

File No. F.No. RCD-020001/1/2021-Regulatory-FSSAI
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 26th October, 2021

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding managing and reporting of Food Borne Illness Outbreak

The Section 16(3)(b)(v) & (vi) of the FSS Act 2006 specifically mandates the Food Authority to search, collect, collate, analyse and summarise relevant scientific and technical data particularly relating to identification of emerging risks; and to introduce of rapid alert system. Accordingly, FSSAI has developed "Framework of Food Safety Emergency Response (FSER) System" and "Guidelines for investigating and managing food borne illness outbreaks in India" (**enclosed**). The same have been approved by Food Authority in its 30th Meeting.

2. In this context, all Food Safety Commissioners of States/UTs are hereby directed to ensure the implementation/compliance of the Guidelines for investigating and managing food borne illness outbreaks in India in accordance with the document on the Framework of Food Safety Emergency Response (FSER) System.

3. Further, the Food Safety Commissioners are required to present the incidences and status of food borne illness outbreak in their states/UTs in the last quarter and action taken thereon in the meeting of the Central Advisory Committee under a standing agenda namely "the status of responses to Foodborne illness outbreak".

4. This issues with the approval of Competent Authority in the exercise of the power vested with Food Safety and Standards Authority of India under section 16(5) of Food Safety and Standards Act,2006.


(Inoshi Sharma)

Executive Director (Compliance Strategy)

To

1. Commissioner of Food Safety of all States/UTs.
2. All Regional Directors, FSSAI
3. All Central Licensing Authorities, FSSAI
4. CITO, FSSAI : For uploading this direction on FSSAI website.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI

Framework of Food Safety Emergency Response (FSER) System

I. Structural Components

1. Introduction

Food Safety Emergency Response (FSER) Plans are a framework developed which aims at managing a potential or confirmed risk to public health arising from food through a timely and coordinated response so as to minimize any adverse impact on health and disruption to trade. Such planning also enables food safety authorities to focus on prevention and preparedness, rather than only on reaction to individual events, and therefore has greater long-term sustainability.

This document is intended as a framework for the concerned agencies involved in facilitating response plans to emergency situations in relation to food safety. As such also include incidents of emergency occurred either intentional or accidental contamination, whether caused by chemical, biological or physical hazards, which are unable to controlled in the normal food control system. This may cause risks or impacts upon health, trade, societies, and economy at both national and international levels that require an urgent and integrated action among relevant agencies. The criteria for determining food safety emergency situations envelop food hazards, size and severity degree of the incident.

2. Objectives:

To establish a framework for:

- i. prevention of food safety related incidents
- ii. managing/responding to any food safety emergency situations which may endanger food safety and public health, both at national and international levels

3. Definitions:

- (a) **Food Safety Incidents:** Any situation within the food supply chain where there is a risk, potential risk or perceived risk of illness or confirmed illness associated with the consumption of a food or foods.”
- (b) **Food Safety Emergencies:** A food safety emergency is a situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.
- (c) **Food Safety Emergency Response:** A process of assessing the risk, making risk management decisions, and communicating risks in the face of time constraints, and possible incomplete data and knowledge.
- (d) **Foodborne outbreak:** The observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.

4. Scope: This plan addresses policies and procedures that will minimize the impact of a food safety emergency situation related to the state’s food supply. In addition, the plan addresses recovery following an incident. The plan stresses local, state and central

interagency cooperation, as well as cooperation with industry. This cooperation will be essential when responding and recovering rapidly to any attack or threat to the state's food supply.

