Aromatic spices
- Odour and taste

Different Forms of Ginger:-

- Dry Ginger
- Ginger Power
- Ginger oil
- Ginger Paste
- Ginger wine

Packaging of Ginger Powder

Material used for Packaging:-

- PET Poly pouches
- PET/ HDPE Containers
- Lined carton

Packaging of Shellac

- Shellac is a resin secreted by the female lac bug on trees in the forests
- It is processed and sold as dry flakes and dissolved in alcohol to make liquid **shellac**

Packaging Material for Shellac Varnish :-

- Metal Containers, Plastic Containers

Packaging Materials for Shellac Bangles:-

- Duplex board carton, Composite containers

Creativity & Innovation

Program Objectives

- To understand the difference between creativity & innovation.
- To understand how brain works
- To provide tools and techniques to bring in more creativity in our work
- To practice the discussed tools and techniques and develop an understanding & comfort to readily using them at work

The program, aims at nurturing one of the four Leadership Attitudes,
"EXPLORE" of E4

Topics

- Difference between creativity and innovation
- Mind mapping
- Reframing
- Assumption reversal
- Analogies and Metaphorical Thinking
- Discontinuity
- Brainstorming
- Discussion and possible barriers
- Putting it all together - Activity

What is creativity

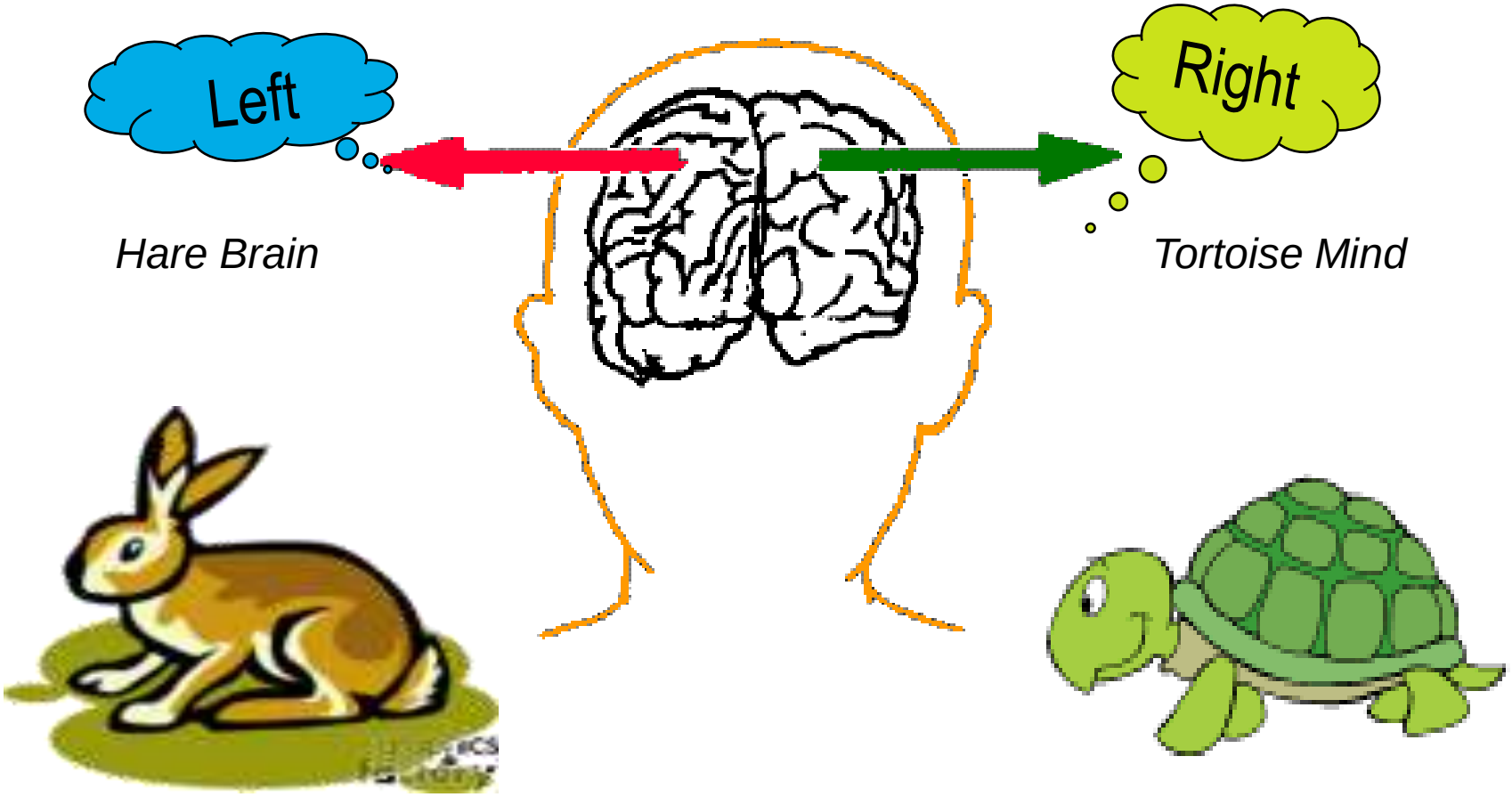
What is innovation

Creativity vs Innovation

CREATIVITY IS THINKING UP NEW THINGS.

INNOVATION IS DOING NEW THINGS.

How our brain works?



Divergent vs Convergent Thinking

Divergent Thinking

Convergent Thinking

Assumption / Problem reversal

Here's an assumption that many businesses make: *customers want good service. But the assumption*
reversal technique proposes that you turn that around: *customers don't want good service.*

By questioning the seemingly obvious assumptions about a problem, you can spark off new ideas for tackling it. Even the most basic assumptions are up for analysis.

Analogies and Metaphorical Thinking

Crisps were like leaves, and then thought about how you would pack leaves efficiently.
If you compress dried leaves, they break. However, you can press leaves so long as they are moist and not dry.

This led the manufacturers to the idea of mixing dried potato with water and then pressing it into shape, so the crisps could be stacked and occupy less space on the supermarket shelves

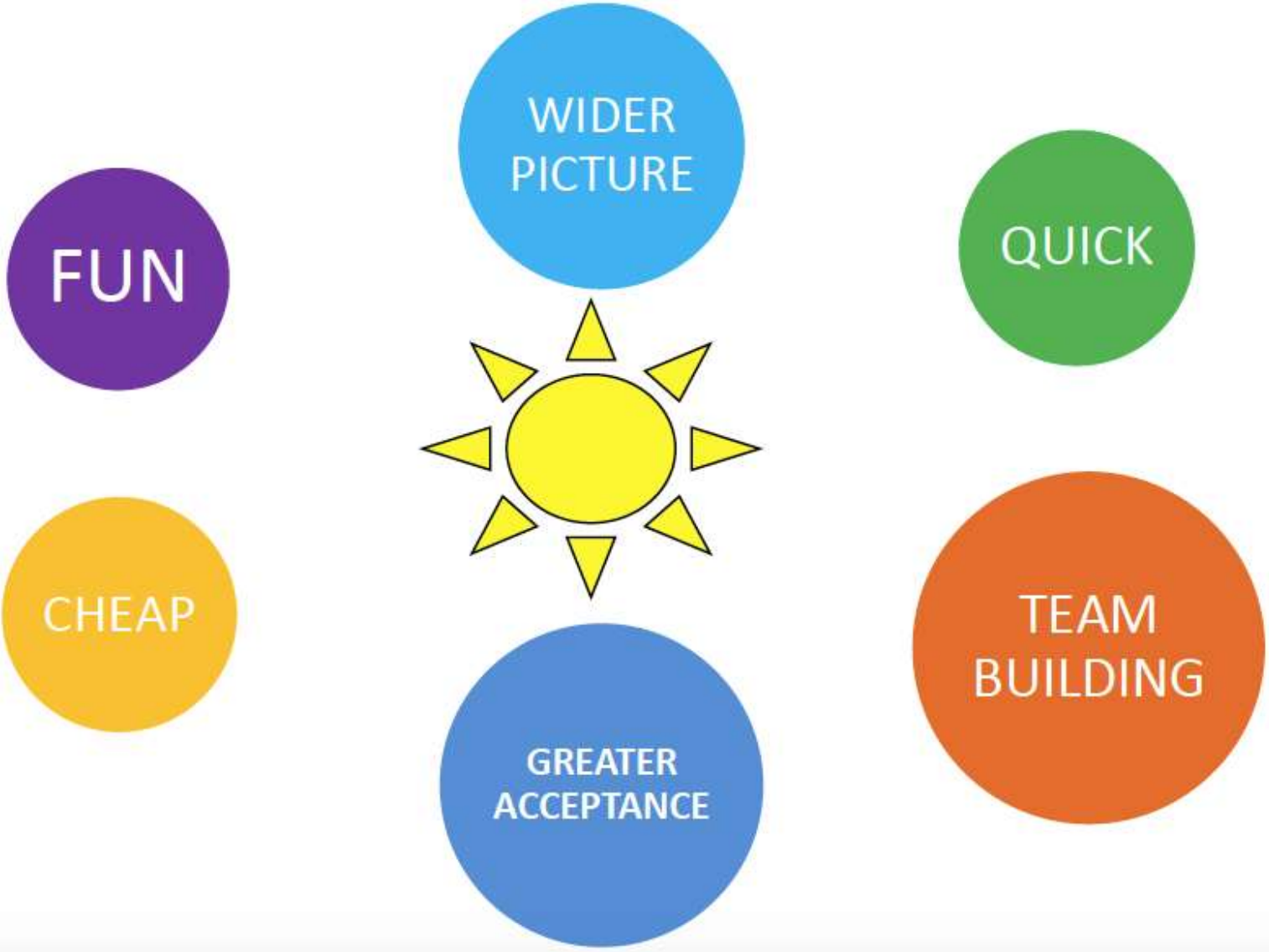
Brainstorming
The creative problem solving method

Why & **When** to use it

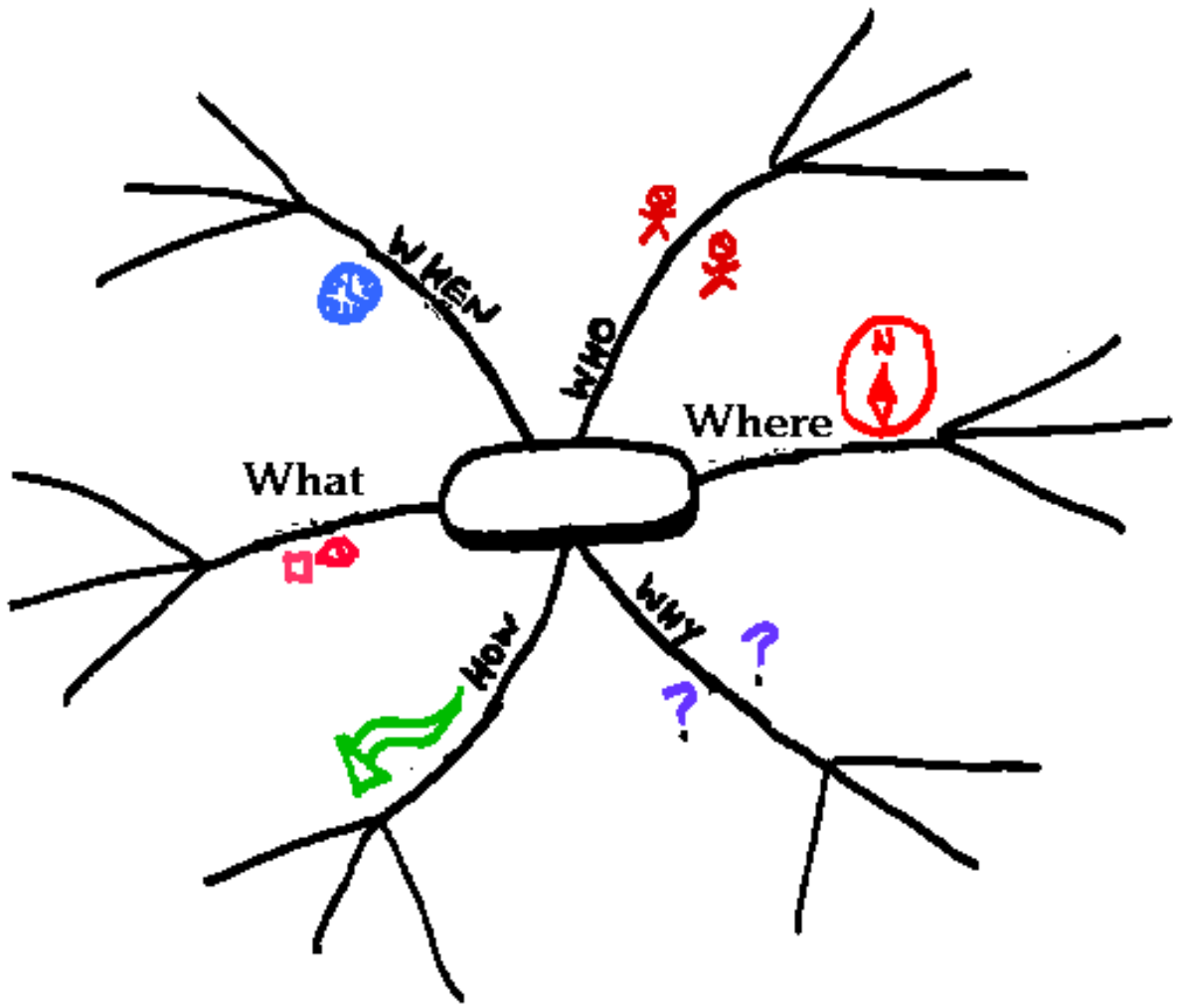
Specific questions:

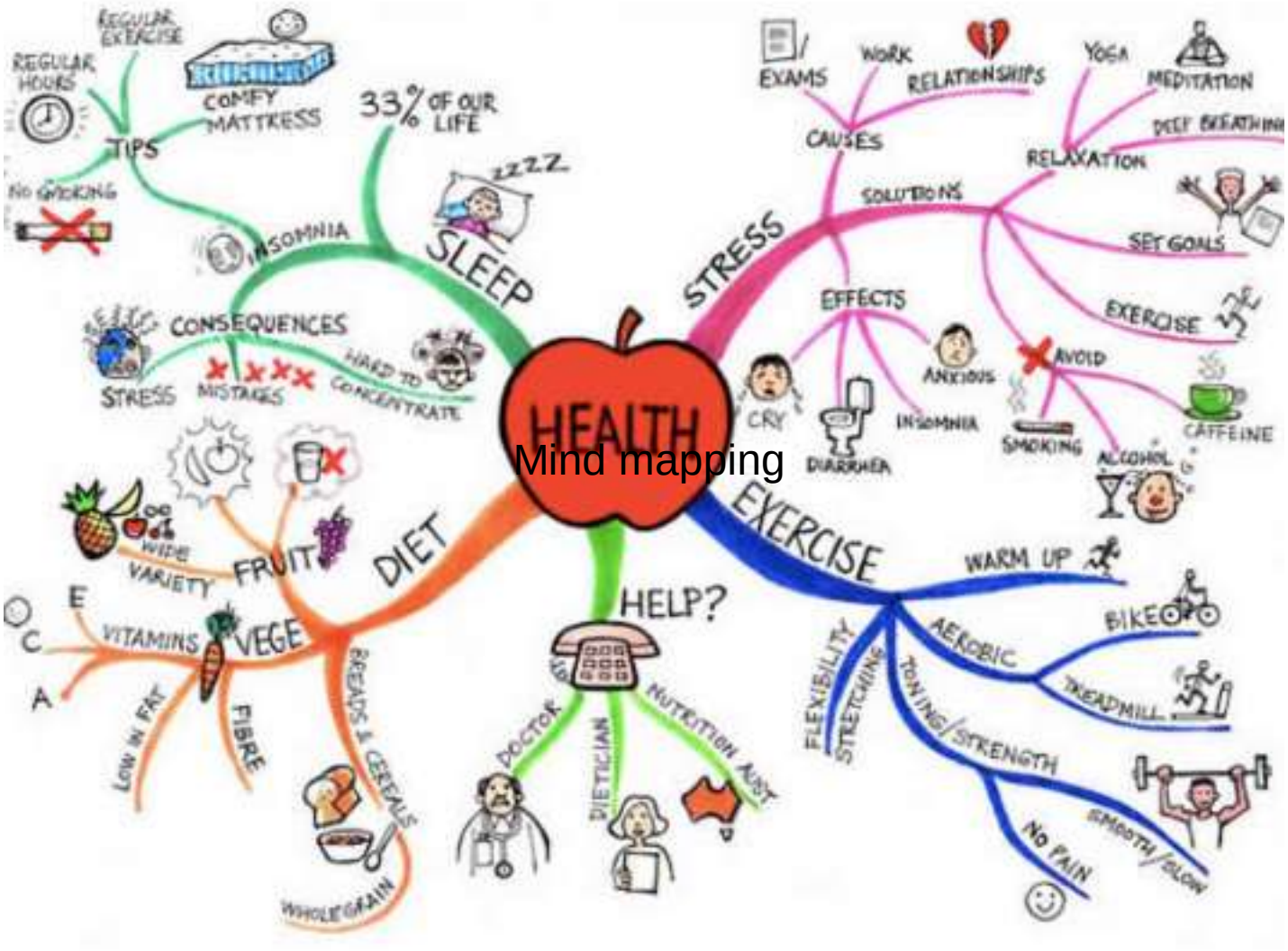
- *How can we promote our products?*
- *What can our company do in 5 years hence?*
- *What can we do to solve the problem XY?*
- *How can we improve co-operation of A and B?*
- *What do our customers really want?*
- *What opportunities do we have this year?*
- *How can we have more fun at work?*

Benefits of Brainstorming



Mind Map





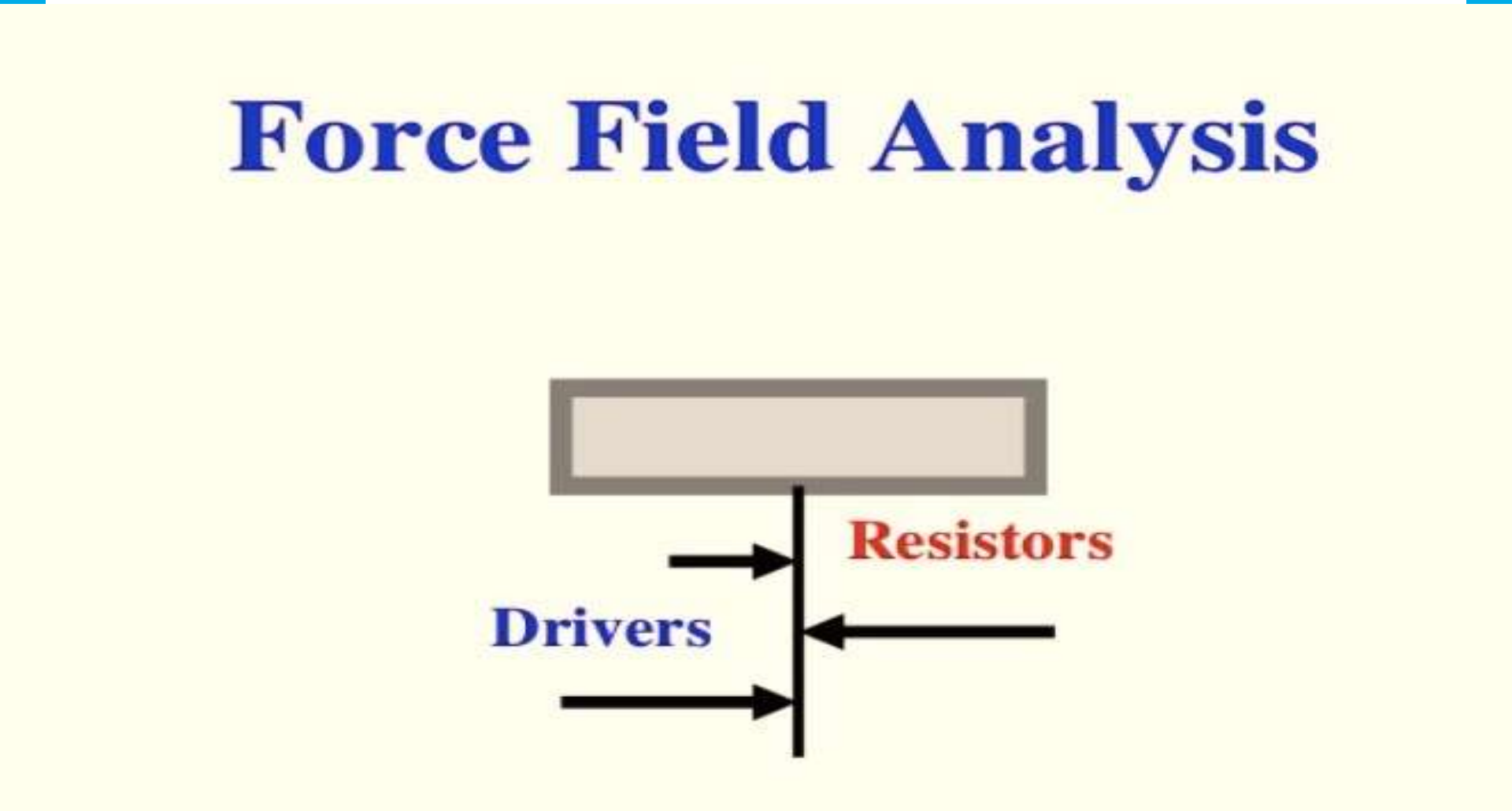
Mind mapping

Discontinuity

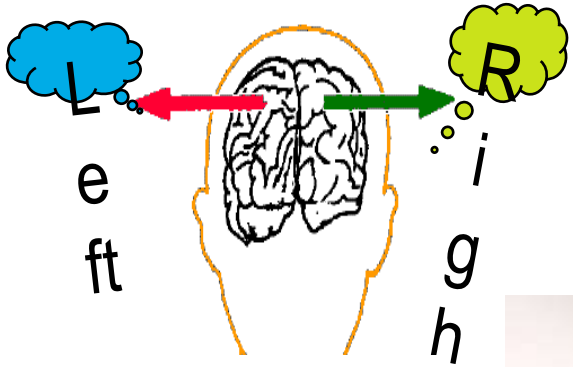
DISCONTINUITY

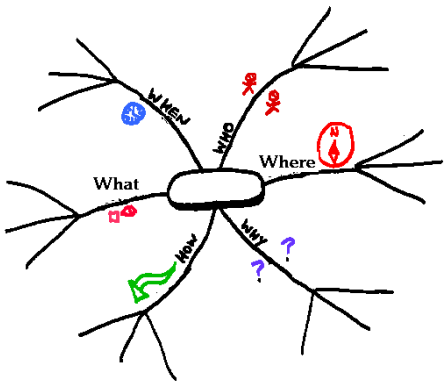
an approach which forces you out of the rut by introducing untypical behavior or ideas

Force field technique



Putting it all together..






CONCEPT
NO
FAIL
STRATEGY
PLAN
HAVE
45% is SALE!
15% - ??
A. B. C.
LOADING TO SERVER
A. ASIA
B. INDIA
C. USA
SUCCESS!
MAIN
300
2000

Eat Right India
सही भोजन. बेहतर जीवन.

सत्यमेव जयते
Ministry of Health & Family Welfare
Government of India

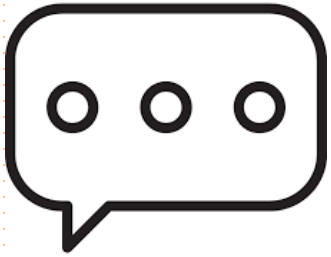
fssai
FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Inspiring Trust, Assuring Safe & Nutritious Food

Indian Scenario of Food Safety, Quality and Regulations for Minor Forest Produce

Presented By :

Partha Das Mohapatra
Deputy Director & Central Licensing Authority
FSSAI ,North Eastern Region

Turn of Mic



ANSWER in CHAT BOX

Put Doubts in Chat Box

Content

1. Food Standards
2. National and International food standards and their role in ensuring food quality and safety
   - CAC (Codex Alimentarius Commission)
   - International Organization for Standardization
   - World Trade Organization
3. National Standards :FSSAI
   - FSSAI Rules and Regulations
   - Licensing and Registration System
   - Standards of Forest Minor Produce
   - Registration Procedure (NEW FOSCOS)

STANDARDS

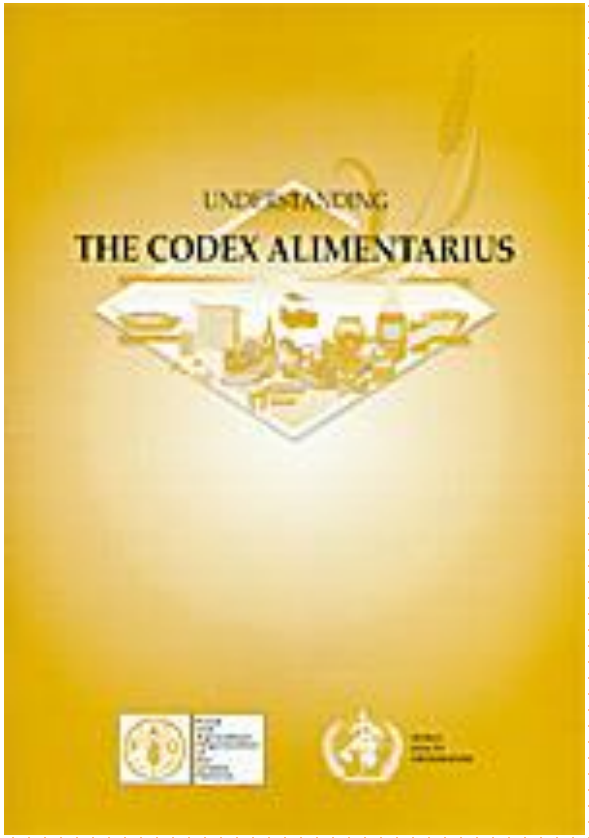
1. **Company Standards:** These are prepared by a Company for its own use. Normally, they are copies of National Standards.
2. **National Standards:** These are issued by the national standards body.
3. **Regional Standards**: Regional groups with similar geographical, climate, etc. have legislation standardisation bodies. (Regional Code of Hygienic Practice for Street-Vended Foods in Asia)
4. **International Standards:** The International Organisation for Standardisation (ISO) and Codex Alimentarius Commission (CAC) publish international standards.

International Organizations and Agreements in the Area of Food Standards, Quality, Research and Trade

The major organisations which are playing a key role are:

1. Codex Alimentarius Commission (CAC)
2. International Organisation for Standardisation
3. World Trade Organisation

What is the Codex Alimentarius Commission?



- A joint FAO/WHO inter-governmental body with 188+1 member countries (as of August 2005) plus 237 observers
- Responsible for implementing FAO/WHO Joint Food Standards Programme since 1962

What is the function of the CAC?

- To protect the health of consumers
- To ensure fair practices in the food trade
- To coordinate food standards work internationally
- To finalise and publish international standards, codes of practice and recommendations in the Codex Alimentarius

The Codex Alimentarius

- ‘Codex Alimentarius’ means ‘Food Code’
- Comprises 14 volumes
- All standards available at Codex web-site
- Codex standards are recommended (not mandated) food quality and safety standards

INTERNATIONAL ORGANISATION FOR STANDARDISATION

- The International Organisation for Standardisation (ISO) is a worldwide, non-governmental federation of national standards bodies (ISO member bodies).
- The work done by ISO results in international agreements which are published as International Standards.
- ISO 9000 is an international reference for quality requirements. It is concerned with “Quality Management” of an organisation.
- Adoption of these standards is voluntary.

World Trade Organisation (WTO)

- WTO was established in 1995.
- The main objective of WTO is to help trade flow smoothly, freely, fairly and predictably, by administering trade agreements, settling trade disputes, assisting countries in trade policy issues.
- In order to enforce adoption and implementation of standards, there is a need for a strong Food Control System. An effective food control system must consist of —
- (i) Food Inspection and
- (ii) Analytical capability.

NATIONAL STANDARDS :

- PFA(Prevention of Food Adulteration Act
- Fruit and Vegetable Product Order
- Meat Food Products Order
- Milk and Milk Products Order

- **BIS , AGMARK etc**

FOOD SAFETY AND STANDARDS ACT 2006

•An Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

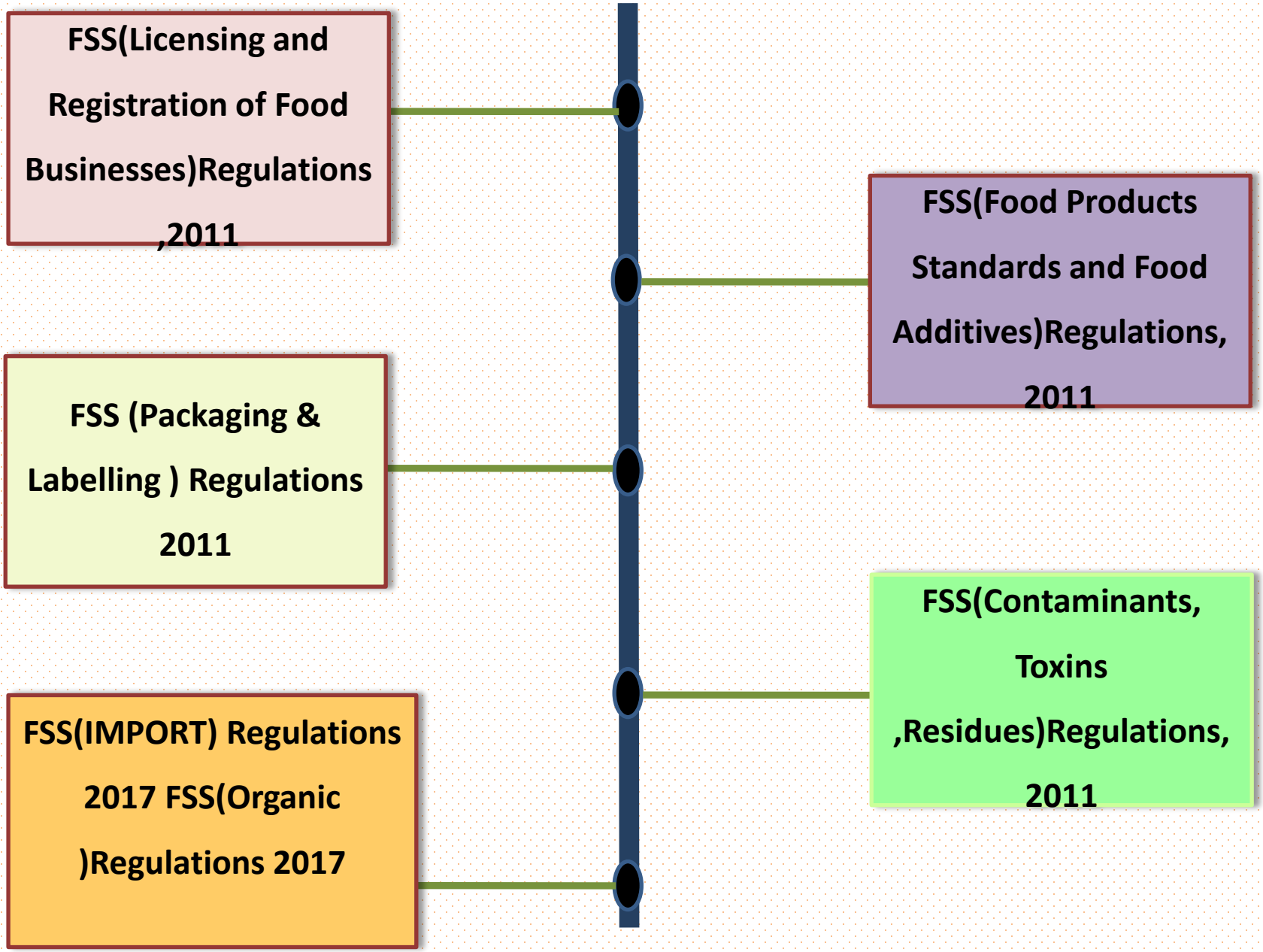
•The Act came into force on 15th October 2007 .

FOOD SAFETY AND STANDARDS ACT 2006

Under Section 31 of the FSS Act 2006 , No Person shall commence or carry on any Food Business except under the license

Food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients

FOOD SAFETY AND STANDARDS REGULATIONS



Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011

- These regulations came into force on or after 5th August, 2011

- 14 Broad Food Categories

- Forest Minor Produce Foods comes under these regulations and under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

Minor Forest Produce	Category	Description
Betel Nut Areca catechu (Dry)	**2.3.55**	(a) "Arecanuts" or "Betelnuts" or "Supari" means nuts obtained from Areca Palm (Areca catechu L.).
		b) The product shall be dry, well matured, sound, clean, whole or cut, fully dehusked, uniform in colour, i.e., bright shining to dull red colour.
		c) It shall be free from synthetic colouring matter and shall be free from insect infestation, visible moulds, fissures and shrinkage and shall not be hollow.

Minor Forest Produce	FSSR Category	Description (FSS Stanadards)	CODEX DESCRIPTION
Black Rice and Johar Rice	Rice[06.1]	Rice shall be whole and broken kernels obtained from the species Oryza sativa L (De- Husked) is obtained from paddy by removing husk and the process of de -husking and handling may result in some loss of bran	Rice is whole and broken kernels obtained from the species Oryza sativa L Quality factors – general: Rice shall be safe and suitable for human consumption. Rice shall be free from abnormal flavours, odours, living insects and mites.

Minor Forest Produce	Category	FSS Description	Codex Description
Mushroom	**Dried fungi [04.2.2.2]**	Products in which the natural water content has been reduced below that critical for growth of Microorganisms without affecting the important nutrients. The product may or may not be intended for rehydration prior to consumption. Includes vegetable powders that are obtained from drying the juice, such as tomato powder and beet powder etc such as dried potato flakes, dehydrated carrots or peas or cabbage or mushroom or spinach leaf or lentil etc.	This standard contains general requirements applicable to all edible fungi, whether fresh or processed, permitted for sale by the competent authorities in the consuming countries, except canned cultivated mushrooms of the genus Agaricus. Different requirements for the products covered by this standard may be laid down in group of products standards or in individual standards.

Minor Forest Produce	Category	Description
Mustard (Rai, Sarson)	12.2.1 Mustard (Rai, Sarson)	Mustard (Rai, Sarson) whole means the dried, clean mature seeds of one or more of the plants of Brassica alba. (L). Boiss (Safed rai), Brassica compestris L.var, dichotoma (Kali Sarson), Brasssica Compestris, L. Var, yellow Sarson, Syn, Brassica compestris L, var glauca (Pili Sarson), Brassica, compestris L. V ar. toria (Toria), Barassicajuncea, (L). Coss et Czern (Rai, Lotni) and Brassica nigra (L); Koch (Benarasi rai). It shall be free from mould, living and dead insects, insect fragments, rodent contamination. The product shall be free from the seeds of Argemone Maxicana L, any other harmful substances and added colouring matter.

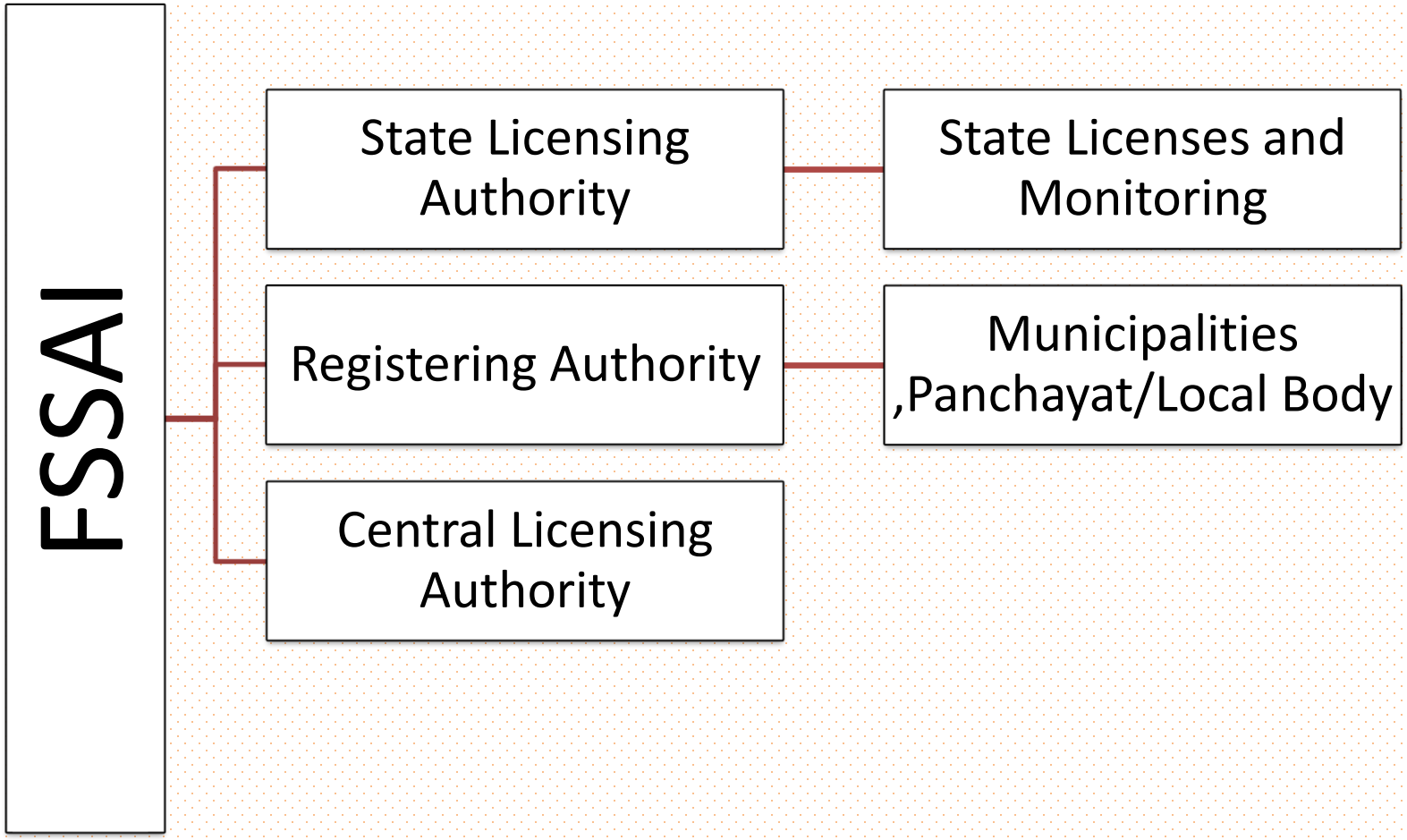
Minor Forest Produce	Category	Description
Cashew Nut (Anacardiumoccidentale)	4.1.2.2 Dried fruits, nuts and seeds	Fruit from which water is removed to prevent microbial growth which includes dried fruit leathers (fruit rolls)prepared by drying fruit purees. Such as cashew nut, almond, raisins, dried apple slices, figs, copra (dried coconut whole or cut), dried shredded or flaked coconut, prunes, dehydrated fruits etc.

Minor Forest Produce	Category as per FSSR	Description
Ginger dry (Zingiberofficinale)	Dried Ginger (Sonth, Dried Adrak)[12.2.1]	Fruit from which water is removed to prevent microbial growth which includes dried fruit leathers (fruit rolls)prepared by drying fruit purees. Such as cashew nut, almond, raisins, dried apple slices,figs, copra (dried coconut whole or cut), dried shredded or flaked coconut, prunes, dehydrated fruits etc.

Minor Forest Produce	Category as per FSSR	Description
a. Rosella (Hibiscus sabdariffa) b. Zanthoxylum (seed and bark), c. Jack fruit (Artocarpus heterophyllus seeds) d. KachriHarra (Terminalia chebula) e. KachriBaheda (Terminalia bellerica)	Extracts of plant botanicals 13 category	Can be used as plant or botanical ingredients Can be used as nutraceutical ingredient

Minor Forest Produce	Category as per FSSR	Description
Honey	11.5 Honey	Honey shall be the natural sweet substance produced by honey bees from the nectar of blossoms or from secretions of plants, which honey bees collect, transform and store in honey combs for ripening. It shall possess pleasant aroma, sweet flavour and taste characteristic of honey and free from any additives

STRUCTURE :


FSSAI
State Licensing Authority
Registering Authority
Central Licensing Authority
State Licenses and Monitoring
Municipalities ,Panchayat/Local Body

Process Flow for Food Business Operator:

Registration : Turnover Less than INR 12 Lakh

State License : Turnover above INR12 lakh upto 20 Cr ,capacity up to 2MT (Mfg)

Central License : Above INR 20 Cr , capacity > 2MT (Mfg) , Importers ,Exporters ,Proprietary Products

FoSCoS: Food Safety Compliance System

- FoSCoS an online application system launched in 2020
- A pan India application for
  - REGISTRATION
  - STATE LICENSE
  - CENTRAL LICENSE
  - Tracking of FBOS

https//: foscos.fssai.gov.in

Log in & Creation of ID

Start a new application

Select KOB & Capacity

File FORM A or B and Upload Docs

Submission of Fee and application

Process Flow for Filing application

fssai FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Ministry of Health and Family Welfare, Government of India

FoSCoS
Food Safety Compliance System

150 YEARS OF CELEBRATING THE MAHATMA

Eat Right India

Standardized Food Products

View all FSSAI Standardized Products

Eligibility of your food business

View all Eligibility Criteria Details

Track Application Status | FBO Search | How to Apply | Application Processing

Enter Application Reference No.

Enter Application Reference No.

Enter Captcha Code

Enter Captcha Code

344089

Submit

Introducing

FoSCoS

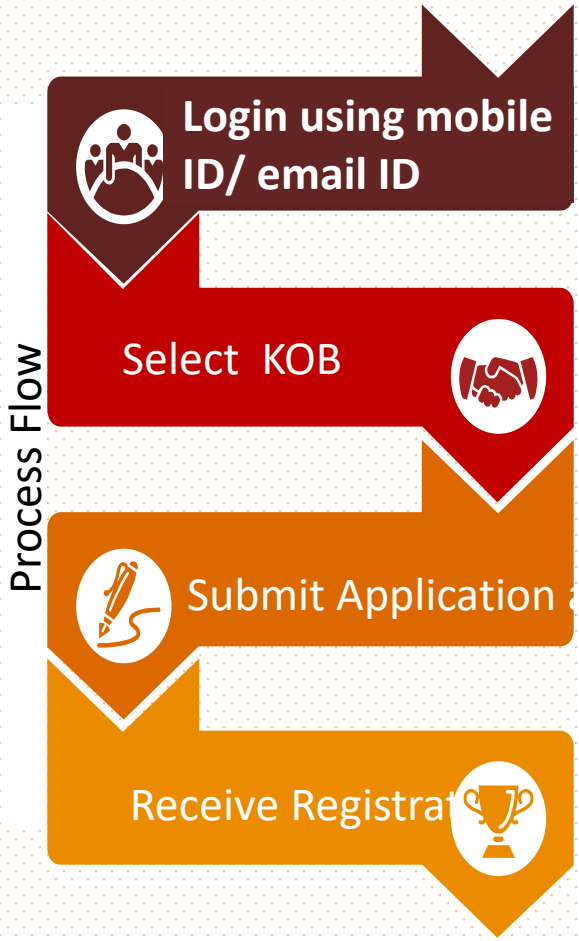
Quick access to your

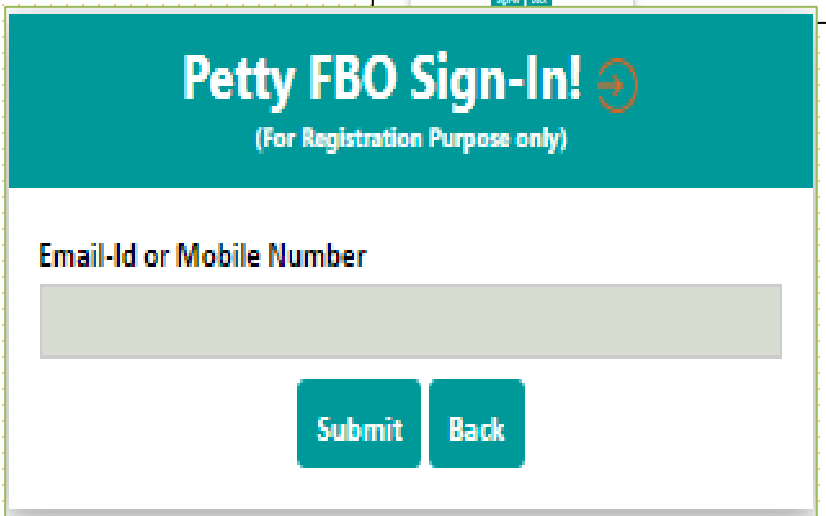
- Ongoing Applications
- Saved Drafts
- Active Licences
- Pending Payments

Petty FBO Sign-In

- Petty FBOs are **small business etc.** who are encouraged to apply for registrations.
- Applicant turnover must be less than Rs. 12 Lacs per annum
- Petty FBOs can login using mobile no. or email ID with OTP validation. Such Users are not mandatorily required to create login and remembering password.

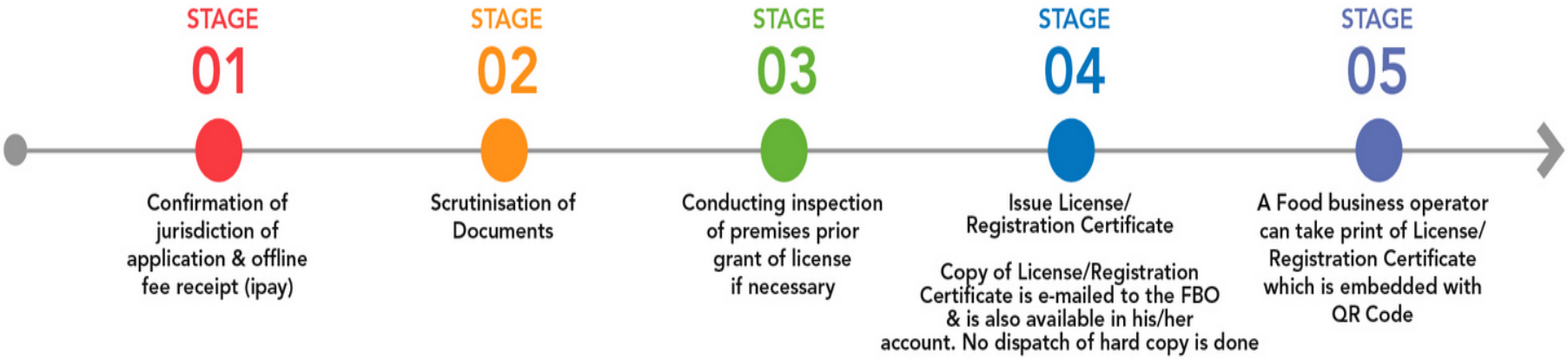
Login Screen for Petty FBOs





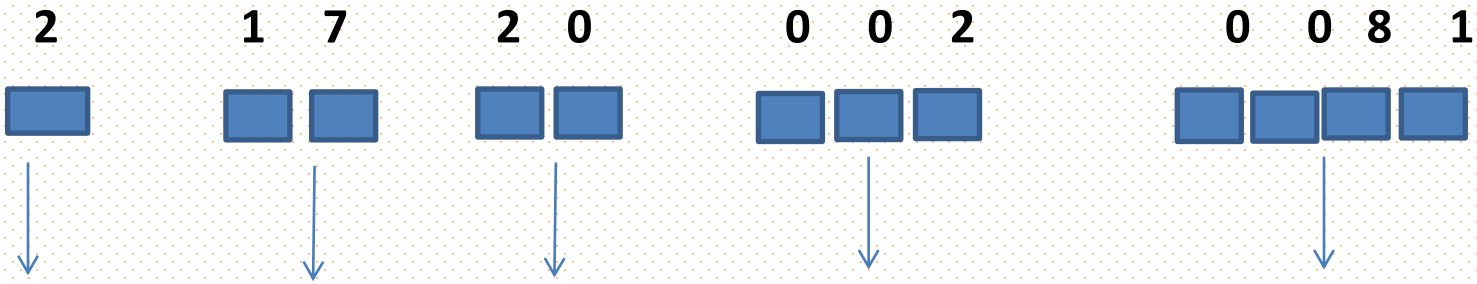
CENTRAL	STATE	REGISTRATION
1. Firm (Prop./partner/company) 2. Photo ID & Address Proof 3. Proof of Premises (Electricity Bill /Lease/Rent Agreement , Sale Deed) 4. Turnover Proof /Declaration or Mfg Machinery List 5. Product Details ,KOB details 6. Recall Plan 7. Trade License /NOC from Panchayat 8. IEC for Import/Export 9. FSMS , FORM IX FORM B , General Declaration	1. Firm(Prop./partner/company) 2. Photo ID & Address Proof 3. Proof of Premises (Electricity Bill /Lease/Rent Agreement , Sale Deed) 4. Turnover Proof /Declaration or Mfg Machinery List 5. Recall Plan 6. Trade License/ NOC from Panchayat 7. Product Details ,KOB details 8. FSMS , FORM IX FORM B , General Declaration	1. Photo 2. PhotoID (Voter/Pan/Aadhar) 3. Address Proof (Voter/Driving License etc) 4. Trade License 5. Form A

Application Processing by Licensing/Registration Authority



FSSAI LICENSE /REGISTRATION NUMBER

14 Digit License / Registration Number is issued to FBO which can be identified as follows :



QA Session ??

Thank You

Eat Right Stay Fit

INDEPTH MANAGEMENT INDIA PRIVATE LIMITED

Innovations and solutions

"Need & various Aspects of Food Testing

Contact Details:

Manoj singh

Manojindepth@gmail.com

+91-9650601103/9886074626

www.indepthmanagement.in

INDEPTH MANAGEMENT INDIA PRIVATE LIMITED

Registered office- A-7 Sai Ashish CHS, Sector-2, Airoli
Navi Mumbai, Thane, Maharashtra,
India- 400708.

INDEX

InDepth

Innovations and solutions

Trainers profile

MANOJ SINGH
Auditor trainer and consultant

An Organic chemist by education from BHU Varanasi having industrial experience of over 25 years in food ,water and chemical testing laboratories and industry.

He carries versatile and multifaceted experience in the field of Technical and system training, Quality Assurance, Assessment – Product Certification, Laboratory setup and management, Quality management, Laboratory accreditation and Vendor assessment A qualified assessor for ISO 17025 completed more than 500 maydays as technical and lead assessor
He is certified green belt in 6 sigma, a certified third party auditor for ISO 9001,14001,22000 and BRC food.
He is a NBQP(QCI) approved consultant for laboratory management system and has successfully completed consultancy and training for GLP,HACCP,PAS 96,22000,BRC food and Packaging, molecular biology, RSPO and ISO 17025 for industry and laboratory.