5. Key Partners of Indian Food Safety Emergency Response (FSER) Plan

As the food safety hazards may originate from multiple sectors (plant, animal, feed, processing, etc.) and impact human health, therefore, the key to a successful response is to involve all relevant stakeholders from food sectors and health sectors. This helps to ensure cooperation and collaboration by all interested parties and facilitates the sharing of information among responsible agencies. The key partners sectors to involve or consult may include Ministry of Commerce, Ministry of Agriculture, Ministry of Health and Family Welfare, Ministry of Environment, Forest and Climate Change, Ministry of Woman and Child Development, State food commissioners, Custom officers, Department of Animal Husbandry & Dairying (DADF)- state officers, Marine Products Export Development Authority (MPEDA), National Centre for Disease Control (NCDC), Agricultural and Processed Food Products Export Development Authority (APEDA), Spices Board, The Federation of Indian Chambers of Commerce and Industry (FICCI)/Confederation of Indian Industry (CII), Export Inspection Council of India (EIC), Indian Council of Agricultural Research (ICAR), National Dairy Development Board (NDDB), TEA Board of India and Indian Council of Medical Research (ICMR), consumer associations and the relevant agencies.

As regard to managing/controlling foodborne outbreaks/incidences, there is a need to establish a link between health and food sectors to exchange information during such situations. Since Integrated Diseases Surveillance Program (IDSP) under NCDC tasked to detect early warning signals of impending outbreaks and help initiate an effective response in a timely manner through district/state surveillance officers and rapid response team (RRT), the coordination of Food Safety Officers (FSOs) with Rapid Response Teams is essential to effectively respond to situations arising out of foodborne disease outbreaks/incidences.

5.1 Structural Components and their roles and responsibilities

5.1.1 National Emergency Contact Point (NECP): It is a contact point from the national authority responsible for coordination of national food safety emergency response. FSSAI will function as National Emergency Contact Point (NECP).

Key Roles and Responsibilities

- Liaisoning with Food safety risk assessment Committee (FSRAC), Food Safety Coordination Committee (FSCC) and relevant stakeholders/focal points including state food authorities
- Providing secretarial support and convening meeting of FSCC and FSRAC, as and when required
- Taking decision as may be necessary, after the approval of CEO, when it is not feasible to call meeting of FSCC and the reasons be recorded in writing

- Responsible for risk communication to related agencies both at domestic and international level, the public and media as appropriate during emergency situations
- Collecting data/information from both domestic as well international agencies as appropriate
- Maintaining the records/database on food safety emergencies and actions taken thereon
- Responding to food safety incidents and trigger on appropriate response
- Maintaining the list of nodal points/national focal points and food analysis laboratories and updating it regularly
- Identifying and promoting need for capacity building and awareness
- Ensure coordination of state food authority with NCDC and other health authorities to investigate and respond to food borne illness
- Also act as INFOSAN Emergency Contact Point of India and therefore shall be responsible for reporting urgent food safety incidents of potential international significance to the INFOSAN Secretariat; requesting international assistance through the INFOSAN Secretariat to respond to a food safety event or emergency, as necessary; and taking action on INFOSAN Alerts and disseminates information accordingly
- Any other additional functions as outlined for National Focal Points (NFP) within its organisation

5.1.2 National Focal Points (NFPs): These are other national authorities who have stake in food safety. The following authorities/organization will nominate national focal points:

- i. Ministry of Commerce and Industry (MoC), Ministry of Agriculture and Farmers Welfare (MoA), Ministry of Health and Family Welfare (MoH&FW), Ministry of Woman and Child Development (MWCD); and Ministry of Environment, Forest and Climate Change.
- ii. State food Authorities,
- iii. Custom Department, Central Board of Indirect Taxes and Customs (CBIC),
- iv. Department of Animal Husbandry & Dairying (DADF)- state officers and,
- v. Marine Products Export Development Authority (MPEDA), National Centre for Disease Control (NCDC), Agricultural and Processed Food Products Export Development Authority (APEDA), Spices Board, The Federation of Indian Chambers of Commerce and Industry (FICCI)/Confederation of Indian Industry (CII), Export Inspection Council of India (EIC), Indian Council of Agricultural Research (ICAR), National Dairy Development Board (NDDB), TEA Board of India, Indian Council of Medical Research (ICMR) and Consumer organisations.