He has been contributing to industry significantly as Technical/ Lead Assessor for National Accreditation Board for Testing and Calibration Laboratories (NABL) and as Technical Expert for EIC Laboratory approval. He has been associated with various organizations like FRAC New Delhi, SGS India Pvt. Ltd., Gurgaon, ITC R&D Centre Bangalore and Intertek India in his past assignments as head of Analytics and Testing for food services

The Process

Quality is generally considered as the degree of excellence.
In relation to seafood, quality is the sum total of its composition, nutritive value, degree of freshness, physical damage and health hazards

Quality control means all the steps taken between harvest and retail trade to protect the quality of the final product.

The compliance is demonstrated through regular inspection and testing

- To ensure that product has been prepared from quality raw material and it never been grossly contaminated.
- To ensure that product is free from pathogens and toxins of public significance
- To ensure that product has reasonably extended shelf life

The Approach

Food safety culture

SSOP sanitation standard operating procedures

IPQC- In process Quality Control

TQM –Total Quality Management

Integrated organisational efforts designed to improve quality of processes at all levels

Fact

Non-compliance of product are-

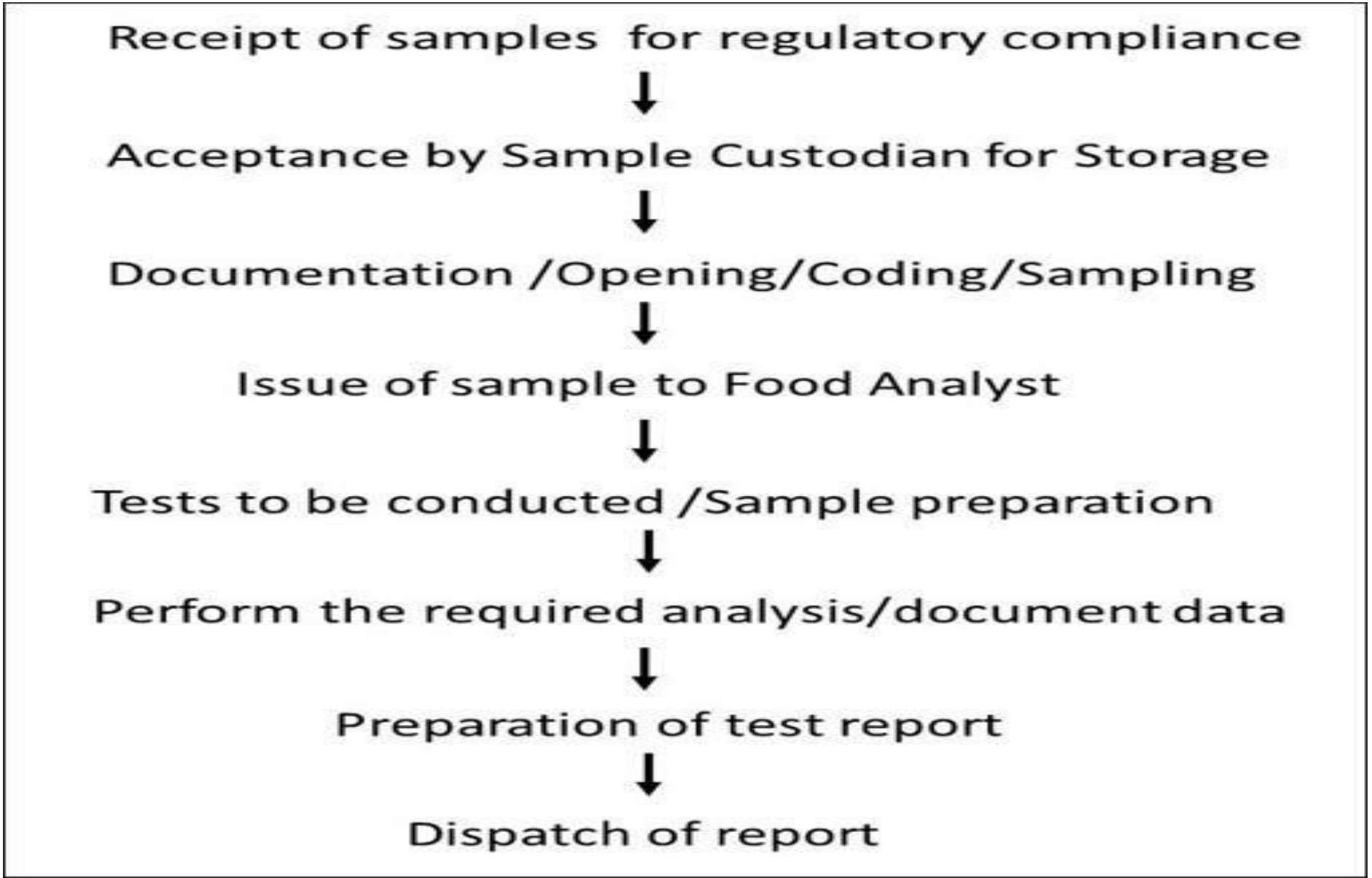
- **90% Microbiological**
- 5% Chemical
- 5% Physical

Prevalence of pathogens-

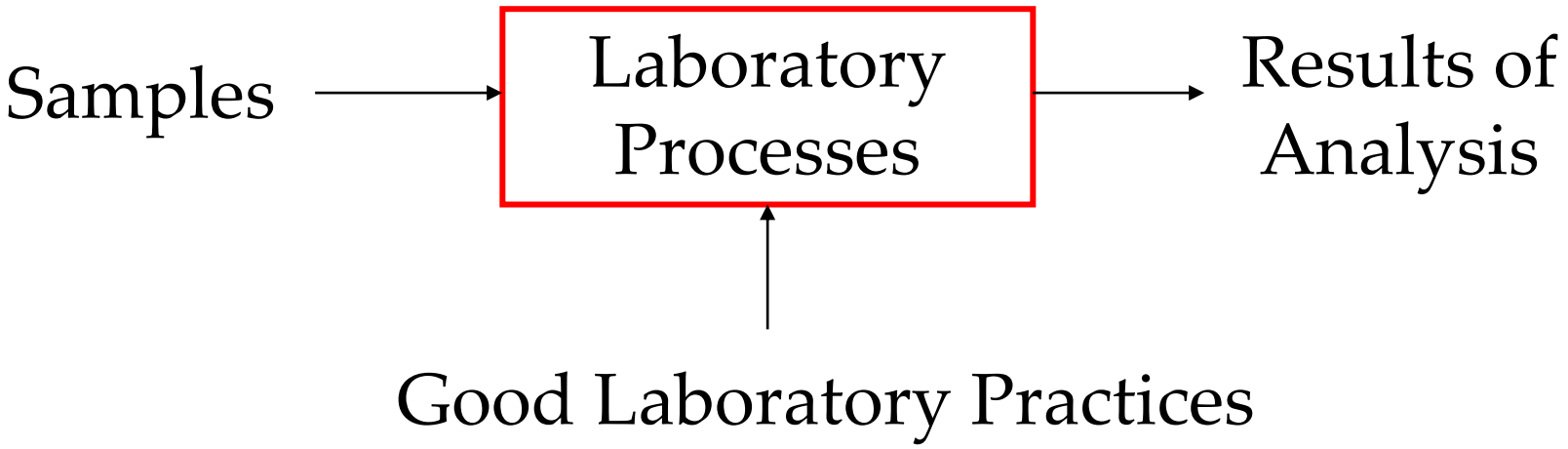
- E Coli-25%,
- Salmonella- 18%,
- Vibrio P. -15%
- Listeria m.-2%

PREVENTING INCIDENTS IS VITAL TO SUCCESS

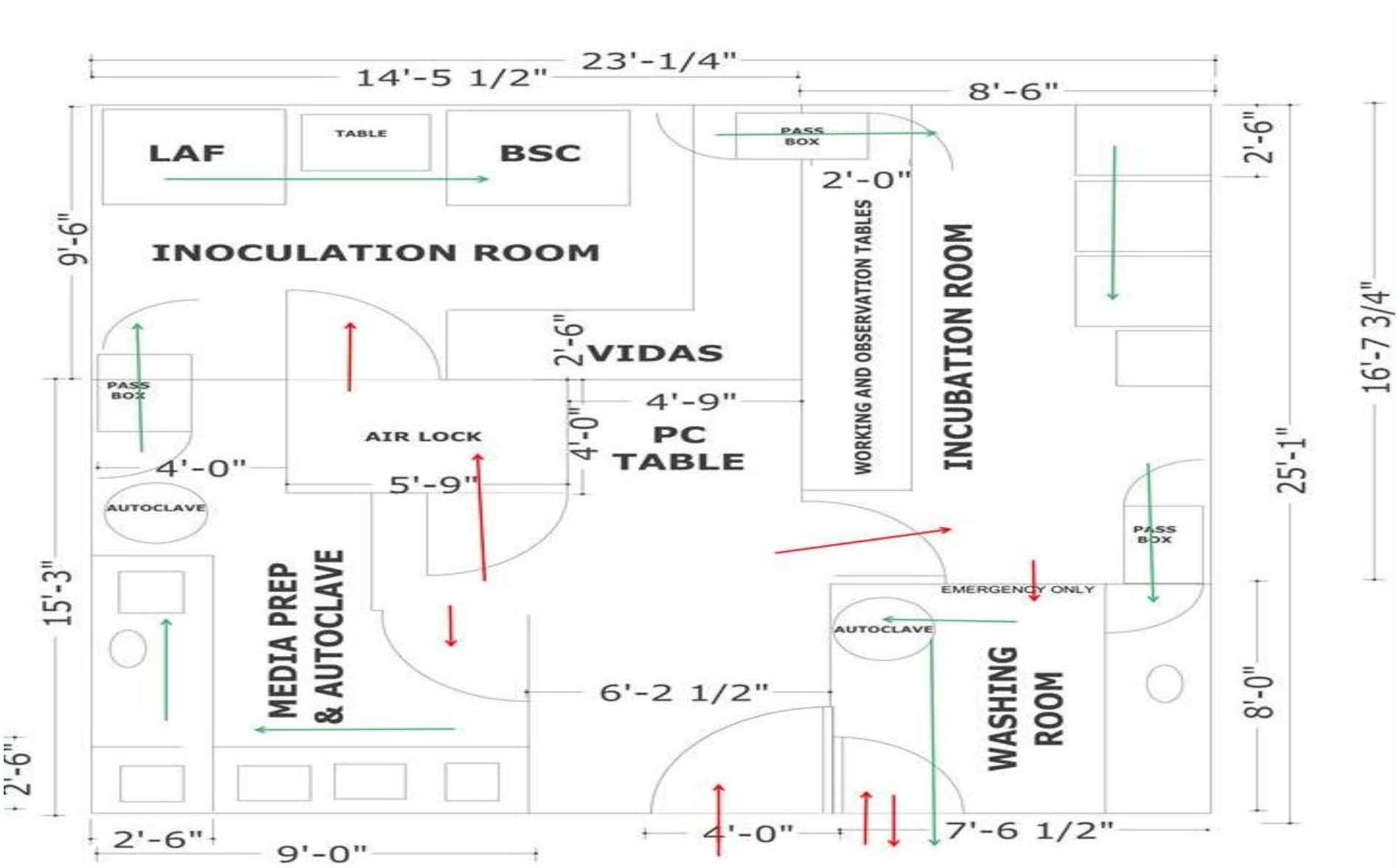
Lab process


Receipt of samples for regulatory compliance
Acceptance by Sample Custodian for Storage
Documentation /Opening/Coding/Sampling
Issue of sample to Food Analyst
Tests to be conducted /Sample preparation
Perform the required analysis/document data
Preparation of test report
Dispatch of report

Process of GLP



Lab Layout


23'-1/4"
14'-5 1/2"
8'-6"
LAF
TABLE
BSC
PASS BOX
2'-0"
2'-6"
9'-6"
INOCULATION ROOM
WORKING AND OBSERVATION TABLES
INCUBATION ROOM
16'-7 3/4"
2'-6"
VIDAS
PASS BOX
4'-9"
AIR LOCK
4'-0"
PC TABLE
4'-0"
5'-9"
AUTOCLAVE
25'-1"
PASS BOX
EMERGENCY ONLY
15'-3"
MEDIA PREP & AUTOCLAVE
AUTOCLAVE
WASHING ROOM
6'-2 1/2"
8'-0"
2'-6"
2'-6"
9'-0"
4'-0"
7'-6 1/2"

EU/EC/ISO-17025-2017

6.3	**Facilities and environmental conditions**
6.3.3	The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.5	**Metrological traceability**
6.5.1	The laboratory shall establish and maintain metrological traceability of its measurement results by means of a **documented** unbroken chain of calibrations.

7.2.1	**Selection and verification of methods**
7.2.1.1	The laboratory shall use appropriate methods and subjected to verification/validation.

BRC Food, Issue 8

4.11.8	Environmental monitoring
SOI	Risk-based environmental monitoring programmes shall be in place for pathogens or spoilage organisms. At a minimum, these shall include all production areas with open and ready-to-eat products.

- Sampling protocol.
- Identification of sample locations
- Frequency of tests
- Target organism(s) (e.g. pathogens, spoilage organisms and/or indicator organisms)
- Test methods (e.g. settle plates, rapid testing and swabs)

BRC Food, Issue 8…

- Appropriate control limits shall be defined for the environmental monitoring programme.
- The company shall review the environmental monitoring
- The positive results
- Consistent negative results
- All product and group must be tested once in year
- Storage and shelf life leading to retesting

IMPORTANCE OF LABORATORY ACCREDITATION

Certification and Accreditation

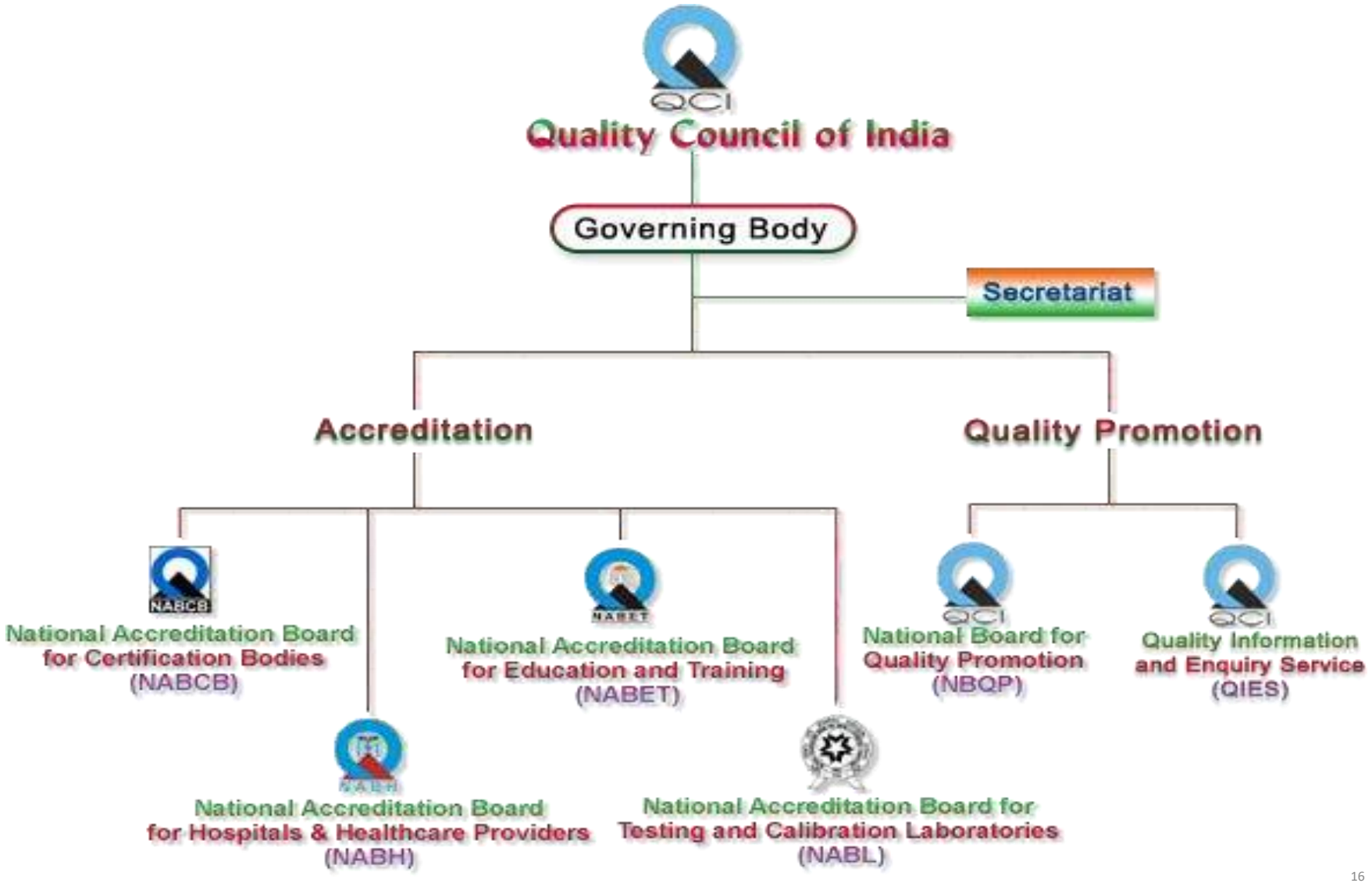
- Certification is a comprehensive evaluation of a process, system, product, event, or skill typically measured against some existing norm or standard.
- Certification does not make any statement about the **technical competence** of the laboratory.
  - Example ISO 9001:2005 Certification

- Accreditation is the formal declaration by a neutral third party that the certification program is administered in a way that meets the relevant norms or standards of certification program
- Uses criteria specifically developed to determine **technical competence** of the laboratory.
- This is an independent evaluation of laboratory's technical competence
  - Accreditation-Example ISO 17025

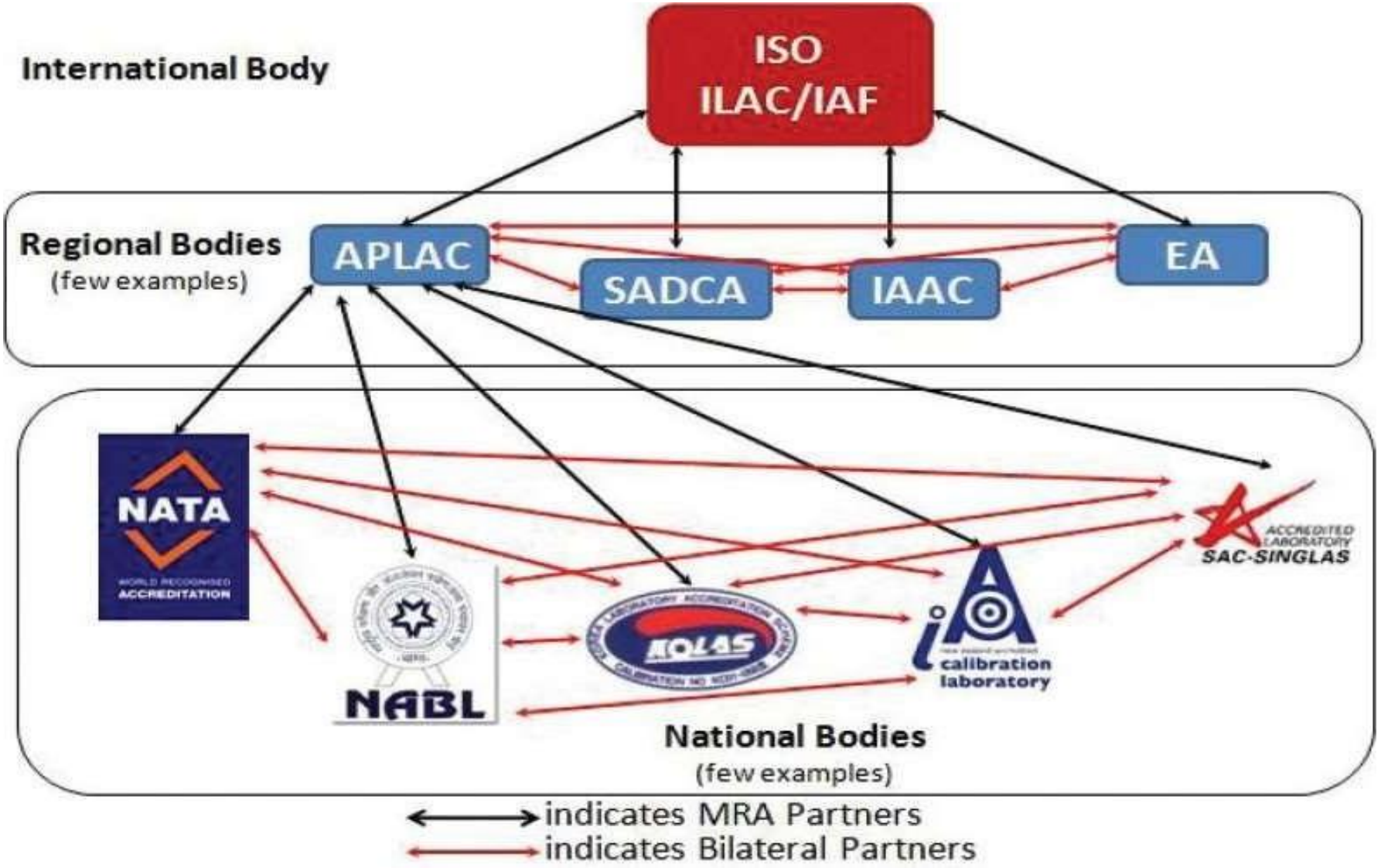
CERTIFICATION

ACCREDITATION

QCI - Quality Council of India



NABL Traceability



Accreditation process

Application for Accreditation
(by Laboratory)

Acknowledgement & Scrutiny of Application
(by NABL Secretariat)

Adequacy of Quality Manual
(by Lead Assessor)

Pre-Assessment of Laboratory
(by Lead Assessor)

Final Assessment of Laboratory
(by Assessment Team)

Scrutiny of Assessment Report
(by NABL Secretariat)

Recommendations for Accreditation
(by Accreditation Committee)

Approval for Accreditation
((by Chairman NABL)

Issue of Accreditation Certificate
(by NABL Secretariat)

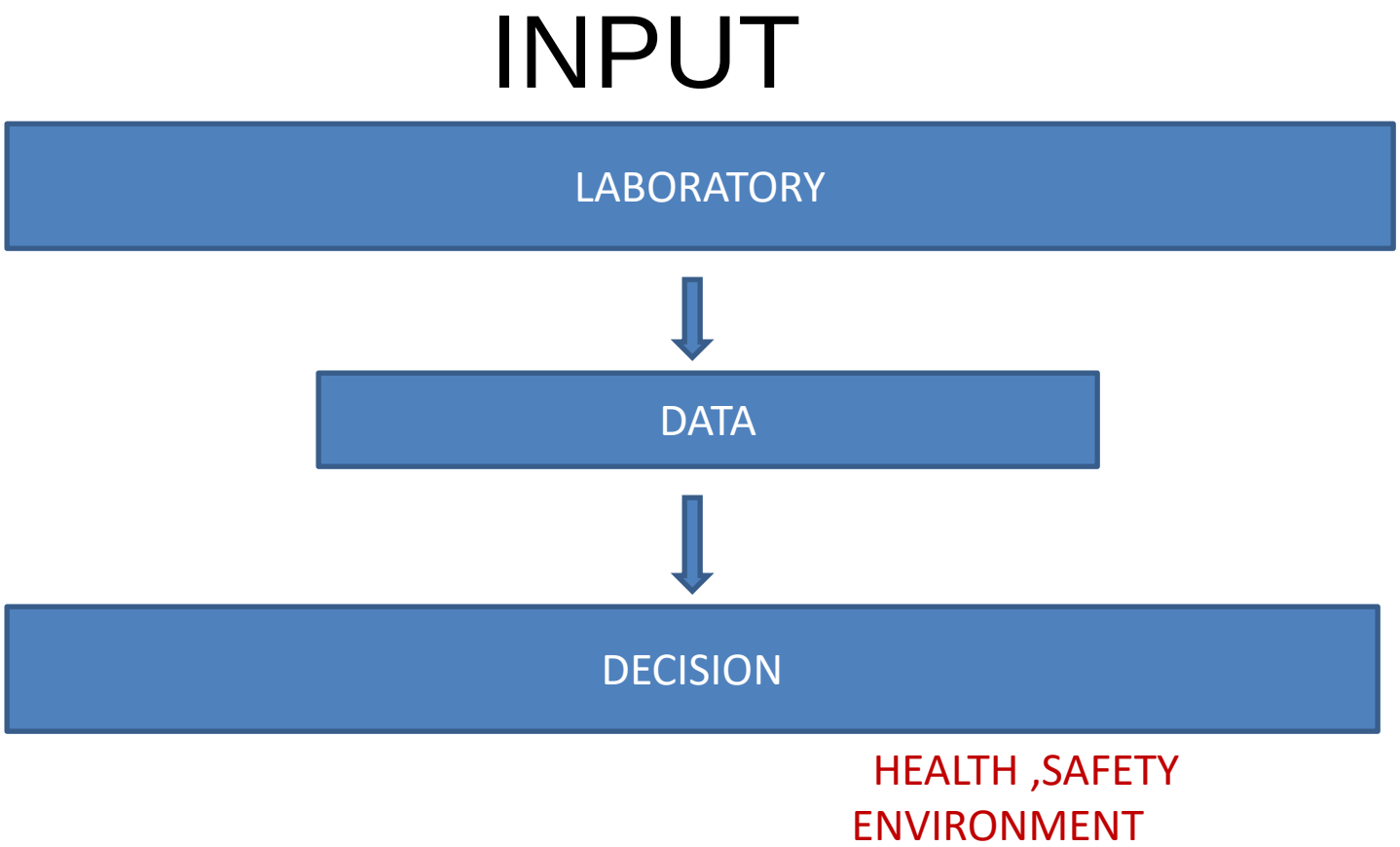
Feedback to Laboratory

and

Necessary Corrective Action by Laboratory

www.nabl-india.org

Importance of Data output from Lab



Comparability in Measurements

- Traceability
- Reference Material
- Test Methods
- Proficiency Testing
- Measurement Uncertainty

COMPETENCE OF A LABORATORY

- In evaluating the competence of a laboratory, the following methods are used:

- On –the-spot assessment of the laboratory by the experts .