Key Roles and Responsibilities

- Nominate Nodal officer and share this information with NECP and other focal points
- Collaborate with and provides technical support to the NECP on food safety incidents/emergencies involving their respective agency

- Support local government efforts through resource and technical assistance during emergencies
- Engage in surveillance of food products in accordance with purview of their organisation
- Engage in sharing information with NECP including surveillance data and other members on food safety issues that may be relevant at the national and/or international level and beneficial to all members, such as, but not limited to: risk assessments on emerging hazards, lessons learnt, identified good practices, etc.
- Disseminate INFOSAN Information Notes, FAO/WHO guidelines, and other important food safety information received from INFOSAN within their agency, as appropriate

The specific responsibilities of State food authority and state health sectors are provided in box 1 below:

Box 1: Specific responsibilities of State food authority and state health sectors

1. Food Safety Commissioners (FSCs): As per the Food Safety & Standards Act, 2006, the state food safety machinery is headed by the Commissioners of food safety, for efficient implementation of food safety and standards and other requirements laid down under this act and the rules and the regulations made there under.

1.1 Responsibilities of FSCs (in addition to already defined responsibilities in FSS Act 2006)

1. Overall governance of food safety incidents/emergencies in the state
2. Ensure proper surveillance of food products and provide surveillance report to NECP (FSSAI)
3. Ensure appropriate and proper investigations during food safety emergencies and take appropriate action/measures to mitigate it
4. Facilitate coordination with other relevant agencies/organisation or authorities during emergencies if required.
5. Carry out post incident review as mentioned in para “E” under Section II-Operational Procedures and present it in Central Advisory Committee (CAC) meeting.

2. Designated Officer: As per the Food Safety & Standards Act, 2006, the Commissioner of Food Safety shall, by order, appoint the Designated Officer, who shall not be below the rank of a Sub-Divisional Officer, to be in-charge of food safety administration in such area as may be specified by regulations. There is one DO for each district.

Box1: Cont...

2.1 Responsibilities of DO

1. Act as **nodal officer** in case of food safety emergency including food borne illness outbreak and coordinate with health authorities, if required.
2. Immediately intimate FSSAI about food safety incidents as and when received.
3. Coordinating with IDSP/NCDC during foodborne illness outbreak.
4. Nominate FSO to be the part of RRT during food safety incidents
5. Transmitting the relevant data/information with respect to the food safety incidents to the NECP, FSSAI
6. Taking immediate actions on the directions given by NECP.
7. Keep track of investigations during food safety emergencies and take appropriate action/measures to mitigate it in consultation with FSC
8. Submit interim report within 48hrs of the incident and final report on completion of the incident to FSC and FSSAI

3. Food Safety Officers (FSOs)- Food safety officers are appointed by the commissioner of food safety for such local area as he may assign to them for the purpose of performing functions under FSS Act and the rules and regulations made thereunder.

3.1 Responsibilities of FSOs

1. Act as a member of Rapid Response Team (RRT)
2. Inspect and investigate facilities associated with suspected or confirmed food borne illness.
3. Trace forward and back products with suspected ingredients.
4. Take field actions to mitigate incident under consultation with DOs and FSCs.
5. Coordinate with local health authorities and other agencies.
6. Regular follow up of the situation during emergency.
7. Preparation of the report on the food safety emergency
8. To follow guidelines investigating and responding to food borne illness outbreak in India as prescribed by FSSAI

4. Responsibilities of State/local health authorities

1. Collection of food consumption history of patients with food borne disease and epidemiological data of food borne diseases.
2. Dissemination of information/data like clinical reports or suspected pathogens and suspected implicated foods etc. to the FSOs related to the Food borne illness outbreak
3. Coordinate with state food authority and NECP, FSSAI during emergency.