- By evaluating the results of a particular test/measurement in a proficiency testing programme.

MRA Evaluations

- WTO;
- Technical Barriers
- Evaluations are based on;
- APLAC MR 001 requirements
- International teams of trained evaluators
- Possible pre-evaluation
- Documentation review (two days):
- ISO/IEC 17011 compliance of management system
- Accreditation criteria consistent with ISO/IEC 17025
- Independence and authority

An Accreditation Body Could be:

- National accreditation body can be a statutory body
- May be established by Act of Parliament
- User and/or government funded, "not for profit" organization
- And has to be a third-party accreditation body Internationally recognized through MRAs

BENEFITS OF ACCREDITATION

- National and international recognition Public and industry acceptance
- Assurance to clients on validity of results Provides global equivalence
- Provides comparability in measurements Decision makers can rely on test results Improves staff motivation
- Ensures better support in the event of legal challenge
- Saves money by getting it right at first time

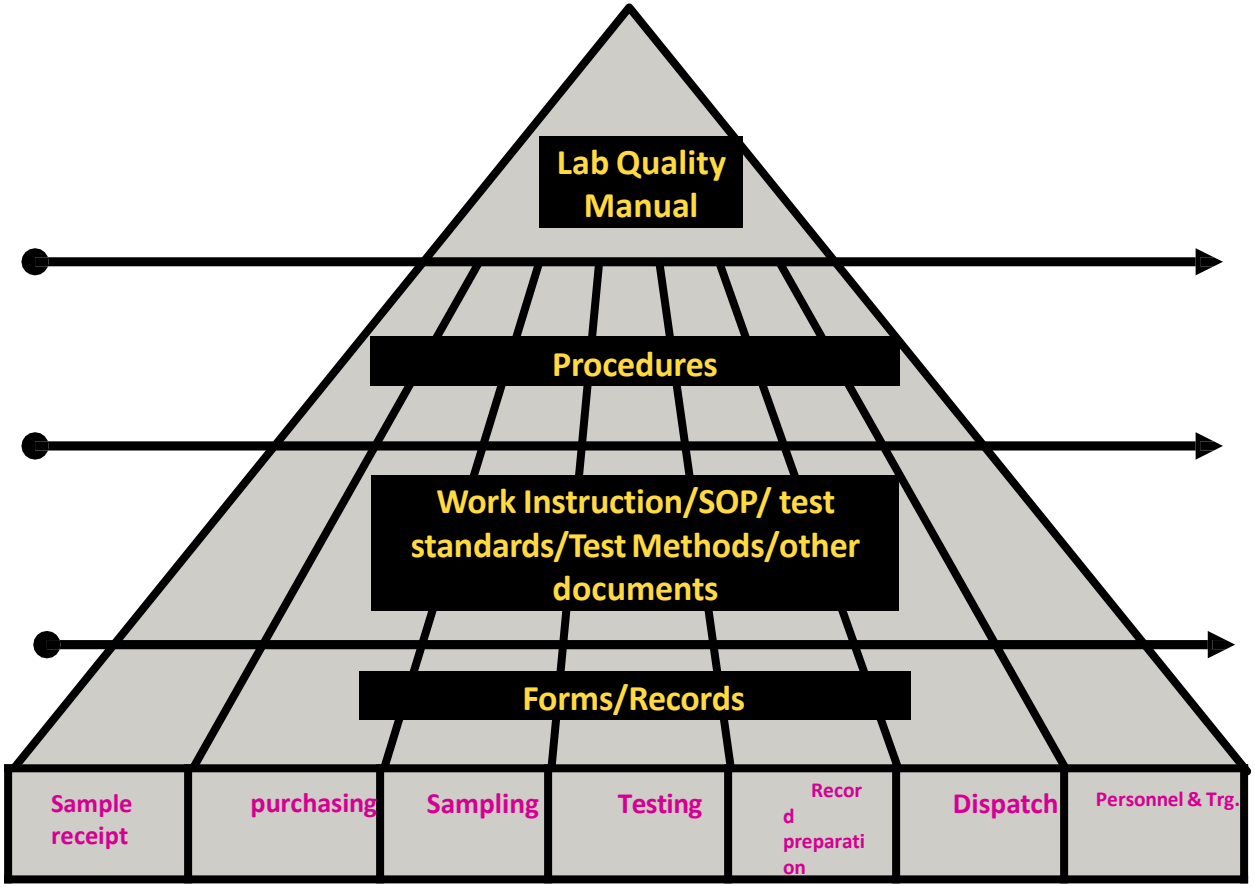
CONCEPT OF MANAGEMENT SYSTEM

SYSTEM

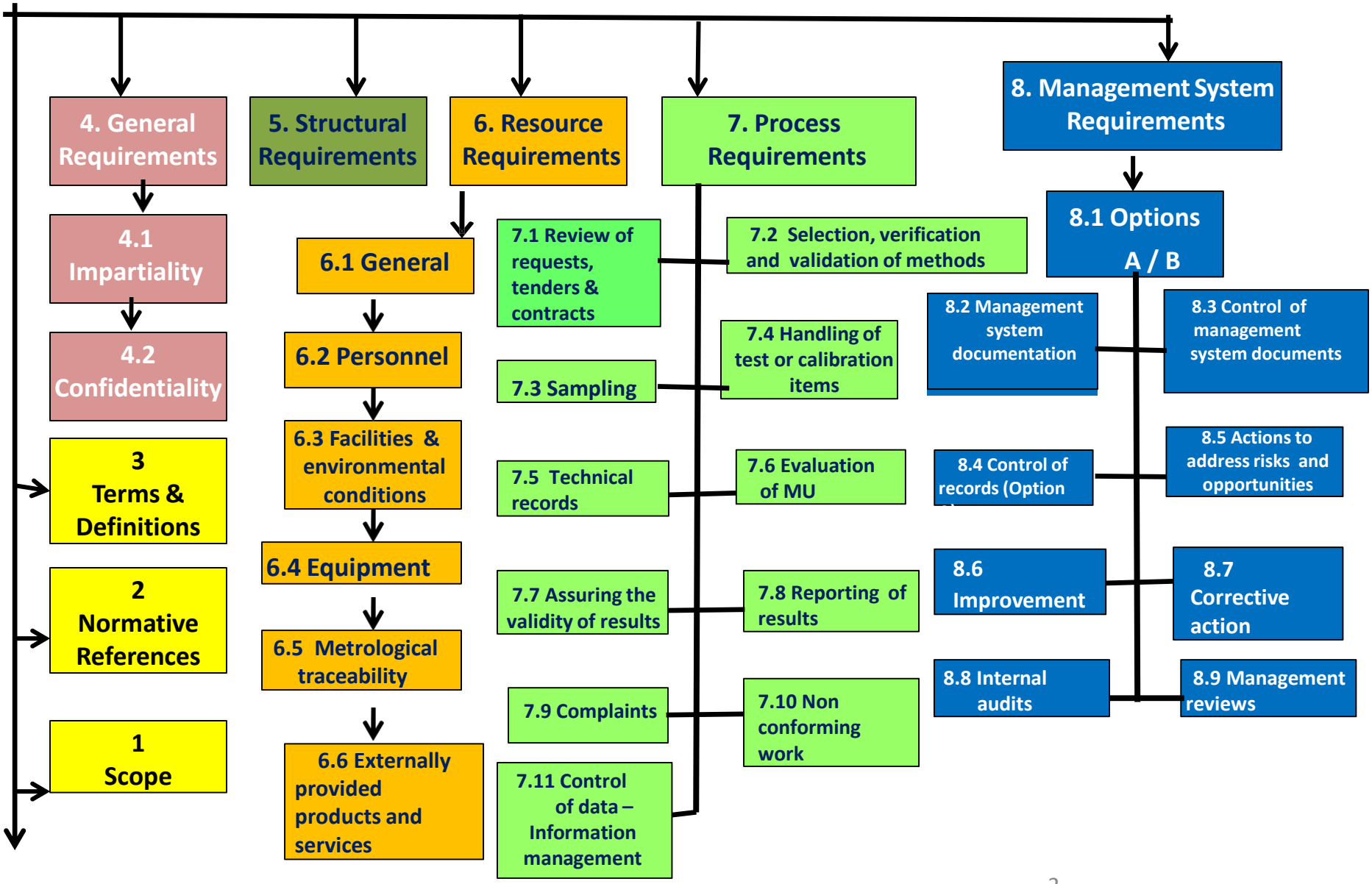
- Taking the attendance of employees by punching cards, is a system.

- Recording of the measurement data in log-sheet is a system.

4 TIER DOCUMENTATION STRUCTURE FOR LABORATORY UNDER ISO/IEC 17025:2017



ISO/IEC 17025: 2017



Quick Testing Techniques

Conventional Microbiology

Quick techniques

Conventional vs RTPCR

Conventional

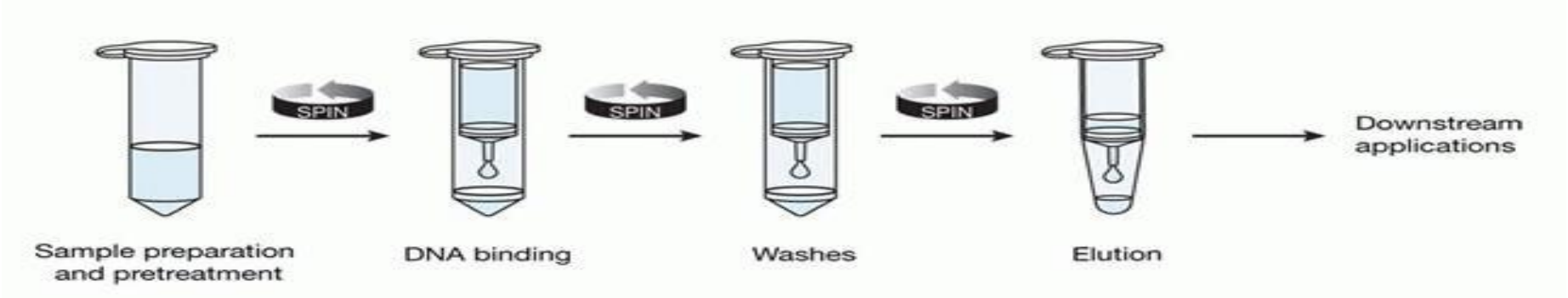
- Selective media, growth time and Biochemical identification then confirmation
- Technical competency and subjective
- 2-7 days for initial and 7-10 days for final results

RT-PCR –DNA Test

Specific DNA micro-biological species
Detection and confirmation in real time
Automated, easy and objective
2 hours for indicator One day for pathogen reporting

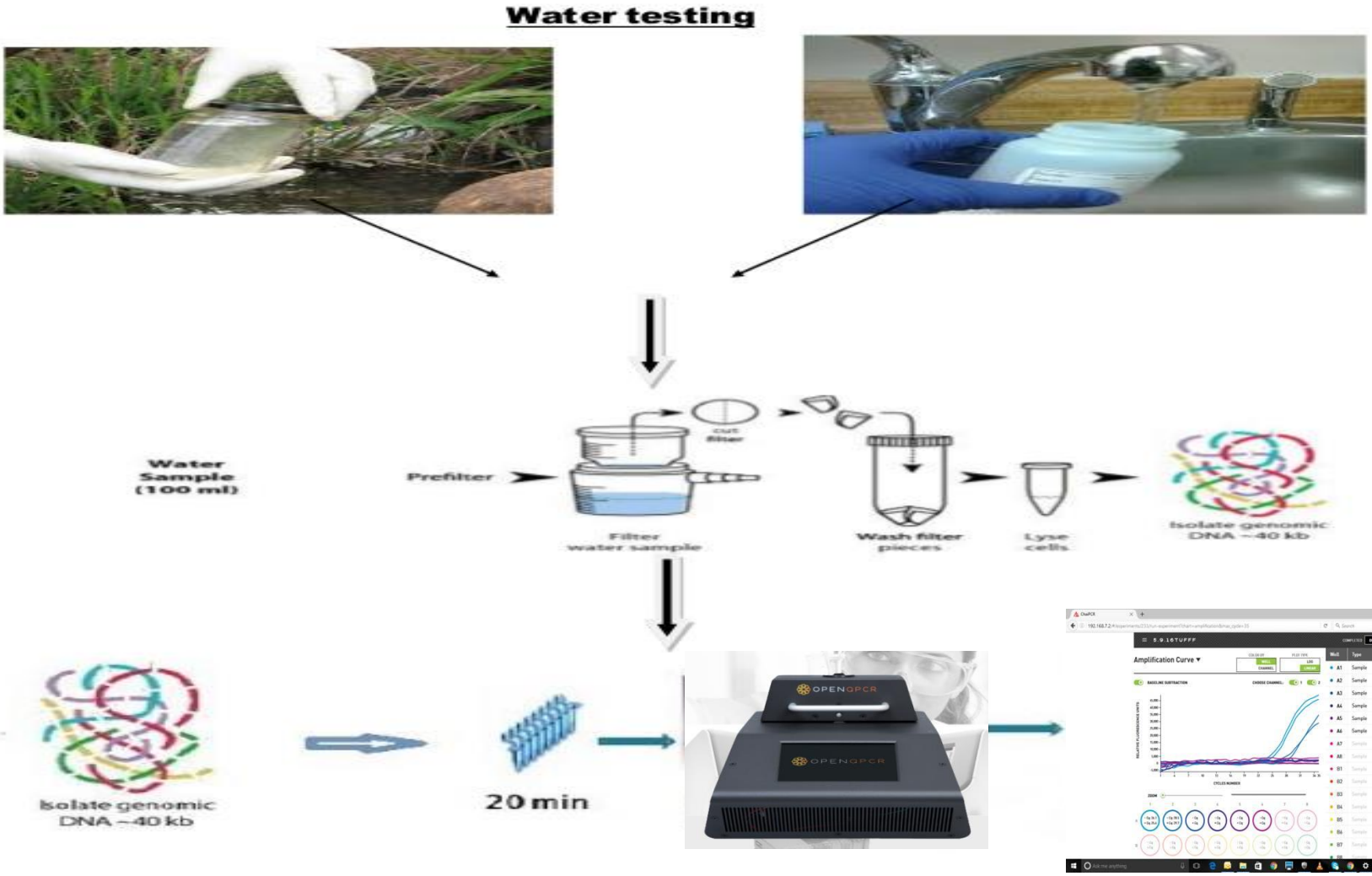
Extraction Chemistry

Magnetic Bead based Extraction Chemistry



Spin Column based Extraction Chemistry

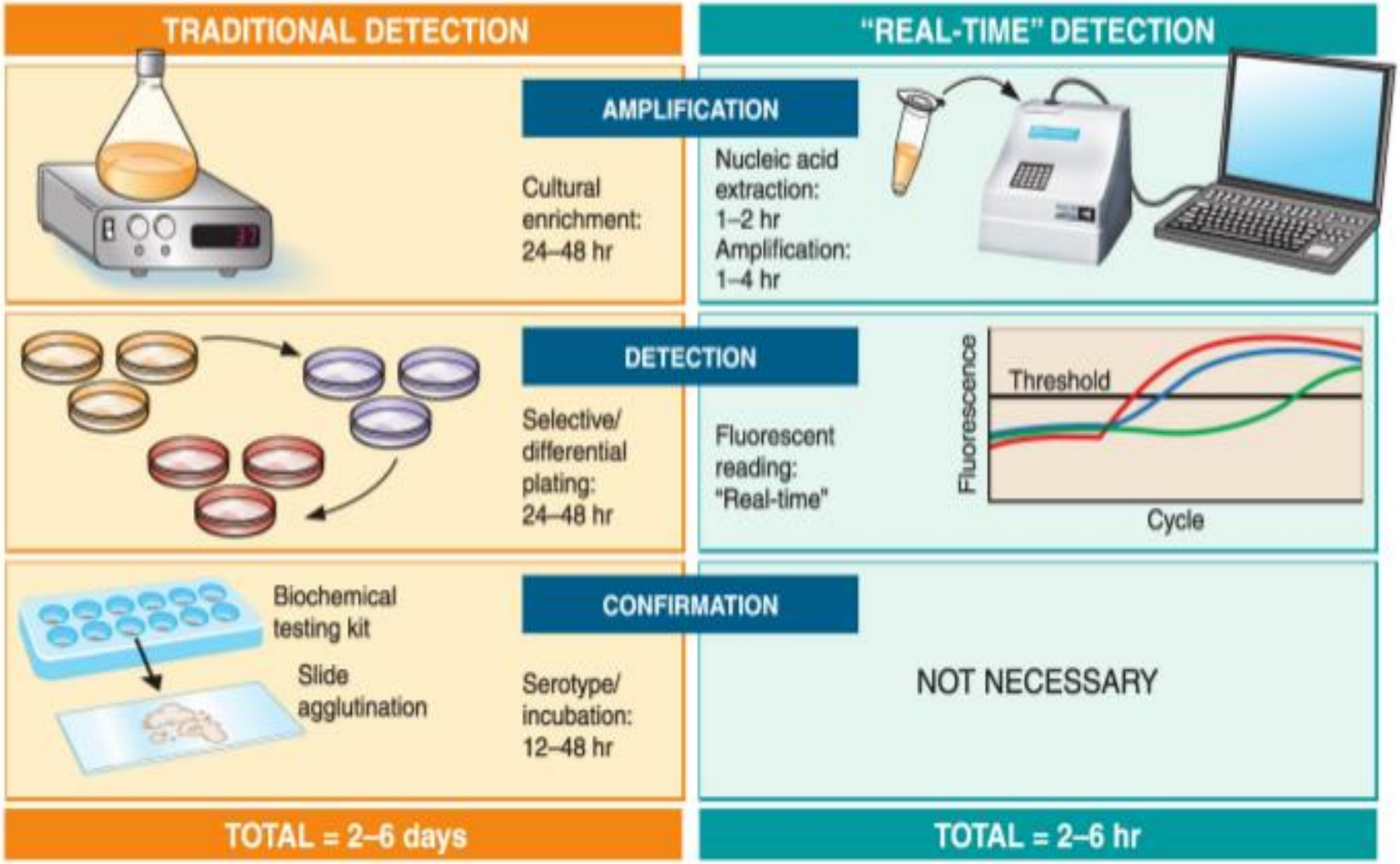
Water testing for Hepatitis A and Entero Virus



Application of RTPCR

- Qualitative & Quantitative Analysis
- Food Pathogen Identification
- GMO screening & Testing
- Food Allergen testing
- Animal species Identification for Meat
- Species Identification in Dairy and Dairy related products
- Halal & Koescher
- Disease Diagnostics such as White and yellow spot, Brucella etc.

Conventional VS Rapid method



What is Elisa

- Enzyme-linked immunosorbent assay (ELISA), also known as an enzyme immunoassay (EIA), is a biochemical technique used mainly in immunology to detect the presence of an antibody or an antigen in a sample.

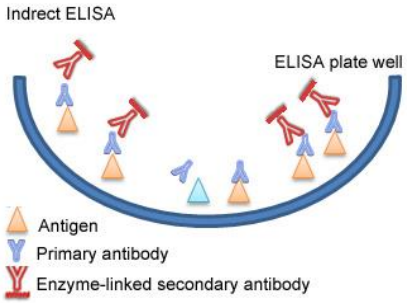
- The ELISA has been used as a diagnostic tool in medicine and plant pathology, as well as a quality-control check in various industries, such as ELISA application in food industry.

- In simple terms, in ELISA, an unknown amount of antigen is affixed to a surface, and then a specific antibody is applied over the surface so that it can bind to the antigen.

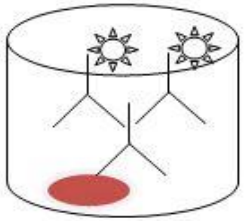
- This antibody is linked to an enzyme, and in the final step a substance is added that the enzyme can convert to some detectable signal, most commonly a colour change in a chemical substrate.