5.1.3 Food safety risk assessment Committee (FSRAC): FSRAC is a risk assessment body and shall be responsible for providing technical and scientific support both in normal or emergency situations. The committee shall provide preliminary information of risk assessment to identify emergency situations and their levels of severity in order to support decision making by the Food Safety Coordination Committee (FSCC) and FSSAI.

Key Roles and Responsibilities

- Establish a system for risk assessment and collecting data in the case of emergency
- Analyse the gathered data/information in order to perform assessment of risk, its magnitude and range of the hazards as well as emergency events
- Provide advice to Food Safety Coordination Committee (FSCC) and FSSAI based on the risk assessment of hazards identified during food safety incidents
- Carry post incident review and evaluation and give suggestions/advices to further improve FSER systems based on gaps identified, if any, to the FSSAI and FSCC

Members for FSRAC

The FSRAC will comprise of following members:

1. Dr. D Kanungo, Human Health Risk Assessment Expert and Former Additional DG of Health Services, Govt of India
2. Dr. V Sudarshan Rao, Scientist E, National Institute of Nutrition, Hyderabad, India
3. Dr. Kaushik Banerjee, National Research Centre for Grapes, Pune, India
4. Members/experts from NetSCoFAN on relevant subject matter
5. Representative from EIC
6. Representative from National Institute Epidemiology, India
7. Head of Food Safety Emergency Cell, FSSAI- Member Secretary/Convenor

5.1.4 Food Safety Coordination Committee (FSCC): Food Safety Coordination Committee (FSCC)

FSCC is a committee constituted by FSSAI and shall be responsible for the implementation or management of food safety emergencies. The committee shall consider information related to range of hazards, its magnitude and affected people while making decisions. The Committee may support finances and other resources, if required, for operations.

Key Roles and Responsibilities:

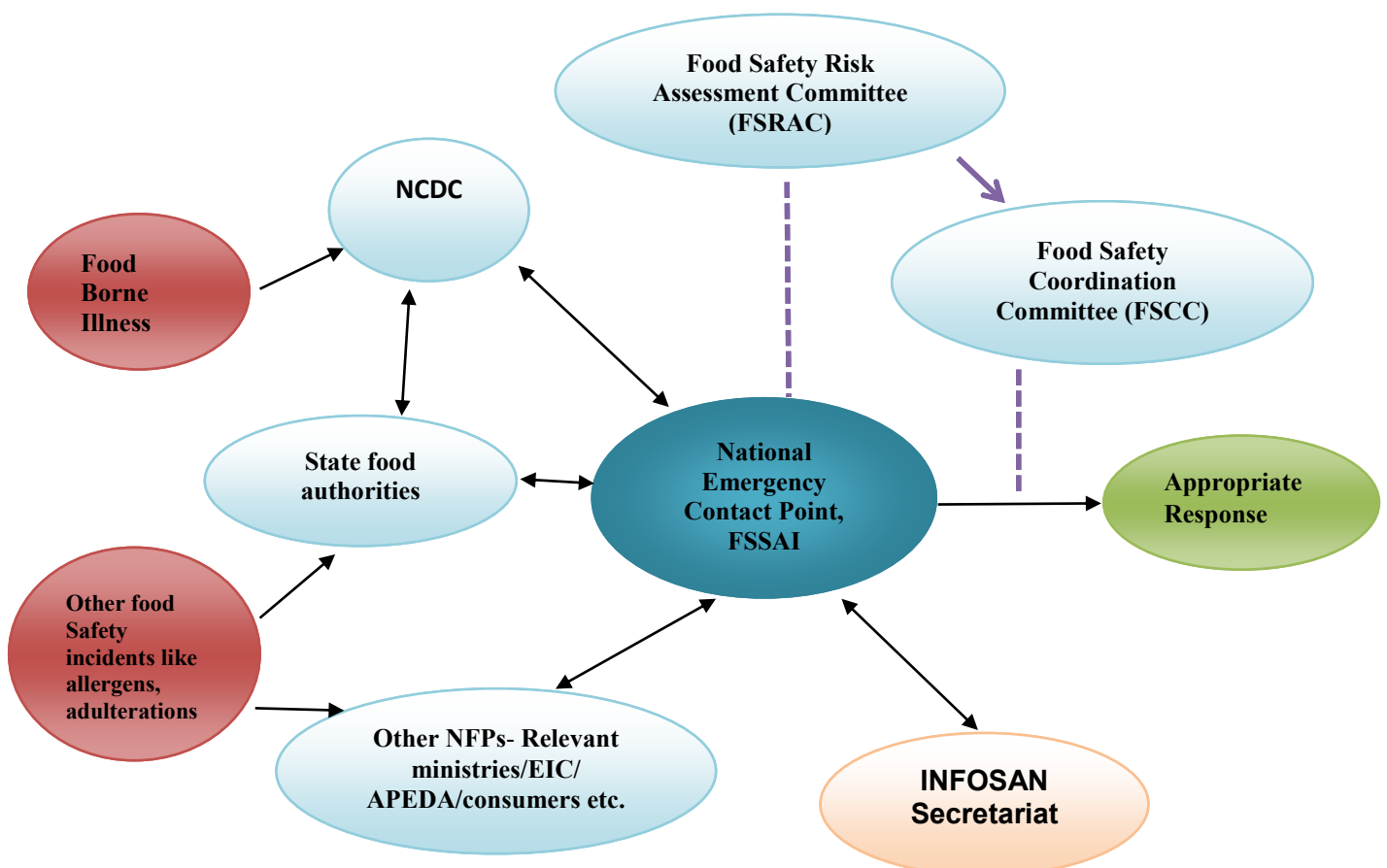
- To take decisions for controlling and management of food safety emergency situations based on the recommendation of FSRAC
- Direct the planned measures to related agencies in implementing control and monitoring actions
- Monitor, evaluate and review the measures used that are fit to the situation.
- Consider and make a decision when the situation has been controlled in order to increase or decrease the response level, including incident closure.
- Advice for policy making for management and control of food safety emergency situation from time to time.

Members of the Committee:

1. CEO, Food Safety and Standards Authority of India (FSSAI) – Chairperson of FSCC Committee
2. Executive Director (Compliance Strategy/Training), FSSAI
3. Advisor (Science & Standards), FSSAI

4. Joint Secretary, Department of Health, Ministry of Health & Family Welfare or his representative
5. Joint Secretary, Ministry of Agriculture and Farmers Welfare or his representative
6. Joint Secretary, Department of Commerce (EP Agri Division), Ministry of Commerce or his representative
7. Joint Secretary (Cattle Dairy Development), Department of Animal Husbandry, Dairying and Fisheries (DAHD) or his representative
8. Joint Secretary, Ministry of Consumer Affairs, Food and Public Distribution or his representative
9. Joint Secretary (Fisheries), Department of Animal Husbandry, Dairying and Fisheries (DAHD), Ministry of Fisheries, Animal Husbandry, Dairying or his representative
10. Joint Secretary (Nutrition), Ministry of Women & Child Development (MWCD) or his representative
11. Joint Secretary (Livestock Health), Department of Animal Husbandry, Dairying and Fisheries (DAHD), Ministry of Fisheries, Animal Husbandry, Dairying or his representative
12. Director, Export Inspection Council of India (EIC) or his representative
13. Director, National Center for Disease Control (NCDC) or his representative
14. Representative of Indian Council of Medical Research (ICMR)
15. Director (Imports), FSSAI
16. Head of Food Safety Emergency Cell, FSSAI- Member Secretary/Convenor

The Networking of all structural components of the FSER system and multi-sectorial coordination are depicted in figure 1 and figure 2 respectively as below:



At Domestic Level

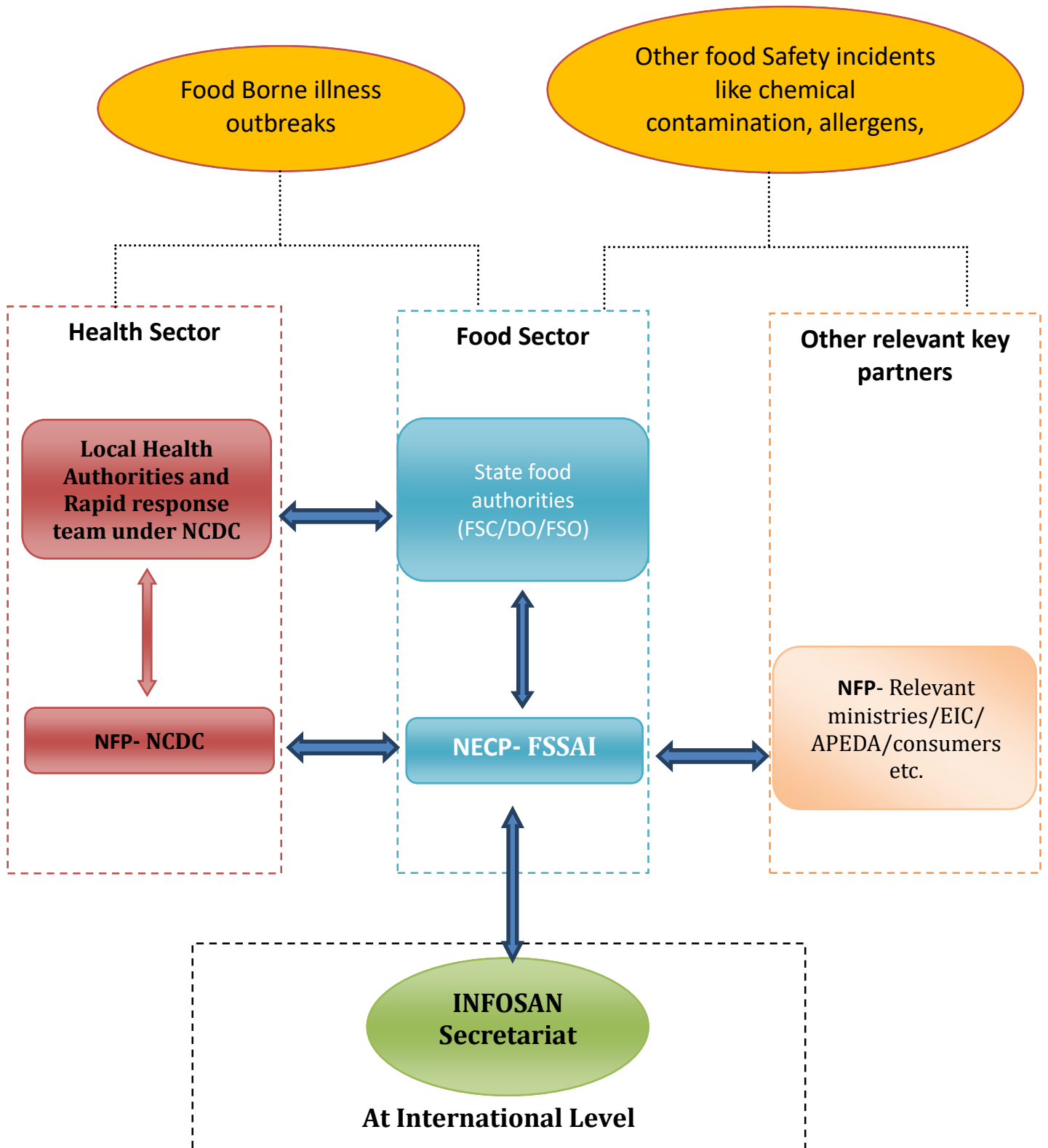


Figure 2: Multi-sectorial Coordination

II. Operational Procedures

Key Elements of FSER

A. Criteria for considerations of food safety emergency

Food hazard characterization: The determination of significant hazard should be conducted by experienced risk assessors and information derived from food safety monitoring at the national level should be considered to identify a level of severity in each food safety incident