Types of Elisa's

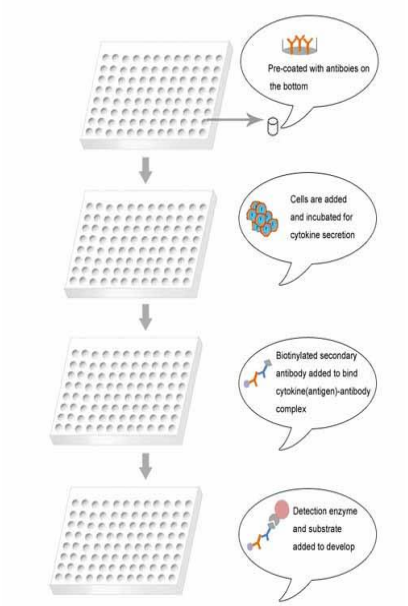
Indirect ELISA



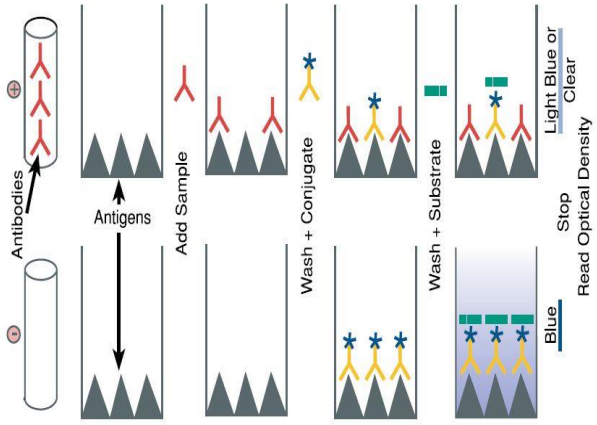
Direct ELISA



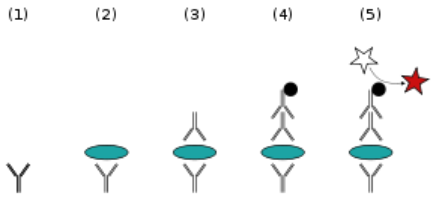
ELISpot



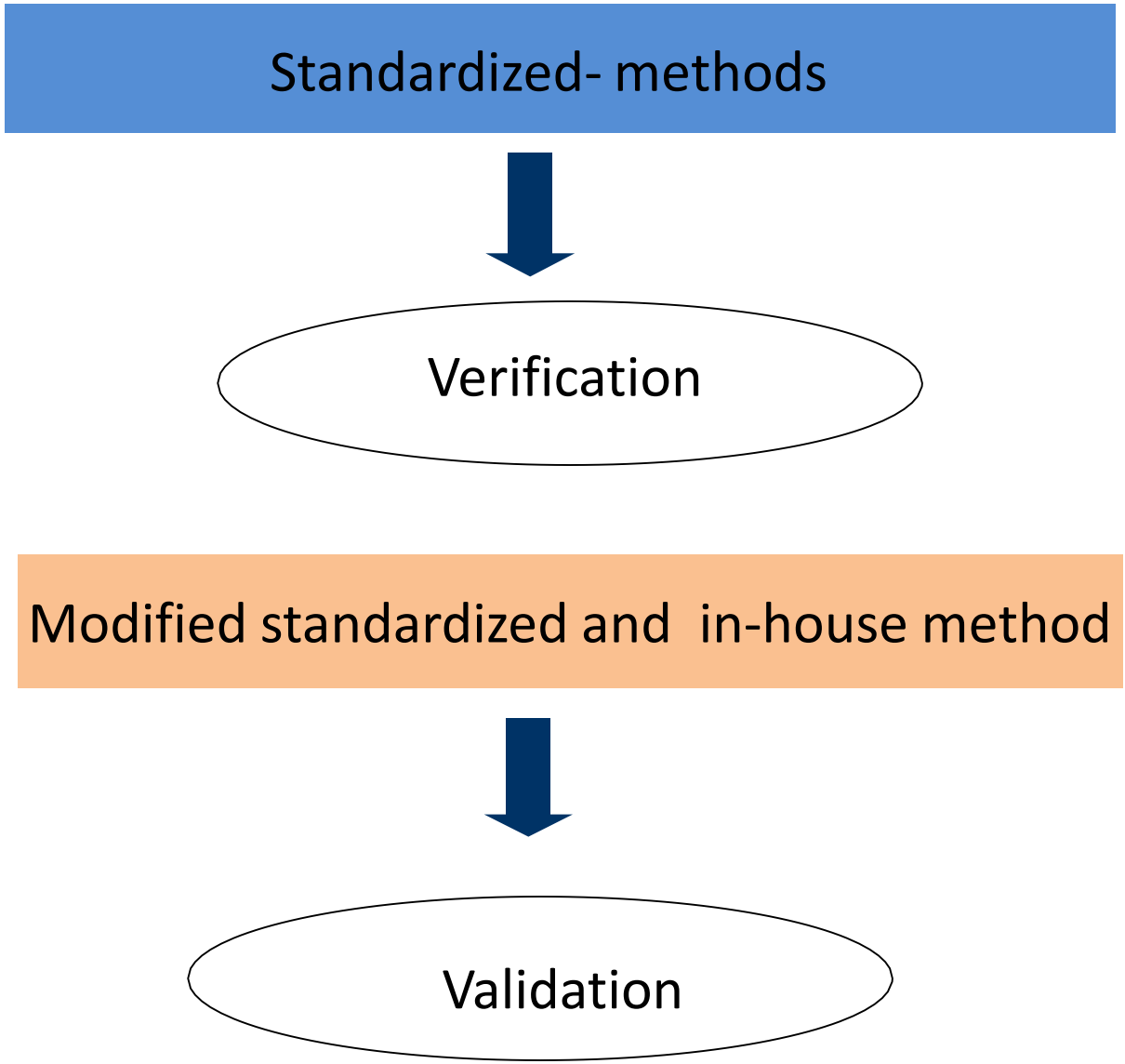
Competitive ELISA



sandwich ELISA



Testing method



5 M

MAN

5M

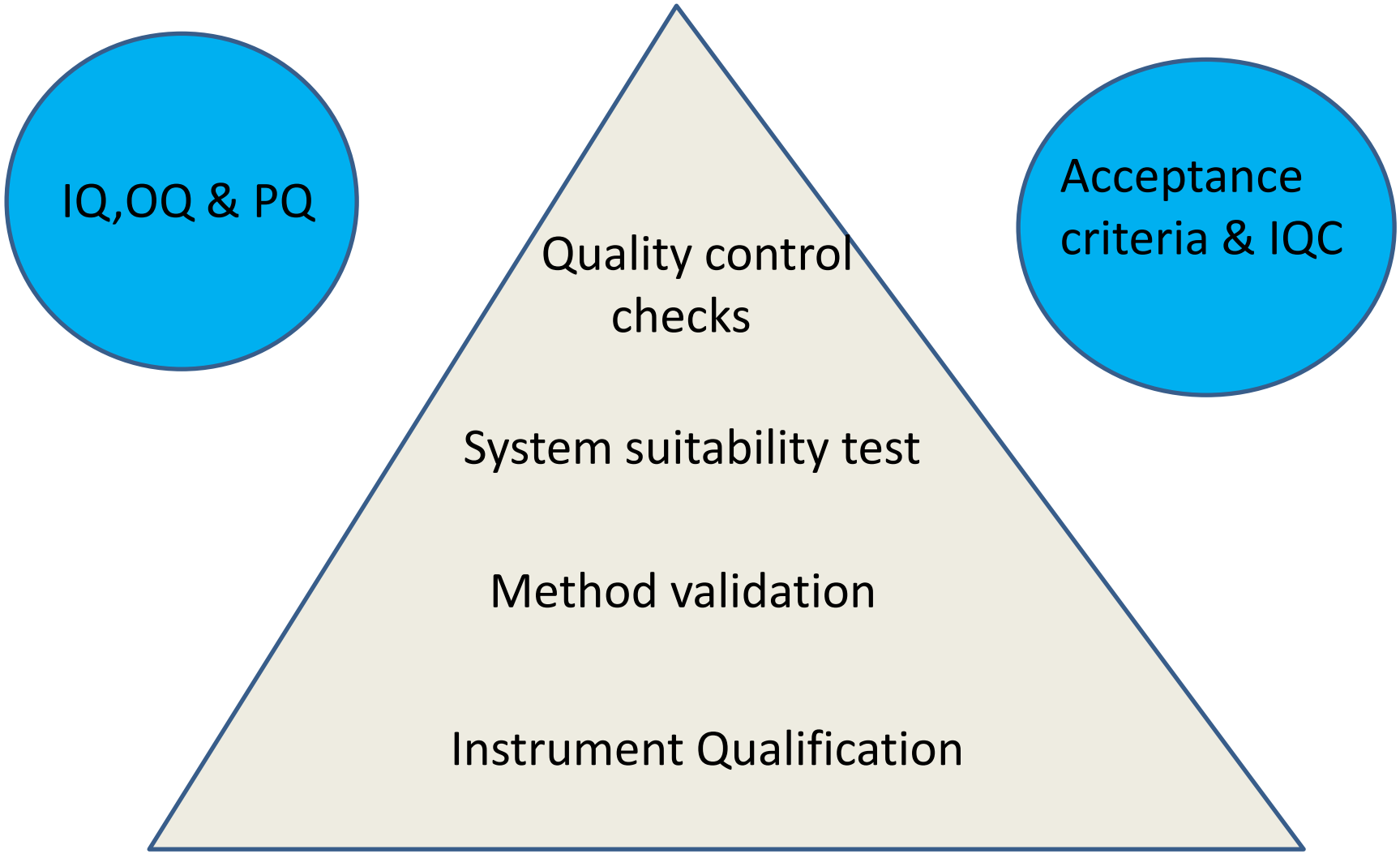
MONEY

METHOD

MACHINE

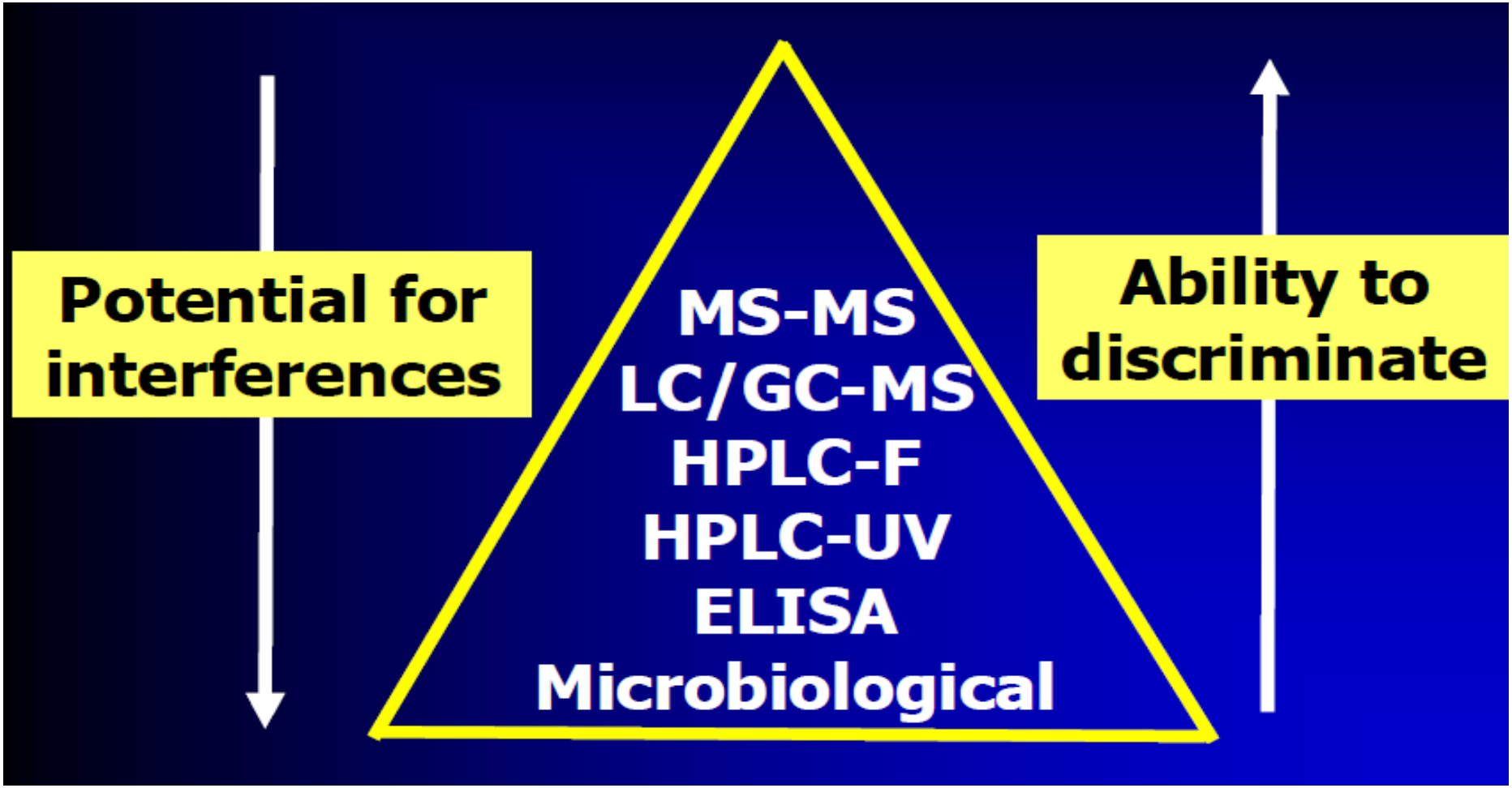
MATRIX

Quality components



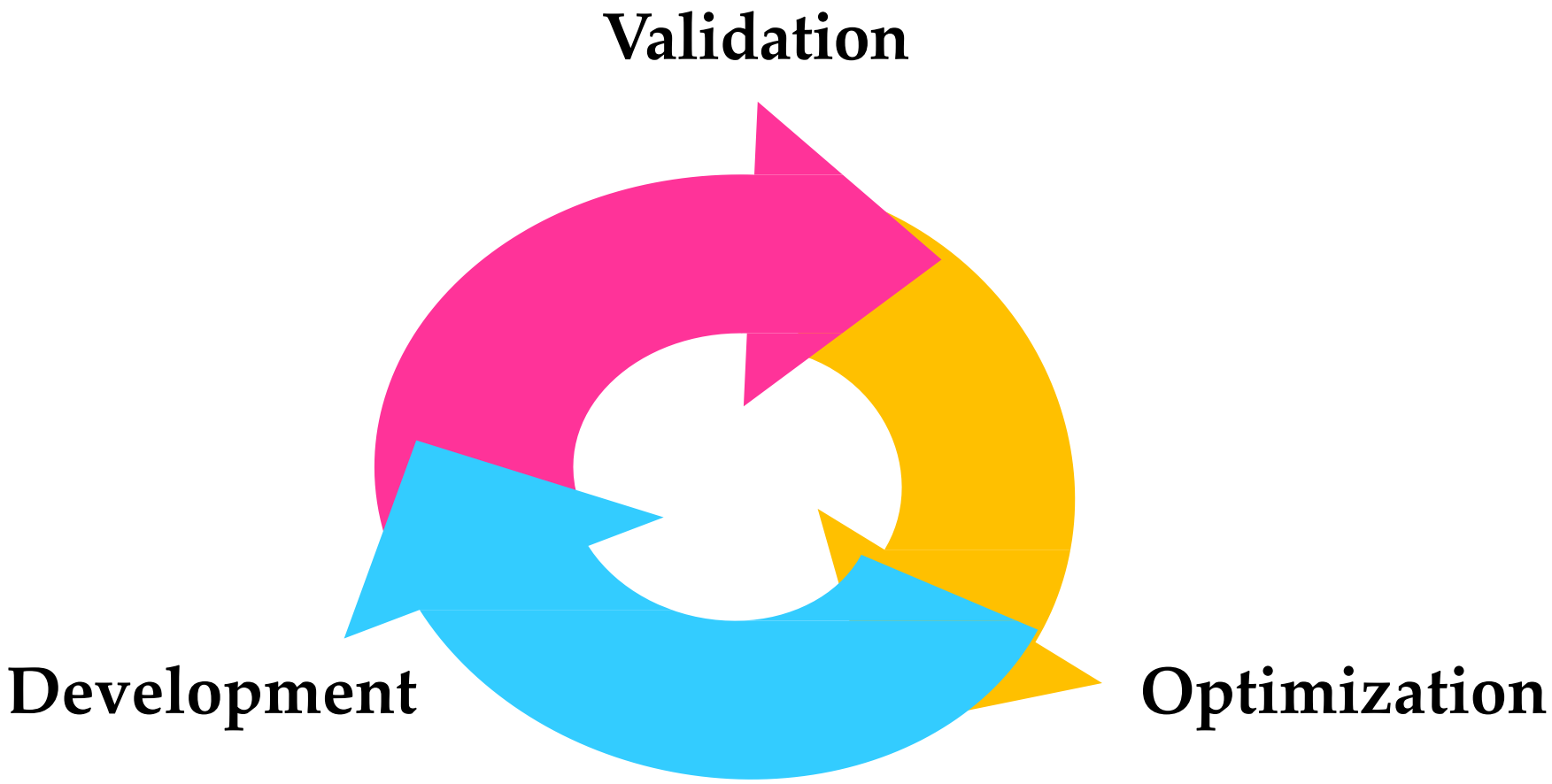
Power to discriminate

False positive/False negative



Discrimination depends on method use

Method Life Cycle

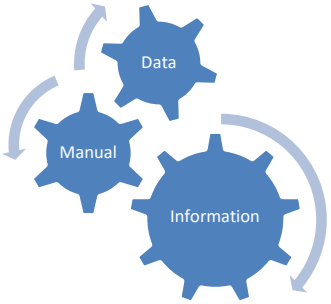


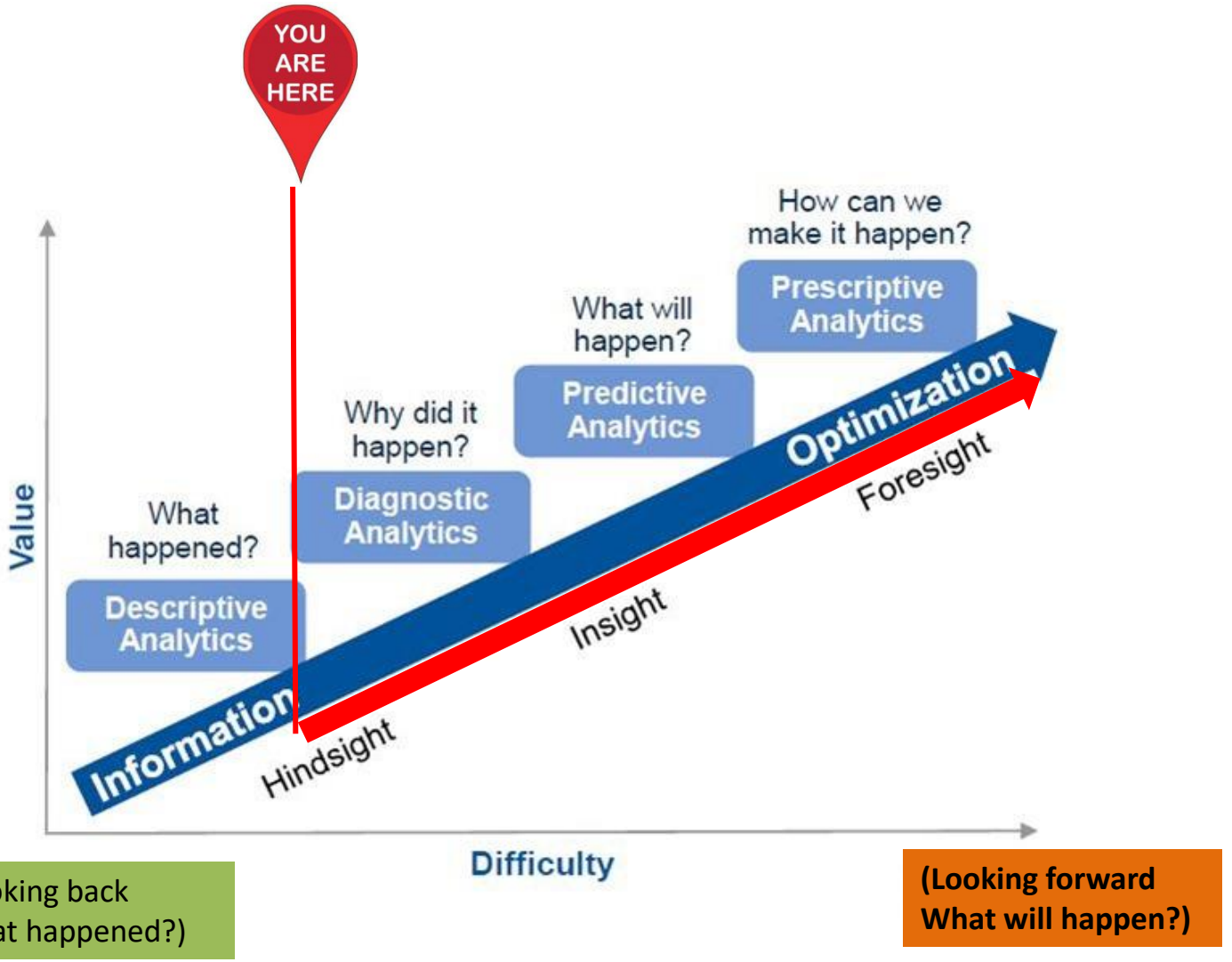
Ensuring the validity of results

- Use of reference materials or quality control materials
- Use of alternative instrumentation that has been calibrated to provide traceable results
- Use of check or working standards with control charts, where applicable
- Intermediate checks on measuring equipment
- Replicate tests or calibrations using the same or different methods
- Retesting or recalibration of retained items
- Review of reported results
- Intra-laboratory comparisons(Round robin test)
- Proficiency testing

Data analytics

Data analytics

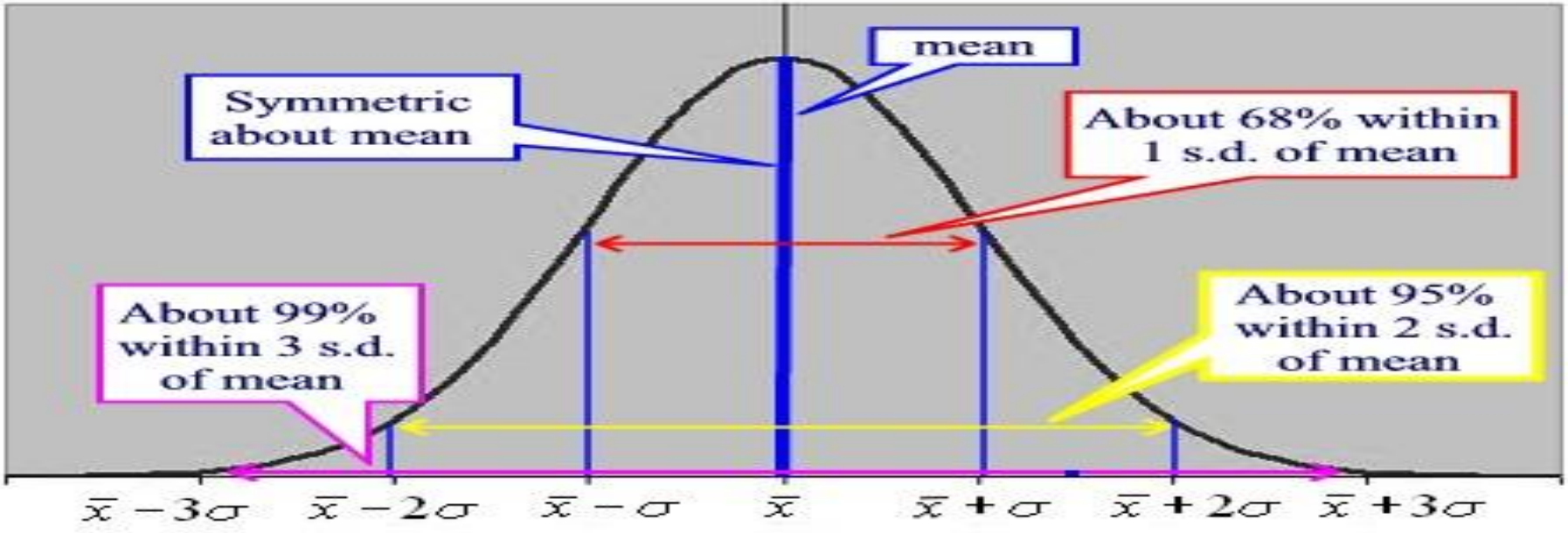




(Looking back
What happened?)

**(Looking forward
What will happen?)**

Uniform Distribution-Normal



The normal probability distribution is by far the most common and most important continuous probability distribution.
The normal curve is symmetrical and, because of its appearance, it is sometimes called a ‘bell-shaped’ curve. Coverage factor: 95 % : Factor = 2

Detecting Error

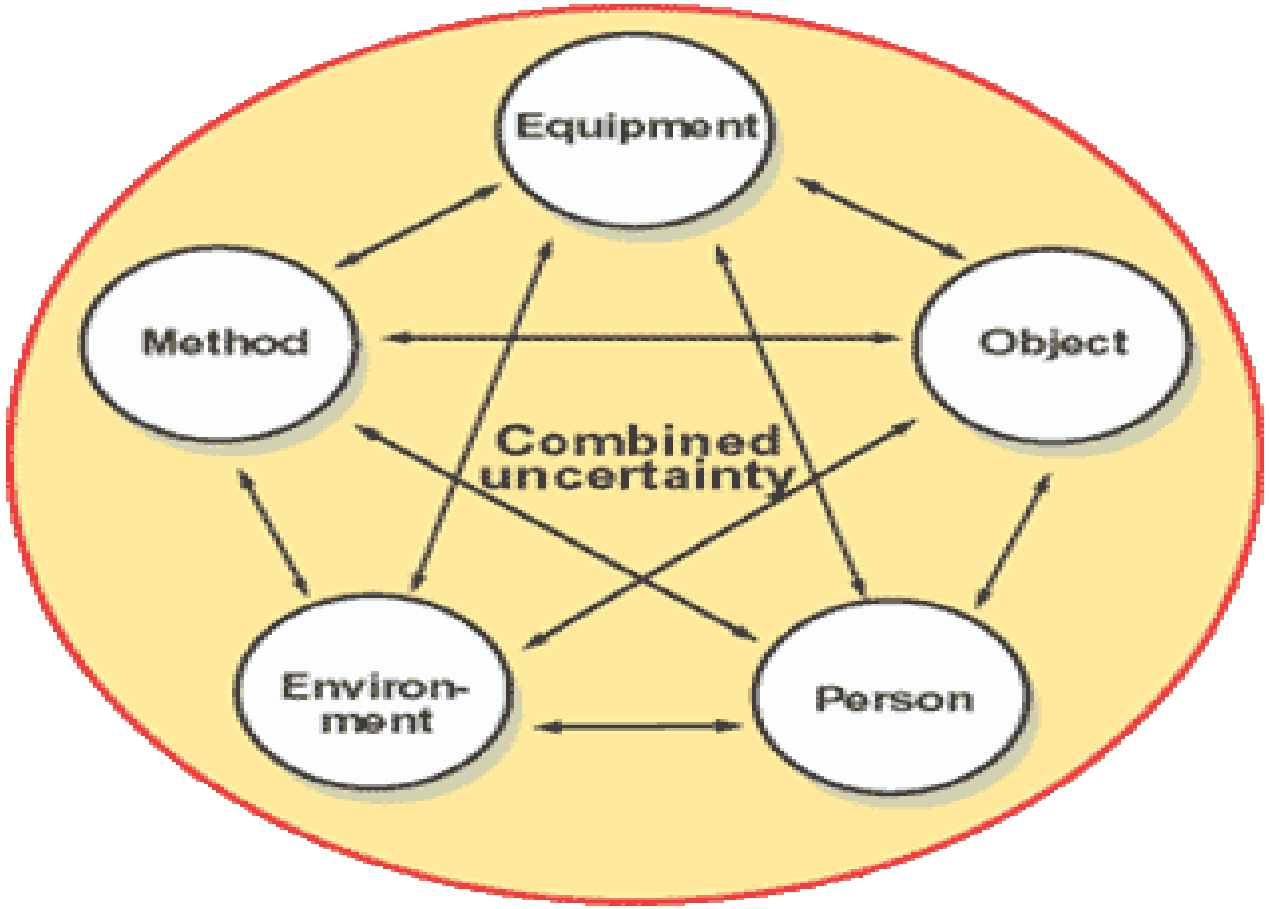
- **Random error**: variation in QC results with no pattern- only a cause for rejection if outside 2SDs.
- **Systematic error**: not acceptable, correct the source of error

  Examples:

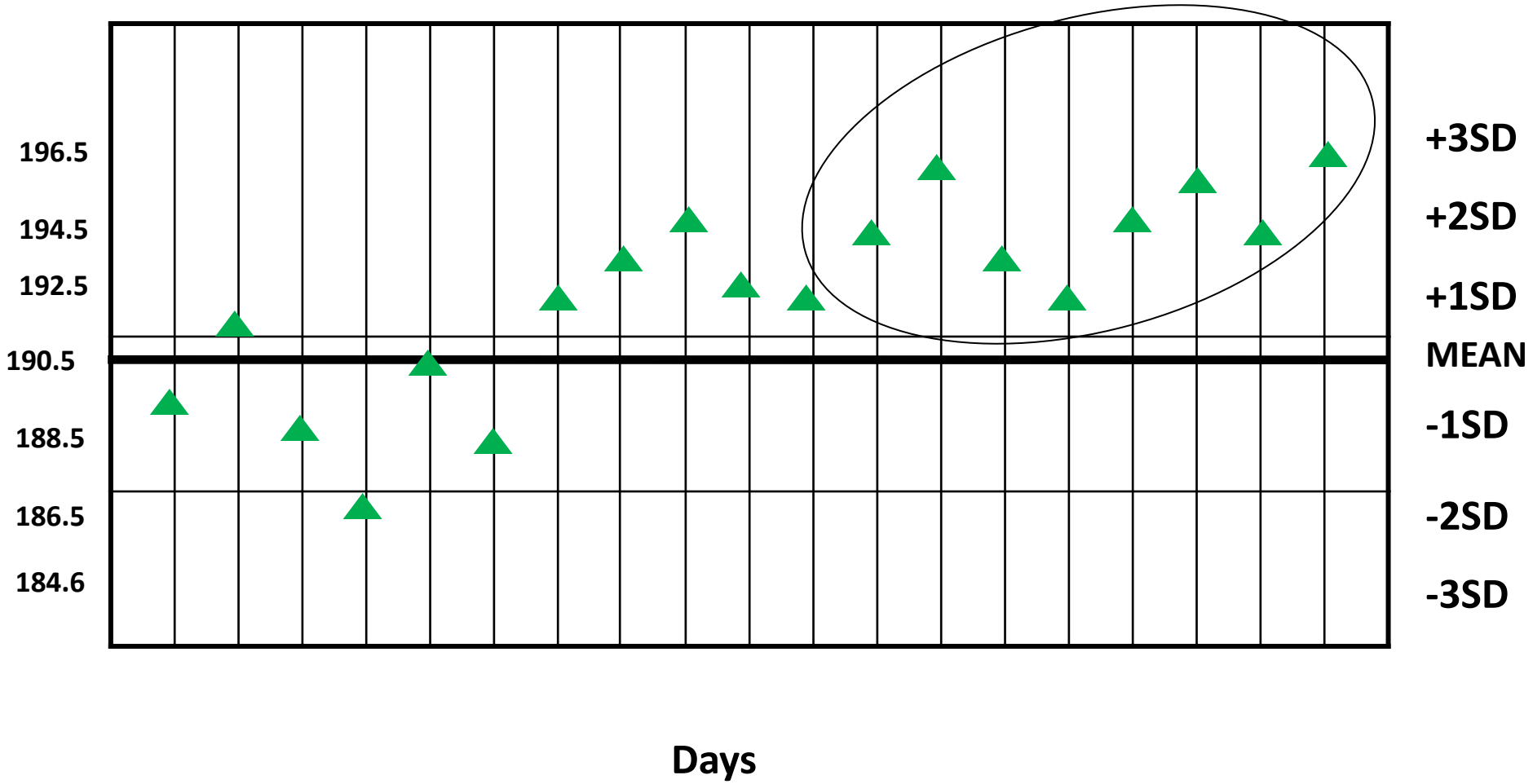
  – **Shift**–control on one side of the mean 6 consecutive days

  – **Trend**–control moving in one direction– heading toward an “out of control” value

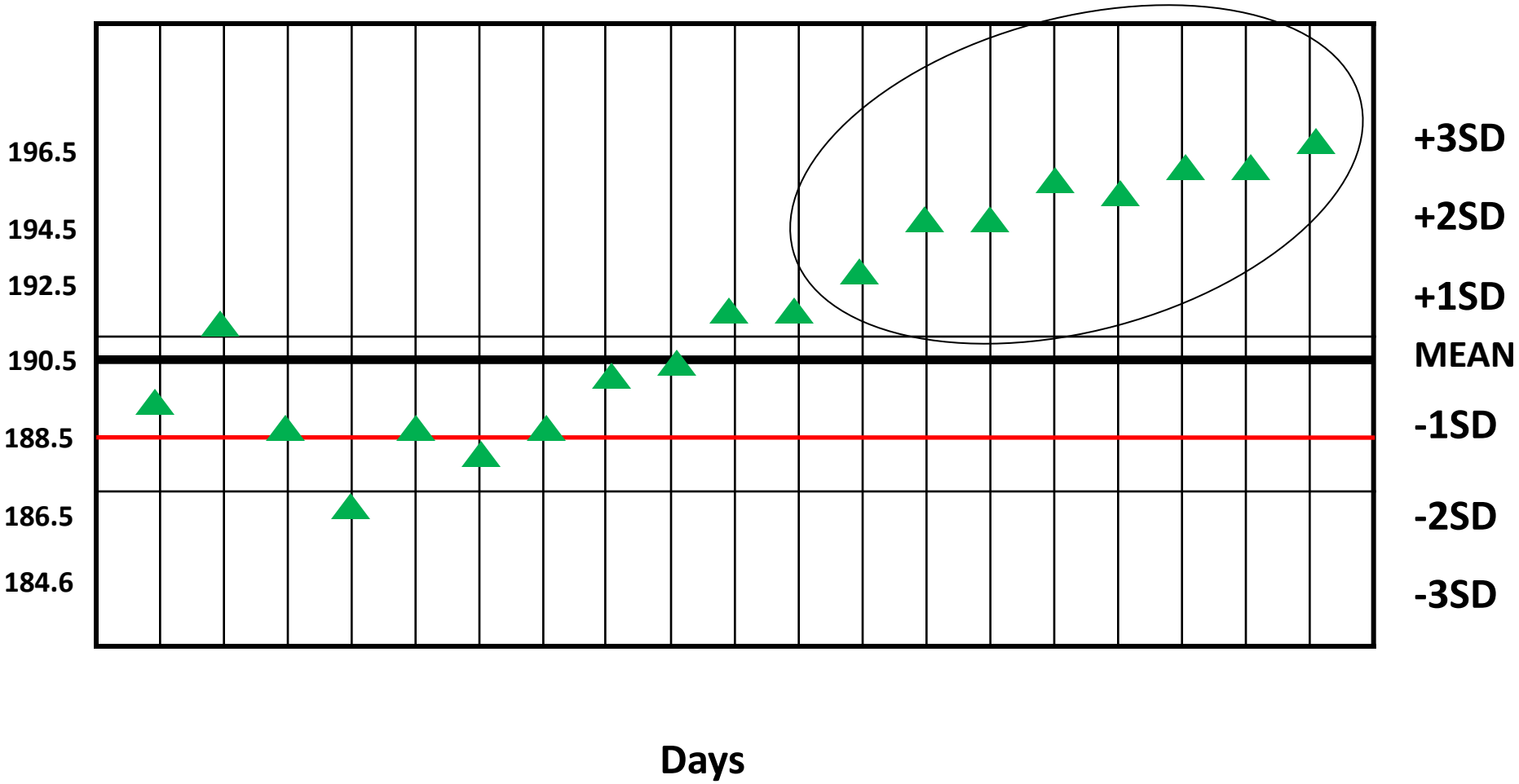
Combined Standard Uncertainty



Shift


196.5
194.5
192.5
190.5
188.5
186.5
184.6
+3SD
+2SD
+1SD
MEAN
-1SD
-2SD
-3SD
Days

Trend

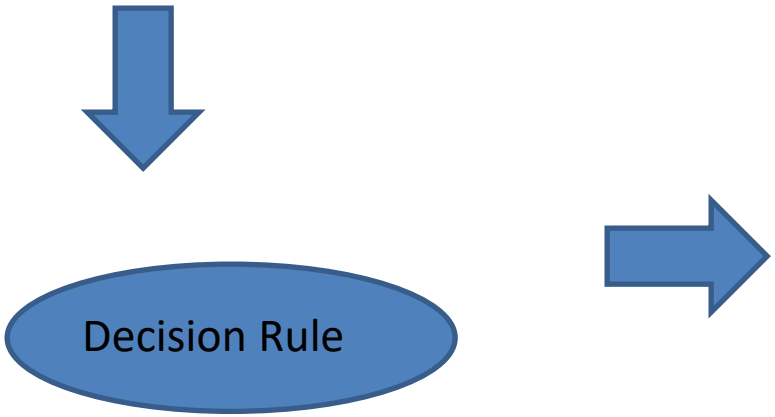

196.5
194.5
192.5
190.5
188.5
186.5
184.6
+3SD
+2SD
+1SD
MEAN
-1SD
-2SD
-3SD
Days

Statement of conformity

Statement of conformity –Refer clause 8.6.1 as per ISO 17025-2017

Based on the customer risk evaluation the basis of compliance/non-compliance need to be communicated to customer and agreed.

The definition of acceptance, rejection zones and guard band assuming a probability of type of error ie PFA(Probability of false acceptance or PFR(Probability of false rejection)



Decision rule

Decision rule: a documented rule that describes how measurement uncertainty will be allocated with regard to accepting or rejecting a product according to its specification and the result of a measurement.

Acceptance zone: the set of values of a characteristic, for a specified measurement process and decision rule, that results in product acceptance when a measurement result is within this zone.

Rejection zone: the set of values of a characteristic, for a specified measurement process and decision rule, that will give noncompliance when a measurement result is within this zone.

Guard band: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary.

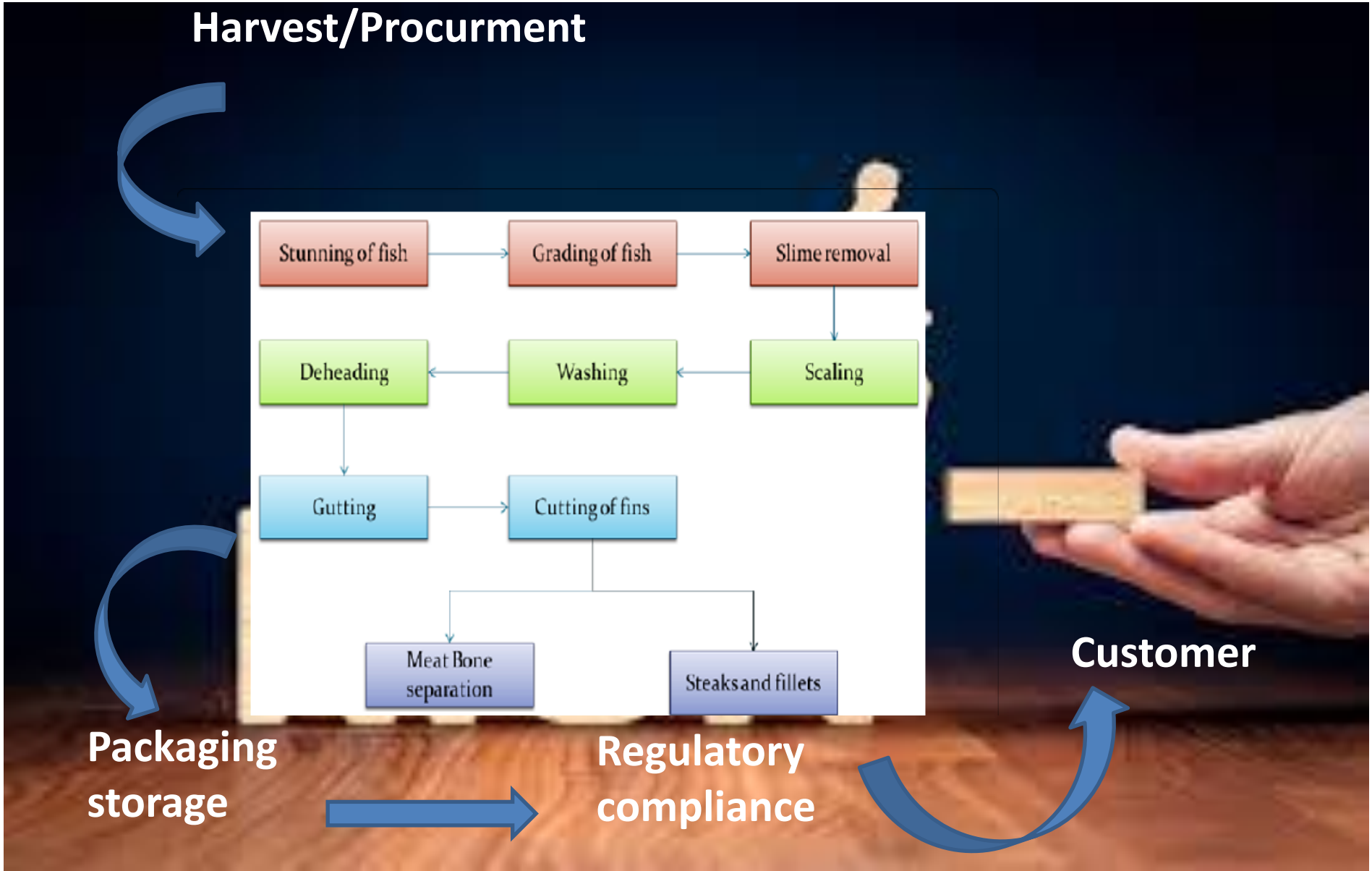
Simplifying Decision Rule

Figure 3a) – Example of areas defined for a tolerance interval in order to minimise the consumer's risk

Legend: TU – Tolerance upper limit ; GU –Acceptance zone upper limit ; TL – Tolerance lower limit ; GL –Acceptance zone lower limit; *U*(*y*) – expanded uncertainty of the measurement.

Figure 3b) – Example of areas for the tolerance interval in order to minimise the supplier's risk

Risk Based thinking



OUR CHALLENGE AND RANGE

HOW TO ENSURE FOOD QUALITY AND SAFETY IN THIS COMPLEXITY


R
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?

QUALITY

- Good quality does not necessarily mean High quality.
- It means "a predictable degree of uniformity and dependability, at low cost, with quality suited to market".

What is Food Safety?

- **Food Safety** is a scientific discipline describing *preparation*, *storage, and handling* of food in ways that prevent food borne illness
- **Food Borne Illness** is an illness carried or transmitted to people by food

Global food safety issues

Food Quality and Safety

- Everyday the World food industry is faced with new problems, food scares, poisoning, product recalls, litigation

These events effect public perception and cause retailers, insurers, shareholders and regulators to react accordingly.

- These reactions have consequences that pass down the food supply chain.

- Events that change our future for ever.

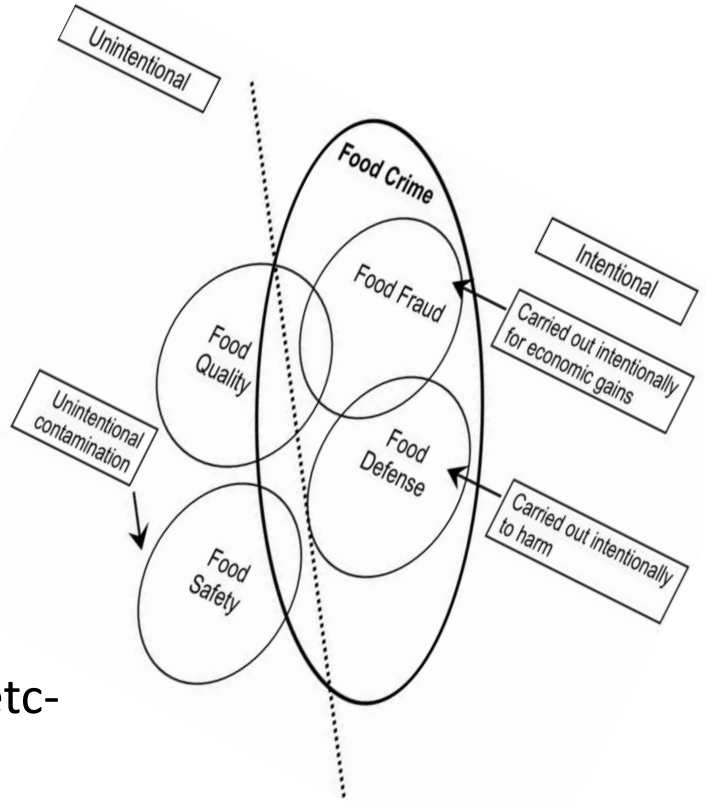
Who is driving Food quality & safety issues?

- Customers (Consumer Preferences)
- Regulatory Bodies (Governments)
- World Health Organization (CODEX)
- Market Access (EC/USFDA)
- Shareholders, Insurers (Litigation/Claims)
- Retailers & Private Labels (Brand Protection)

WHAT CAN GO WRONG

Offences

- Causing food to be injurious
- Abstracting any constituent
- Deliberate adulteration
- Nonconformance in label information etc-



Unintentional	Intentional	Motivation
Food Quality	Food Fraud	Economic gain
Food Safety	Food Defense	Harm

Need

The Food Industry is experiencing many new paradigm shifts. These are about changing rules & regulations relating to:

- Food Safety
- Quality
- Regulatory
- Market Requirements

Objectives of FSSA

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

Risk analysis

Zone 1

Product Contact Surfaces

(fillers, hoppers, screens, conveyer belts, air blowers, employee hands)

Zone 2

Non-Product Contact Surfaces

(framework, refrigeration units, equipment housing)

Zone 3

(air return covers, phones, hand trucks, forklifts, drains)

Zone 4

(locker rooms, cafeteria, hallways, loading dock, maintenance areas)

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

The **severity** of its consequences if it does

The **likelihood** that a hazardwill affect us

Sampling and Sample collection

Ensuring the validity of results

- Use of reference materials or quality control materials
- Use of alternative instrumentation that has been calibrated to provide traceable results
- Use of check or working standards with control charts, where applicable
- Intermediate checks on measuring equipment
- Replicate tests or calibrations using the same or different methods
- Retesting or recalibration of retained items
- Review of reported results
- Intra-laboratory comparisons(Round robin test)
- Proficiency testing

Shelf Life study

The Shelf life

Shelf life and food safety

Factors affecting shelf life

Steps in shelf life determination

Shelf life and regulation

Few Key words

Perishable food is unprocessed or processed food that has a short shelf life at room temperature before showing signs of deterioration or spoilage (often mould or bacterial growth seen as fur or slime), e.g. fruit or pre-packaged bread.

Shelf life is the period of time, established under intended conditions of distribution, storage, retail and use, that the food would remain safe and suitable.

Shelf life testing requires foods to be stored under the expected conditions of storage and distribution for a period of time to determine at what point chemical changes, deterioration and/or spoilage of the food occurs.

Shelf-stable food is food of a type that, because of its composition (low moisture, high salt or sugar content) does not require to be refrigerated for storage or a food which would normally be stored refrigerated but which has been processed so that it can be safely stored in a sealed container at room temperature for a usefully long shelf life.

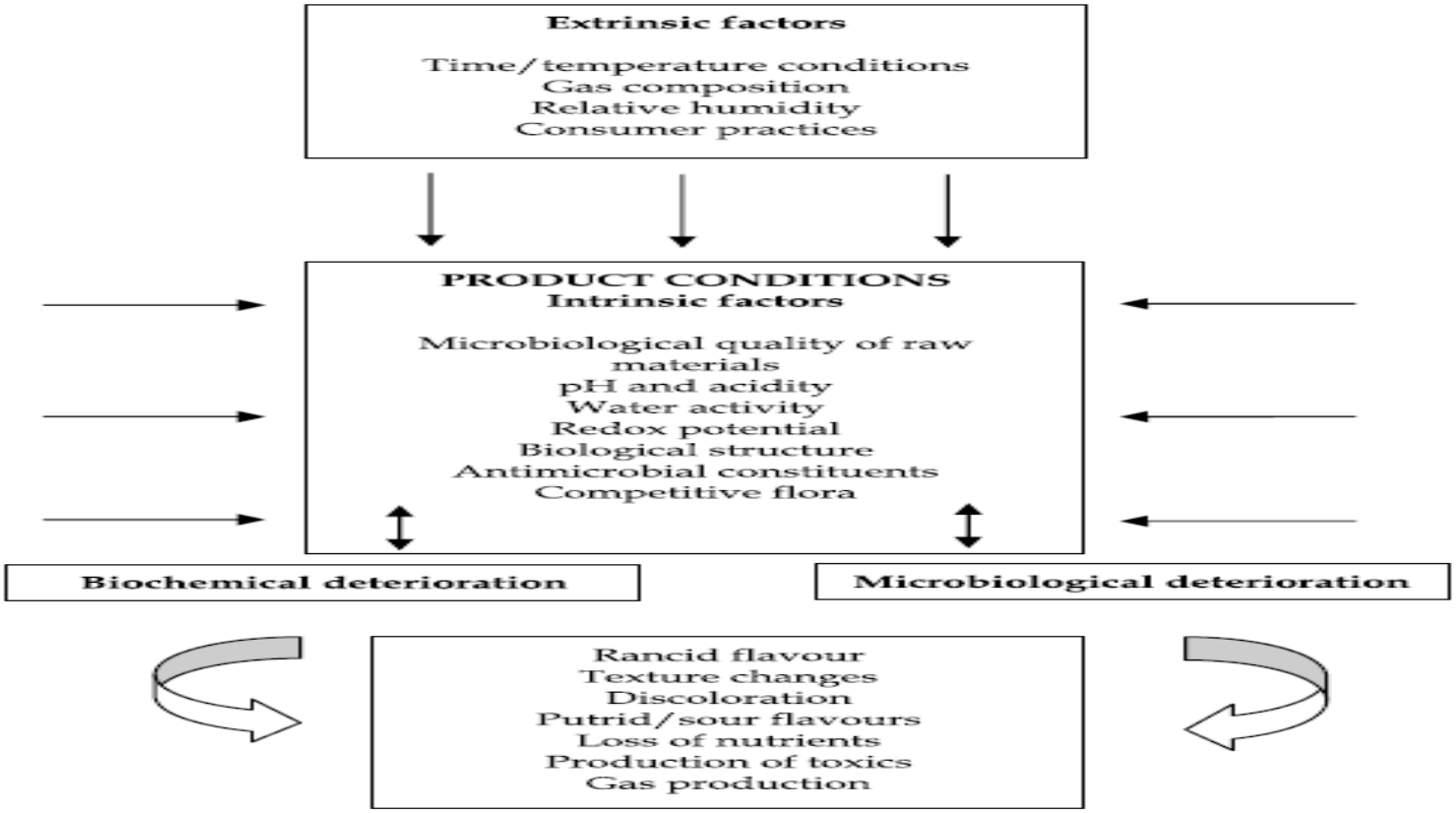
Shelf life

The stated shelf life of a food is the period of time for which it remains safe and suitable for consumption, provided the food has been stored in accordance with any stated storage conditions. This means that the food:

Must remain safe to consume, i.e. should not cause food-poisoning because of the growth of pathogenic bacteria or the production of toxins (bacterial and fungal) in the food during storage;

Has not deteriorated in quality or spoiled in any way that the consumer would find unacceptable; and has not lost significant amounts of any nutrients listed on the label.

Understanding shelf life



Changes that may occur during processing and storage

There are many factors that may affect the shelf life of a product. Some factors relate to the food itself (intrinsic factors), such as moisture and pH, while others are external to the product (extrinsic factors), e g. the packaging conditions, materials and storage conditions.

Setting up the study

subjective sensory testing, e.g. colour and textural changes, smell and taste; or
– objective laboratory tests, e.g. numbers of spoilage bacteria or yeasts appearance of mould growth, presence of a chemical indicator of deterioration, such as D-alanine in fruit juice, rancidity, histamine in seafood, etc.

The study should be repeated with several (at least three) batches of product to identify variability within and between batchers. If there is a large variability within and/or between batches you will need to work out how to reduce the variability.

Factors affecting shelf life

How the product is made;

The composition of the food;

The type of packaging;

The hygiene of the processing environment; and/or

The quality of the ingredients

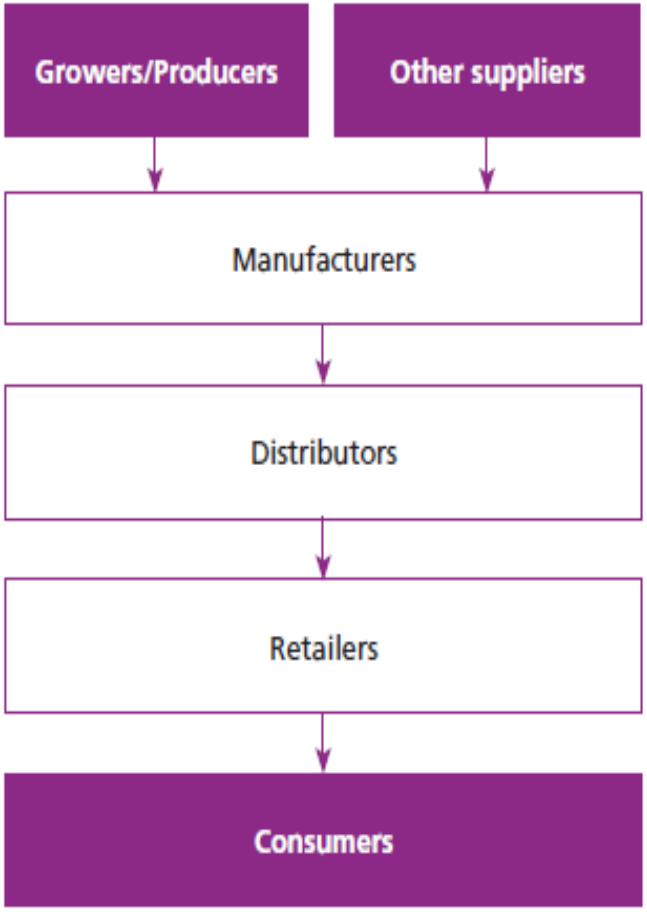
Why Conduct a Shelf Life Study? What Are the Benefits?