Magnitude and severity degree of the food safety incident: To determine, numbers of cases, magnitude of a hazard and the degree of consequences due to consumption of foods or food products reported are taken into account. This also includes potential of incident spreading with respects to distribution route, consumption rate and consumer trends. Magnitude and severity degree of the incidents are divided into

(1) “Restricted area” defines as foods or food products afflicted are distributed or sold or caused illnesses from consumption in the restricted area, which is under the responsibility of sole province and stays under control.

(2) “Widespread area ” defines as foods or food products afflicted are distributed or sold, or caused illnesses from consumption in widespread areas covering more than one province, or exported to other countries, or spread out to various areas domestically and internationally. Such incidents can barely be managed within the sole province.

In addition to above, following queries may also be considered:

- Whether the event caused by intentional contamination
- Whether the event poses a risk to public health that requires an urgent action
- Whether the event poses a potential to illnesses or deaths of public, which may spread intra or inter- country, or causes serious impacts on society, as well as domestic and international trade

B. Incident Identification: Surveillance will be essential in identifying a food emergency or the initial signs of an emergency unfolding. Local sources will be instrumental during the initial identification of an unintentional or deliberate food-related incident. These local sources would include consumers, local health departments, food retailers, manufacturers, distributors, processors, producers and media. Events detected through national food control system may be assessed, for identifying whether an event is an emergency or not, considering criteria as mentioned above in section 5.2 (A). Food safety incidents/emergencies may include cases of illness due to an outbreak of food and water-borne diseases, cases of food or food products contaminated by chemicals like metallic contaminations, residues of pesticides or veterinary drugs which poses potential risk to health, cases of food adulterations etc.

Food safety emergency situation shall be declared by FSSAI or FSCC after reviewing and analysing the information collected for food safety incident. In case of food borne illness, outbreak shall be declared by NCDC/health departments in consultation with FSSAI. If incident is identified as emergency then a response phase will be initiated.

C. Emergency response phases

- i. **Alert phase:** Notifying identified food safety incident to INFOSAN Secretariat and/or National authorities or organization or media, if required. The kind and extent of alert will be decided by Coordination Committee based on the analysis report submitted by FSRAC to Coordination committee.
- ii. **Action phase:** Food Safety Coordination Committee will take immediate actions/safety measures in order to control food safety emergency situation. Following measures may be taken based on the need of the situation:
 - a) investigation for the source of food throughout the food supply chain, from import, production and distribution including those related to food or food products that may pose additional risk
 - b) In case of food borne illness outbreak, actions may be initiated by state food authorities as per the guidelines prescribed by FSSAI for “Food borne illness outbreak investigation and response”.
 - c) Directing related agencies for surveillance/prevention/disease control according to their roles and responsibilities
 - d) Enforcement of law e.g. i) prohibit or stop the distribution, detention, control or recall in order to remove food or food products from markets, case by case; ii) place measures to protect the public from food hazards that may affect health.
 - e) Advise consumers on the extent of risk, measures taken by the authority, measures to be taken by the consumers or issuing other relevant advisories time to time (via television, radio, cable operators, internet, social media sites etc.)
 - f) Monitor and evaluate the situation continually and adjust the measures until the event is controlled
- iii. **Stand down phase:** If the risk is mitigated or situation seems to be in control then advisory should be withdrawn and further advice to industry and consumer should be issued, if necessary. This will be decided by FSCC. Spoke person who is assigned by the FSCC will inform relevant agencies, stakeholders, media and the public that the event has been implemented and solved and returned to normal condition normal. The measures used in emergency management, lesson-learned and impact of the food safety event will be reviewed and evaluated to restore and prevent of the incident that may happen in the future.