- Confidence in having an actual calculated shelf life and not just an estimate
- Prevent recalls
- Maintain quality
- Protect brand/reputation
- Improve profitability
- Avoid expensive litigation
- Consumer safety

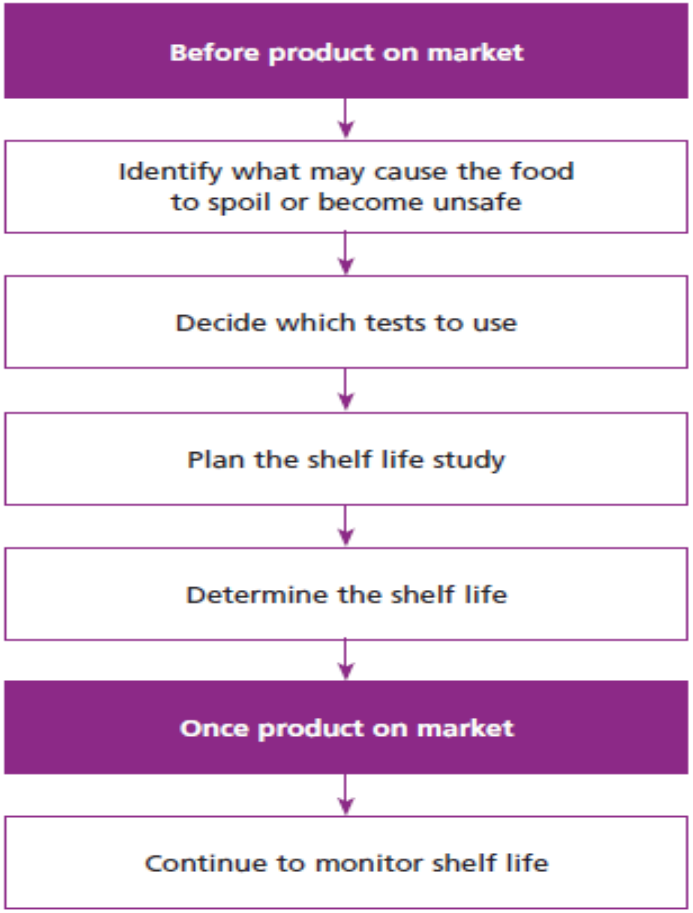
When to Conduct a Shelf Life Study

- New product launch
- Package re-design/New packaging
- Challenge the lifespan
- Collect data for validation
- Change in ingredients
- Change in supplier materials
- As part of your QA/QC Program
  - Is your current package still performing?

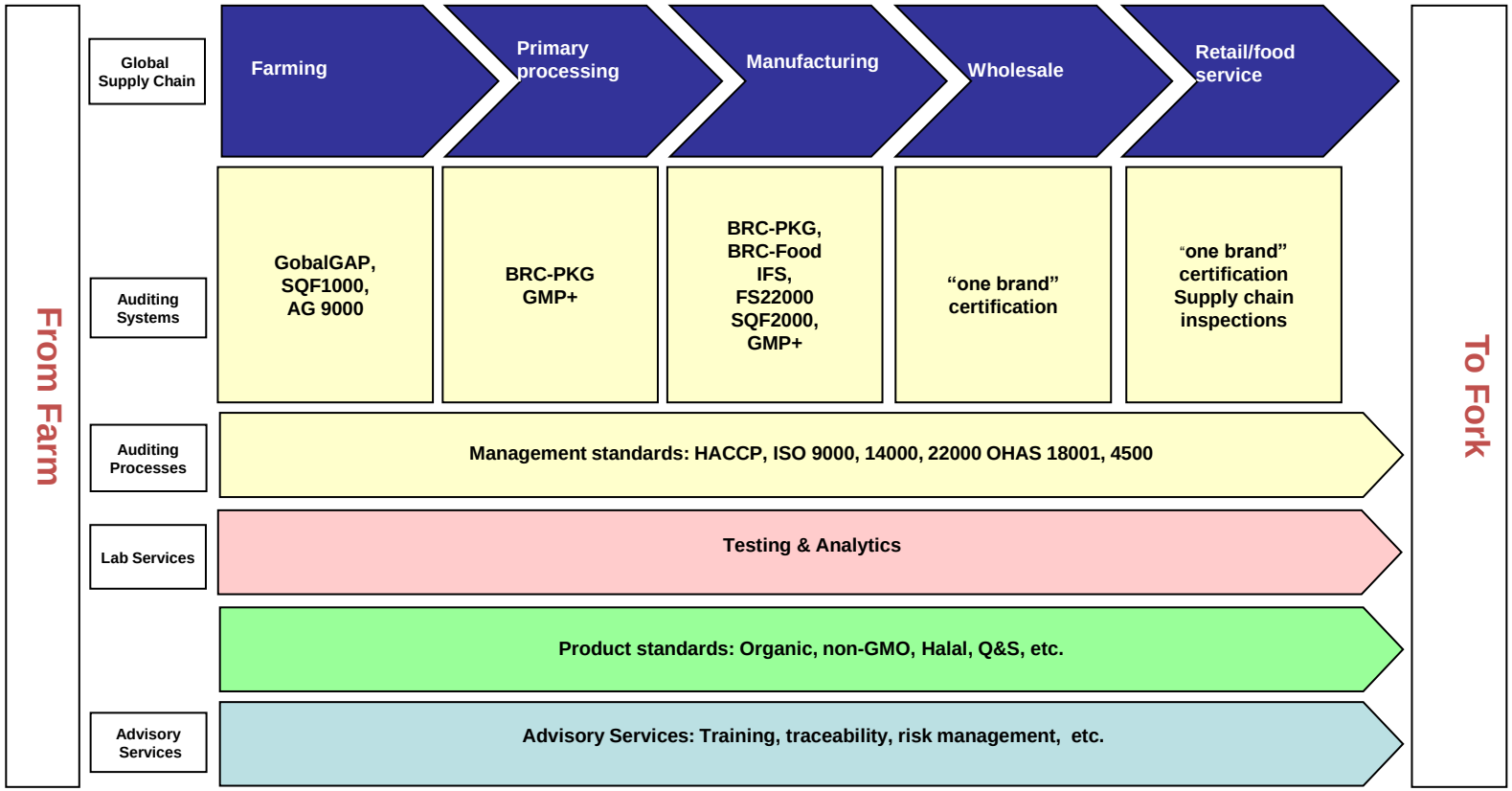
Who is responsible



Stages



farm to fork

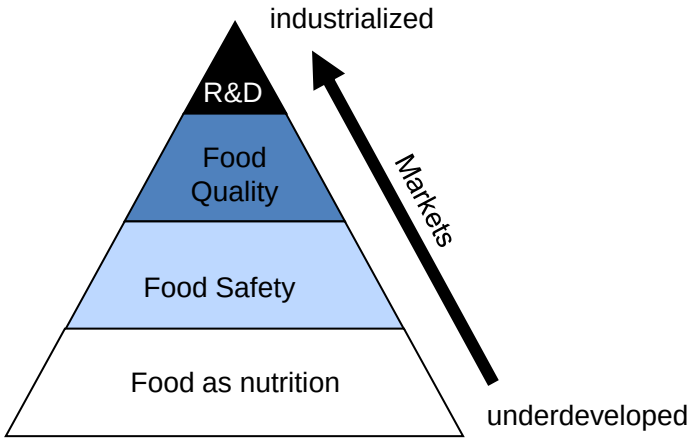

From Farm
Global Supply Chain
Farming
Primary processing
Manufacturing
Wholesale
Retail/food service
Auditing Systems
GobalGAP, SQF1000, AG 9000
BRC-PKG GMP+
BRC-PKG, BRC-Food IFS, FS22000 SQF2000, GMP+
"one brand" certification
"one brand" certification Supply chain inspections
Auditing Processes
Management standards: HACCP, ISO 9000, 14000, 22000 OHAS 18001, 4500
Lab Services
Testing & Analytics
Product standards: Organic, non-GMO, Halal, Q&S, etc.
Advisory Services
Advisory Services: Training, traceability, risk management, etc.
To Fork

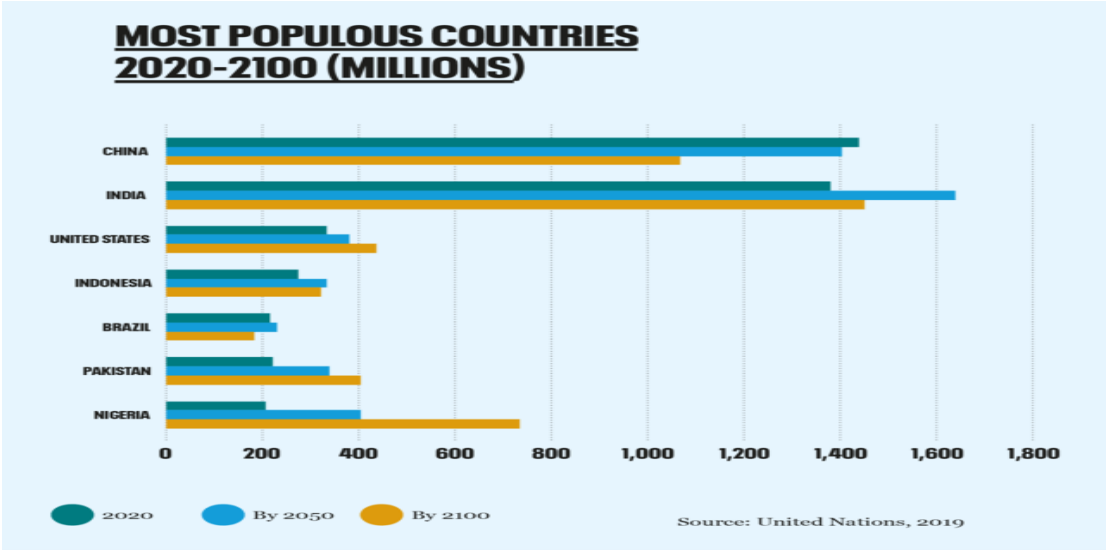
Total Quality Assurance Value Proposition

Systemic Approach to Quality and Safety with ATIC Solutions

Food industry & growth of population

- Growth of food industry in direct relation with global growth of population





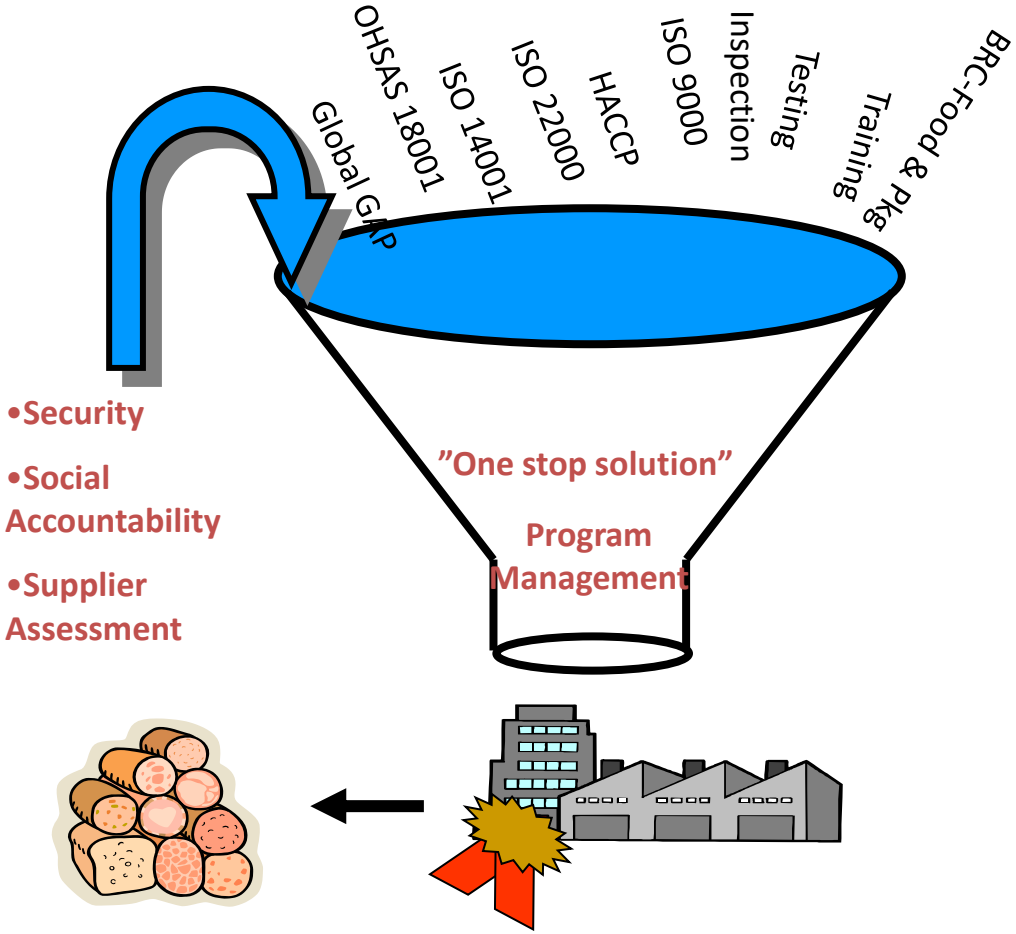
- Fast growing need for food from developing countries and emerging nations

What does the consumer expect?

- ✓Wide choice of food products
- ✓Huge volume of different product and testing marks
- ✓Rising health ‘trend’ through all population
- ✓Information ‘jungle’ overloads consumers
- ✓Consumers in EU, Japan, etc.: do not accept GMO-Food (75 - 80%)
- ✓Consumers do not accept food scandals and crises - want to have safe food
- ✓Asking for neutral monitoring and control mechanism

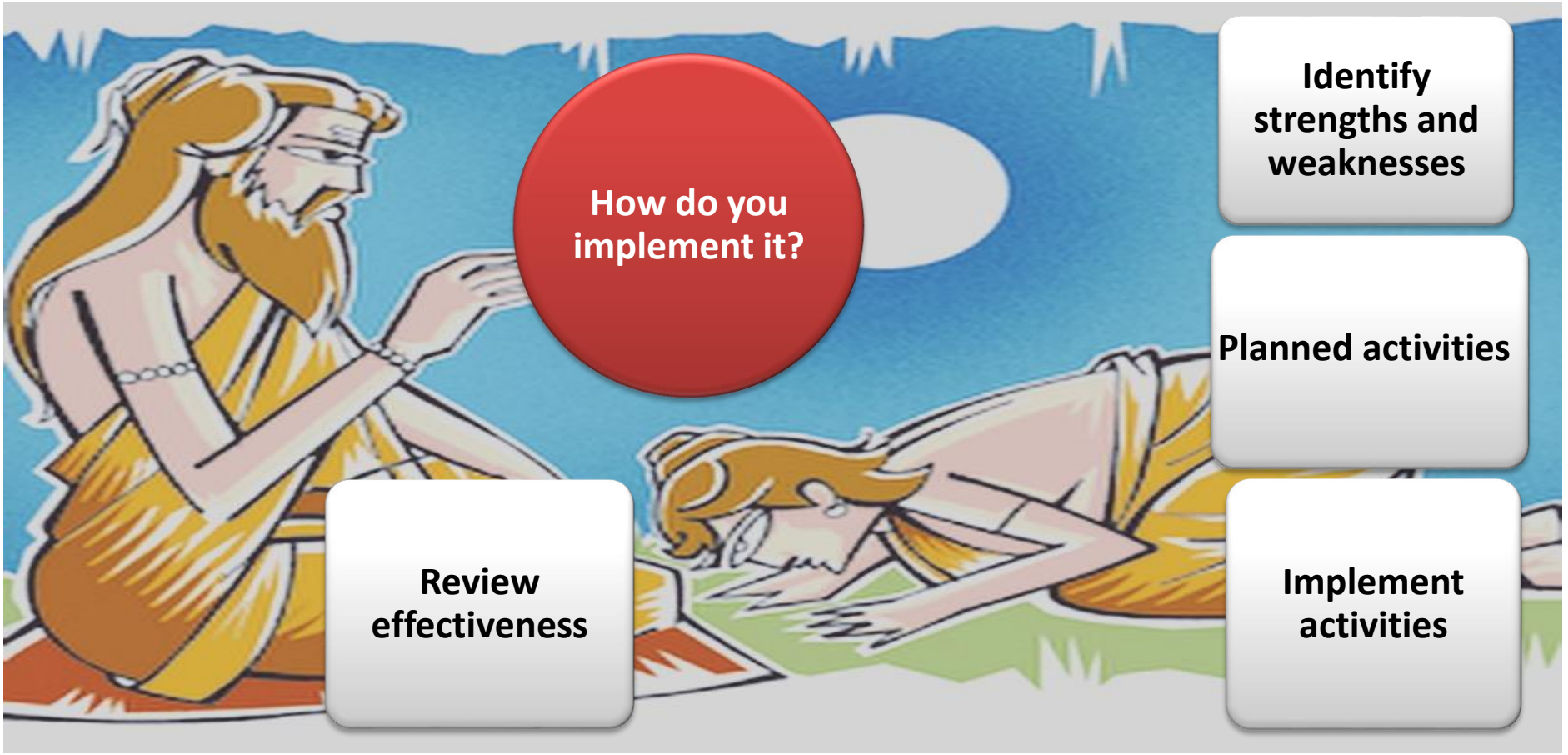
→ Consumer does require more information on food products and the supply chain

What Customers can expect

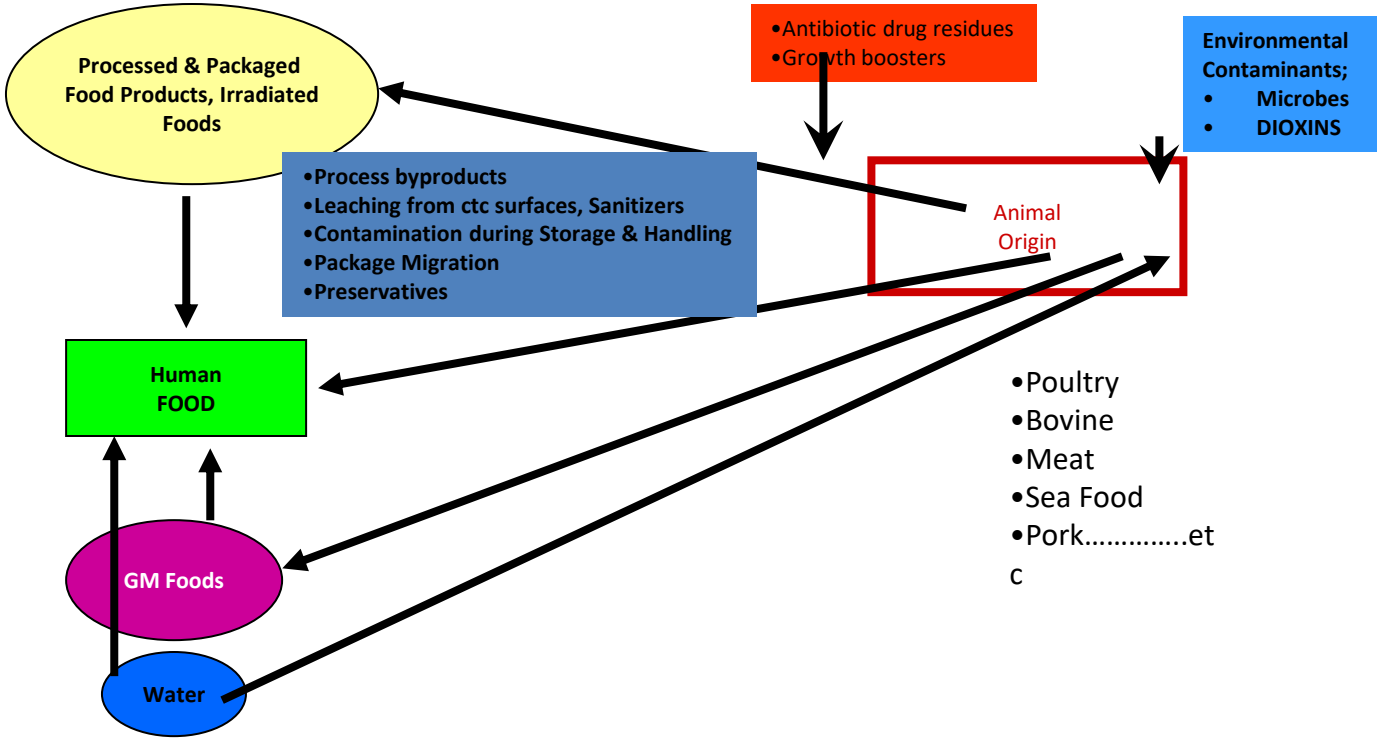


Food safety culture plan

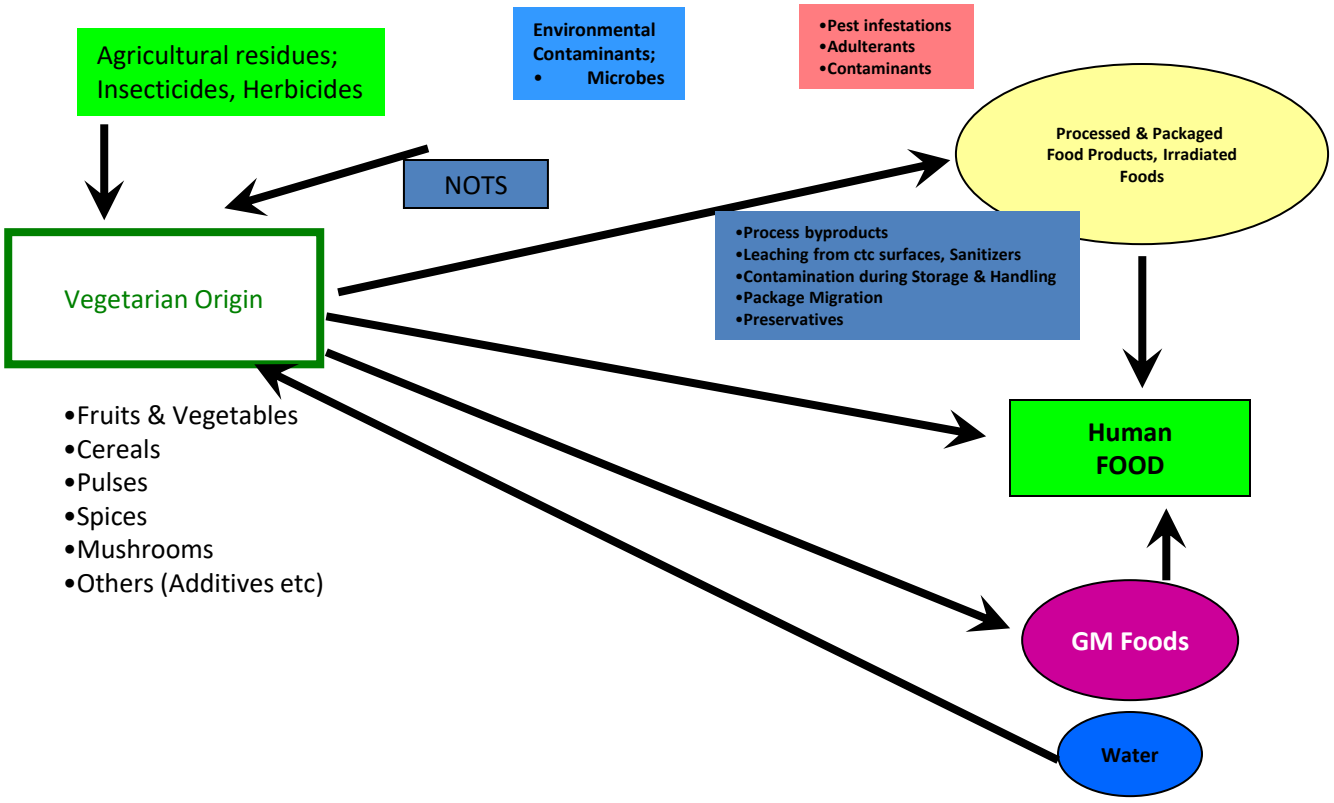
Food Safety Culture Plan



Hazards in Foods of Animal Origin



Hazards in Foods of Plant Origin



FOOD CERTIFICATION – MEANS TO DEMONSTRATE COMPLIANCE

HACCP
BRC
FSSC 22000
IFS
SQF 1000 & SQF 2000
ISO 22000:2005
ORGANIC
Global GAP
SUPPLIER DRIVEN STANDARDS
SA ,EMS,QMS

Food packaging ?

Selection of the sample material

The **determination of migration** is carried out on the **material or article.**

The sample shall be placed in contact with the foodstuff or simulant in a manner representing the **contact conditions in actual use**.

Regulation EU 10/2011.

May analyse foods directly (complex matrix; analysis is challenging).

Simulants represent major food – Phys/Chem properties.

Food Simulants

Food Simulant	Abbreviation	Type of Foods
Ethanol 10%	Food Simulant A	Hydrophillic
Acetic Acid 3%	Food Simulant B	Hydrophillic, with pH< 4.5
Ethanol 20%	Food Simulant C	Hydrophillic, Alcoholic, lipophilic
Ethanol 50%	Food Simulant D1	Lipophilic, > 20% Alcohol, Oil in water
Vegetable Oil	Food Simulant D2	Foods with free fat at surface
Tenax	Food Simulant E	Dry Foods

- For OML combination of simulants is indicated.
- For plastics OML = 10 mg/dm2 or OML = 60 mg/kg food.
- Specific migration limits for many individual components e.g. monomers
- Aromatic amines must be Not Detectable (LOD 0.01 mg/kg)

What has to be tested?

Global Migration (GM):

The overall migration limit is a measure of the inertness of the material and prevents an unacceptable change in the composition of the foodstuffs.

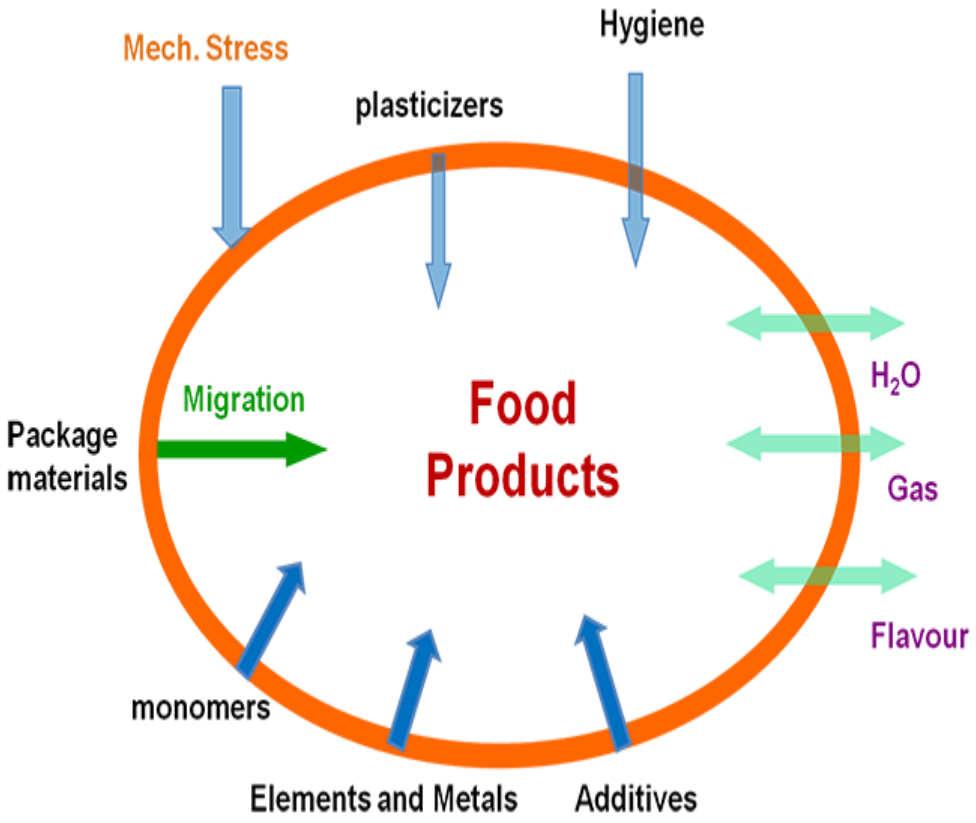
Specific Migration (SML):

Specific migration limit in food or in food simulant for monomers and additives of the plastic directive.

Maximum permitted quantity in the polymer (QM):

Maximum permitted quantity of the ‘residual’ substance in the material or article (e.g. Cadmium)

Packaging is more important than product



Summary

- Packaging is used to **protect** food and keep it **hygienic**.
- It is used to **advertise** the product and give **information**.
- Too much packaging is **wasteful** and bad for the environment.
- We should try to **recycle** packaging when we can.
- Plastic which breaks down when it is buried is called **biodegradable**.
- Packaging can be made of **glass**, **plastic**, **card**, **steel** or **aluminium**.

Advances in testing

“Protect your brands and reputation with better agricultural and food supply chain management, from farm to fork”

Food Testing Classification

1. Nutritional & Proximate analysis
2. Toxic Contaminants
3. Microbiological

Toxic Contaminants Categories

Pesticides Residues / NOTS/ VOC's:

- OC Pesticides
- OP Pesticides
- Synthetic Pyrethroids
- Insecticides/ Fungicides
- NOTS: Saffrole
- THM
- VOC's

Antibiotics & Drugs Residues/ Mycotoxins/ Dyes/ Pesticides:

- Antibiotics & Drugs- Tetracyclines, Sulfonamides, Nitrofurans, Chloramphenicol, Streptomycin,
- Aflatoxin B1, B2, G1, G2, M1
- Ochratoxin, DON, ZEA
- Sudan Dyes, MG, LMG
- Pesticides & Insecticides
- Carbamates
- NOTS: Hypericine, Agaric Acid

Heavy Metals Residues:

- Lead
- Cadmium
- Arsenic
- Mercury
- Chromium
- Copper
- Zinc
- Tin
- Nickel

Advancements in Gas Chromatography

GC
(Gas Chromatograph)

GCMS (Gas Chromatograph with Mass Spectrometer) Ion Trap or Single Quad

GCMS/MS
Triple Quad Mass Spectrometer

GC-TOF (Time of Flight)

GC-HRMS
(High Resolution Mass Spectrometer)

ppm (mg/kg)

ppm (ug/kg) with mass Confirmation

ppb (ug/kg) With MRM

ppt level with high mass resolution, best for unknown Identification

with high Mass Resolution for ppt level Quantification

Advancements in Liquid Chromatography

HPLC (High Performance Liquid Chromatograph) With PDA, RI, Fluorescence detectors

LCMS/MS Triple Quad Mass Spectrometry

UPLC (Ultra Fast Liquid Chromatograph)

UPLCMS/ MS (UPLC with QQQ Mass Spectrometer)

EA/ LC-IRMS (Isotope Ratio Mass Spectrometer)

ppm (mg/kg)

ppb (ug/kg) with SRM

ppm to ppb (ug/kg) With shorter runtime and better resolution

ppt level

Better peak resolution, shorter run time and ppt level of quantification and High throughput

Elemental Analyzer and LC with Isotope Ratio confirmation and Quantification

Heavy Metal Contaminants

Heavy Metal Residues

- Lead
- Cadmium
- Arsenic
- Mercury
- Chromium
- Copper
- Zinc
- Tin

UV/VIS Spectrophotometer

% to ppm (mg/kg)

Atomic Absorption Spectrophotometer (AAS)

ppm (mg/kg)

AAS with Graphite Furnace

ppb (ug/kg)

(Inductively Coupled Plasma Mass Spectrometer (ICP-MS)

ppb to ppt (ng/kg) level of quantification with mass confirmation

Sample Prep for Pesticides Residues

Liquid-liquid extraction:

Traditional methods for sample prep for pestcides residues in food & agricultural products

Solid Phase Extraction (SPE)

QuEChERS:

Quick, Easy, Cheap, Effective, Rugged, and Safe, the QuEChERS ("catchers")

QuEChERS was developed using an extraction method for pesticides in fruits and vegetables, coupled with a cleanup method that removes sugars, lipids, organic acids, sterols, proteins, pigments, and excess water. This technique offers a user-friendly alternative to traditional liquid-liquid and solid phase extractions.

- **European EN 15662 Method**
- **AOAC Official 2007.01 Method**

Sample Prep for Antibiotics/ Drugs Residues

Liquid-liquid Extraction/ Liquid-solid Extraction:

Traditional methods for sample prep for Antibiotics & Drugs residues in food & agricultural products

Solid Phase Extraction (SPE):

"Retention-Cleanup-Elution Strategy"

As the sample is loaded onto the cartridge, the analytes of interest

are retained by the sorbent.

If needed, an optimized series of washes are used to remove matrix interference from the cartridge.

A strong solvent is used to elute the analytes from the cartridge.

Sample enrichment results when the final elution volume is smaller than the load volume.

Food Testing Equipment Manufacturers

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Sampling of food and water

SAMPLING: Definitions

- '**lot**' means an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.
- **'sublot'** means a designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separate and identifiable;
- **'incremental sample'** means a quantity of material taken from a single place in the lot or sublot
- **'aggregate sample'** means the combined total of all the incremental samples taken from the lot or sublot
- **'laboratory sample'** means a sample intended for the laboratory

SAMPLING: GENERAL PRINCIPLES

- ✓ **Each lot/sub-lot must be sampled separately**
- ✓**When there are two or more consignments in one "ship" or container, each consignment must be sampled separately even if the product is identical (i.e groundnuts both).**

- **Lots are sampled according the size**
- **Number of primary samples depends on the size of the lot**
- **Each primary sample should be taken from a randomly chosen position in the lot**
- **Primary samples should be combined and mixed well to form the aggregate sample**

Conti....

- Minimum size of the laboratory sample depends on the contaminant and on the product
- Sampling must be recorded properly
- Samples should be sealed and labelled
- Should be sent to the laboratory as soon as possible

General Provisions

- **Sampling shall be performed by an authorized person.**
- **Each lot which is to be examined shall be sampled separately**
- **Large lots shall be subdivided into sub-lots to be sampled separately**
- **The sampling apparatus must be made of materials which cannot contaminate the products to be sampled.**
- **Sampler should follow safety.**

Notified Labs

FSSAI Notified NABL Accredited Food Testing Laboratories vide notifications number (E) dated 13th February, 2020 and File No. 12012/01/2019-QA dated 23rd July, 2020 for the purpose of carrying out Analysis of Samples taken under Section 47 of the Food Safety and Standards Act, 2006.

Total labs -188

National Referral Labs

FSSAI Notified Referral Laboratories under section 43 (2) of FSS Act, 2006

S. No.	Name of Laboratories
1.	**Central Food Laboratory**, 3 Kyd Street, Kolkata - 700016
2.	**Food Safety & Analytical Quality Control Laboratory**, C/o Central Food Technological Research Institute, Mysore-570013
3.	**State Public Health Laboratory**, Stavely Road, Cantonment Water Works Compound, Pune-411001
4.	**National Food Laboratory**, Ahinsa Khand-II, Indirapuram Ghaziabad-201014
5.	**Indian Institute of Horticultural Research**, Hessaraghatta lake post, Bangalore-560089
6.	**Quality Evaluation Laboratory**, Spices Board, Palarivattom P.O. Kochi-682025
7.	**Quality Evaluation Laboratory**, Spices Board, Chuttugunta Center, GT Road, Guntur-522004
8.	**Quality Evaluation Laboratory**, Spices Board, Plot No. R-11, Sipcot Industrial Complex, Gummidipoondi, Thiruvallur Dt., Chennai-601201
9.	**Quality Evaluation Laboratory**, Spices Board, First Floor, Banking complex II, Sector 19A, Vashi, Navi Mumbai-400703
10.	**Centre for Analysis and Learning in Livestock in Food (CALF), National Dairy Development Board** (NDDB), Anand-388001, Gujarat
11.	**CSIR-Indian Institute of Chemical Technology**, Uppal Road, Tarnaka, Hyderabad - 500007
12.	**National Research Centre on Meat**, Chengicherla, Boduppal, Hyderabad – 500092
13.	**Indian Institute of Food Processing Technology**, Food Safety and Quality Testing Laboratory, Pudukkottai Road, Thanjavur – 613005, Tamil Nadu
14.	**ICAR- Central Institute of Fisheries Technology**, Indian Council of Agricultural Research, Willingdon Island, CIFT Junction, Matsyapuri P.O., Cochin – 682029, Kerala
15.	**ICAR-National Research Centre for Grapes**, P.O. Manjiri Farm, Solapur Road, Pune - 412307
16.	**Pesticide Formulation and Residue Analytical Centre, National Institute of Plant Health Management**, Rajendranagar, Hyderabad - 500030
17.	**Punjab Biotechnology Incubator**, Mohali SCO7 & 8, Phase-5, SAS Nagar, Mohali - 160059, Punjab
18.	**CSIR-Indian Institute of Toxicology Research**, Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow - 226 001, Uttar Pradesh, India

National Reference laboratory

S. No.	Name of the Laboratory/ Institution/Organization	Address	Specific area for which declared as NRL
1.	Central Food Technological Research Institute	FS & AQCL Department, CFTRI, Mysore - 570020	Nutritional information and labelling
2.	Export Inspection Agency	27/1767 A, Shipyard Quarters Road, Panampilly Nagar (South), Kochi, Kerala 682036	GMO testing*
3.	Punjab Biotechnology Incubator	SCO 7-8, Phase-V, SAS Nagar, Mohali – 160059, Punjab	Sweets & Confectionary including Honey
4.	ICAR-National Research Centre For Grapes	P.O. Manjiri Farm, Solapur Road, Pune – 412307	Pesticides Residues and Mycotoxins
5.	Central Institute of Fisheries Technology	CIFT Junction, Willingdon Island Matsyapuri P.O., Kochi - 682029	Fish & Fish Products
6.	Centre for Analysis and Learning in Livestock and Food - National Dairy Development Board	Opposite IRMA Main Gate, Near Anandalaya School, Anand - 388001	Dairy & Dairy Products
7.	CSIR-Indian Institute of Toxicology Research	Vishvigyan Bhawan, 31, Mahatama Gandhi Marg, Lucknow – 226001, Uttar Pradesh	Toxicological evaluation/risk assessment of nutraceuticals, functional foods and novel/emerging foods/ food ingredients
8.	Trilogy Analytical Laboratory Pvt. Ltd.	Plot No. 7, C.F. Area, Phase-II, IDA Cherlapally, Hyderabad - 500051	Mycotoxins in cereals & pulses, spices & condiments and related PT activities
9.	Edward Food Research & Analysis Centre Limited	Subhas Nagar, Barasat P.O., Nilgunj Bazar, Kolkata - 700121	Veterinary drug residues, antibiotics & hormones
10.	Vimta Labs Limited	Life Sciences Campus, 5, MN Park, Genome Valley, Shameerpet, Hyderabad - 500101	Water, Alcoholic and Non-Alcoholic Beverages
11.	Fare Labs Pvt. Ltd.	L-17/3, DLF, Ph – II, IFFCO Chowk, M.G. Road, Gurugram – 122002	Oils and Fats
12.	Neogen Food & Animal Security (India) Private Limited	Uchikkal Lane, Poonithura P.O., Kochi - 682038	Food Allergens

*(*subject to implementation of GMO regulations)*

S. No.	Name of the Laboratory/ Institution/Organization	Address	Specific area for which declared as ANRL
Government Laboratories as NRL			
13.	Export Inspection Agency EIA, Chennai	6th Floor, CMIDA Tower-II, 1, Gandhi Irwin Road, Egmore, Chennai - 600008	Support facility as PTP in microbiological testing
14.	Export Inspection Agency EIA, Kolkatas	101, Southend Conclave, 1582, Rajdanga Main Road, Kolkata - 700107	Support facility as PTP in the area of heavy metals in all food categories

InDepth

Innovations and solutions

thank you!

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manojindepth@gmail.com

9650601103,9886074626

Processing and Value Addition of Mushroom

Dr. Dayaram

Project Director

ADVANCE CENTRE OF MUSHROOM RESEARCH

DR. RAJENDRA PRADAD CENTRAL AGRICULTURAL UNIVERSITY

CHALLENGES

- **Unemployment**
- **Land division (shrinking cultivated land)**
- **Climatic change**
- **Crop residue burning**
- **Migration**
- **Removal of rural poverty**
- **Malnutrition**
- **Water shortage**

OPPUTURNITIES

- Temperature ranges (10-38 0C)
- Huge amount of crop residue
- Higher density of population

CHALLENGE DELIBERATION

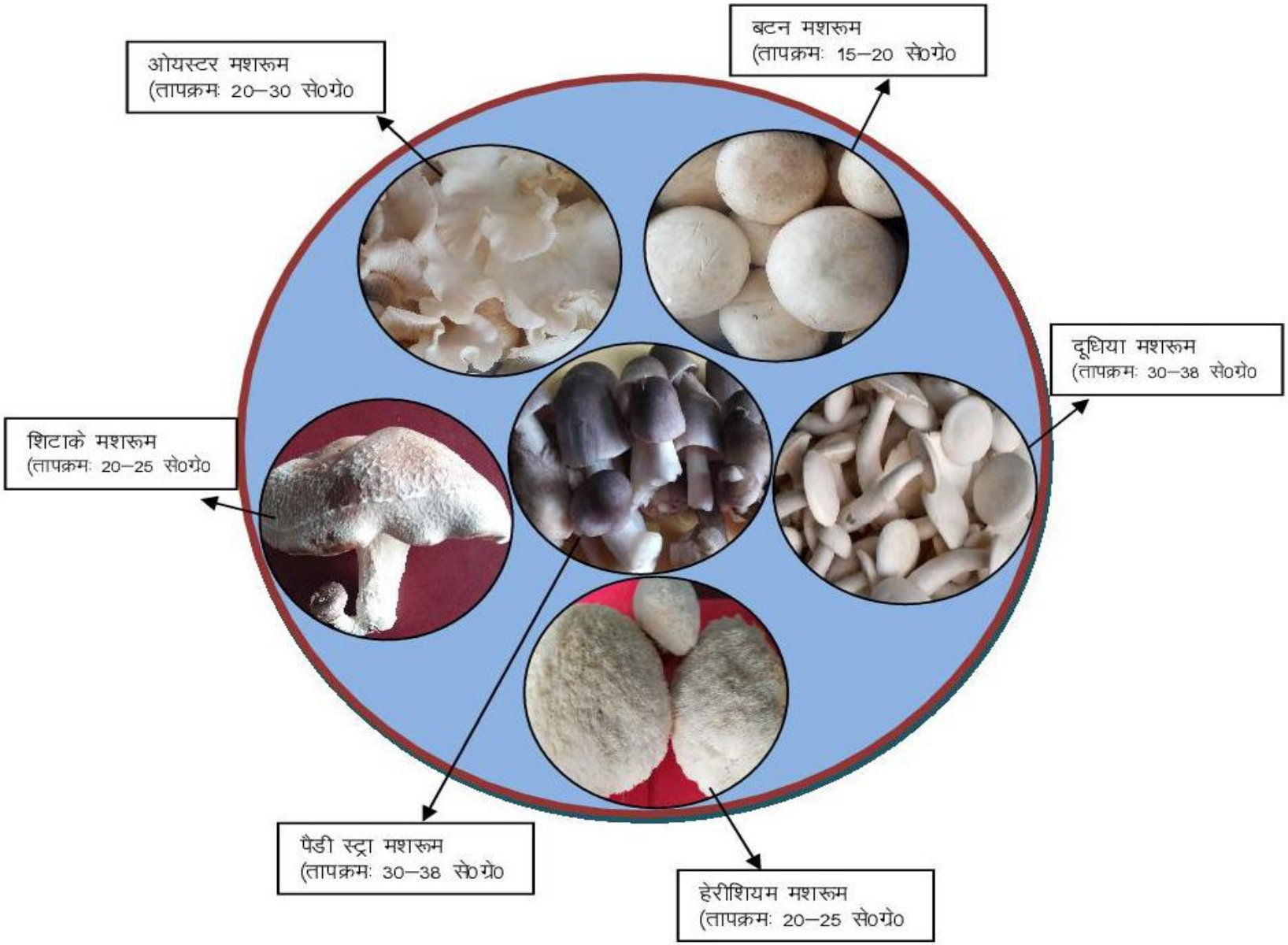
- Kheti Bina Khet Ke/ Vertical farming
- Short duration crop
- Crops under different temperature regime

Temperature:

Minimum 10 oC

Maximum 38 oC

CULTIVATED VARIETY



ENTREPRENEURSHIP POTENTIALITY OF MUSHROOM

[redacted]

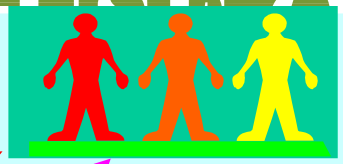
[redacted]

[redacted]

Product Development

[redacted]

EFFICIENT USE OF AGRO

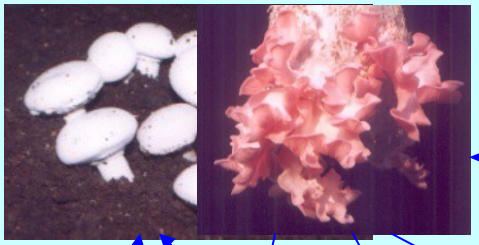


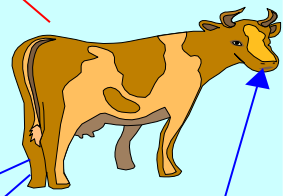
Grains

Milk

come Generation

Kitchen Garding





Myco straw

Trad. Compost

Dung

rmicompost

Qualitycompost

POST HARVEST MANAGEMENT TECHNOLOGY

HARVESTING OF CROPS

Oyster Mushroom

Button Mushroom

Contd….

Milky Mushroom

Paddy Straw Mushroom

Contd….

Hericium Mushroom

Shiitake Mushroom

Contd….

Clining and Grading : Standard size mushroom should be separated

Packaging : Poly Packaging

Marketing and

Transportation : Ice packing for long distance and marketing

READY TO COOK

- **Dehydration:** Oyster and milky mushroom at 65°C.

Button mushroom can be dehydrated by cryogenic dehydration.

- **Powder**
- **Laddo**
- **Pakauda**
- **Cutlet**
- **Chaup**
- **Kheer**
- **Gujhiya etc**

Contd….

Mushroom Pakauda

Mushroom Cutlet

Contd….

Mushroom Litti

Mushroom Gujhiya

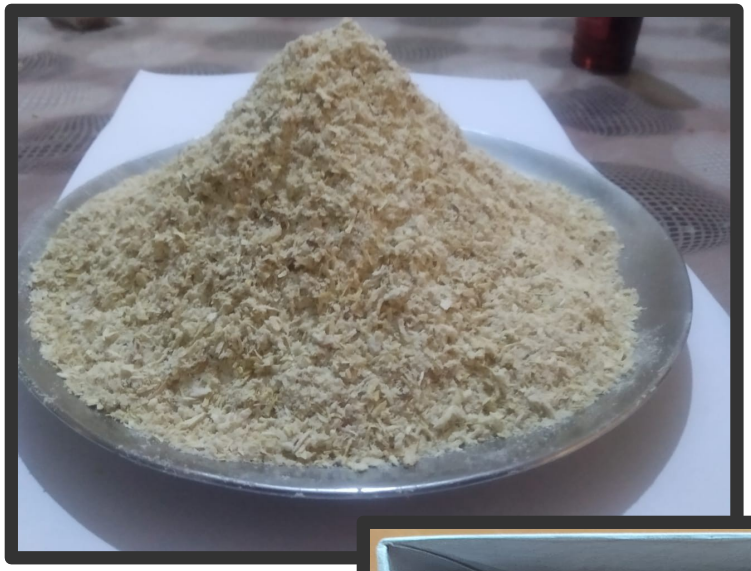
Contd….

Mushroom Chaup

Mushroom Halwa

READY TO EAT

Mushroom Powder



Mushroom Laddu

Contd….

Mushroom Bhujia

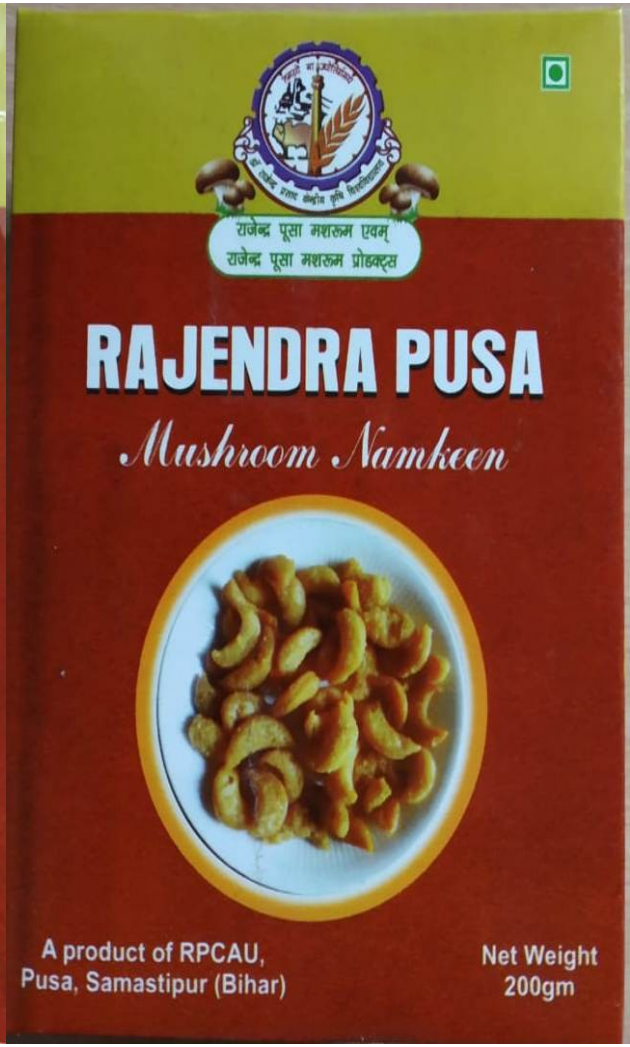
Mushroom Samosa

Contd….

Mushroom Namkeen

Mushroom Saus

BRANDING OF VALUE ADDED PRODUCTS




राजेन्द्र पूसा मशरूम एवम्
राजेन्द्र पूसा मशरूम प्रोडक्ट्स
RAJENDRA PUSA
Mushroom
Bhujia
A product of RPCAU,
Pusa, Samastipur (Bihar)
Net Weight : 200gm


राजेन्द्र पूसा मशरूम एवम्
राजेन्द्र पूसा मशरूम प्रोडक्ट्स
RAJENDRA PUSA
Mushroom
Pickle
A product of RPCAU,
Pusa, Samastipur (Bihar)
Net Weight : 200gm

Thanks