D. Communication: It is an important process to inform of the efficiency of the measures to the public and stakeholders through various means like media/press. Communication language during emergency event must be easy to understand and must cover all groups of stakeholders, press and media, public and international organization.

Effective communication is a crucial aspect of successful food safety emergency management. Throughout the course of emergency, it is important to share relevant information with:

- the general public.
- the media;
- the people directly affected;
- authorities and other professional groups;

Communication with the public: The purpose of public information in the event of a food safety emergency is to provide: - accurate information about the food safety incidents/emergency; - information on implicated food products and how they should be handled; - advice on personal hygiene measures to reduce the risk of person-to-person spread.

State Food authority should periodically issue mitigation measures or do's/don'ts through press releases to the public.

If a food safety emergency has attracted intensive publicity, it may be necessary to establish a telephone helpline for the public. It is important that such help lines are staffed by individuals who have been trained in gathering additional information (e.g. details about cases) from callers.

Communication with the media: As the major interface between the general public and the health authorities, the media play an important role during food safety emergency. Developing good relationships with the media before an outbreak occurs may be very helpful in facilitating crisis-related communication. The media may be notified of such outbreaks either officially through the FSSAI or State Food Authority media releases. In either circumstance it is important for local government to contact the FSSAI before releasing any outbreak information to the media and to ensure that any investigatory work undertaken by the FSSAI is accurately reflected in the media correspondence.

Communication with authorities and other professional groups: The most relevant authorities and professional groups include local health authorities, food, water, agricultural and veterinary authorities, and educational organizations. Whenever possible, established communication channels and regular meetings should be used as the most efficient means of keeping authorities and other professional groups fully informed. It is the responsibility of the Food Safety Commissioner to communicate with authorities and other professional groups, if needed, through appropriate means from time to time during food safety emergency.

Responsibility of the Food safety agencies/authorities during food safety emergency situation:

- Establish communication channels such as social network, phone etc.;
- Arrange meeting using teleconference and/or video conference to communicate in emergency events
- Provide an update situation of food safety emergency and reporting via website and
- allocate personnel to take charge on a 24 hour basis

E. Post incident review and evaluation: It includes the review process for response activities, communication methodologies, and regulatory procedures to prevent production/distribution of implicated foods, capacity & reporting of laboratories, inspection services, and effectiveness of product recall. Based on the review learning lessons from the food safety incidents or emergencies, gaps may be identified which could be addressed to improve measures of the FSER plan and also preparedness for resources and development systems or of structure that can be implemented by the measures more efficiently. Further, it also includes maintenance of record of such emergencies faced like product description, type of hazard and health effects observed, actions taken and their result, duration of emergency etc.

A district level and/or state level advisory committee are responsible for post incidence monitoring and review and therefore should:

- Identify the long-term and structural control measures, and plan their implementation;
- Assess the effectiveness of FSER plan and difficulties in implementing them;
- Assess whether further scientific studies should be conducted;
- Clarify resource needs, structural changes, or training needs to optimize future outbreak response;
- Identify factors that compromised the investigations, and seek solutions;
- Identify necessary changes to current investigation and control guidelines and development of new guidelines or protocols as required; and
- Discuss any legal issues that may have arisen.

7. References

- i. Enhancing INFOSAN in Asia and Implementation of Regional Food Safety Strategies: Meeting Report 2012 by FAO/WHO.
- ii. The International Food Safety Authorities Network (INFOSAN): Progress Report 2004-2010 by FAO/WHO.
- iii. FAO/WHO Framework for Developing National Food Safety Emergency Response Plan
- iv. National Food Incident Response Protocol: *A guide for the coordination of Australian government agencies responsible for food safety and food issues in the event of a national food incident*
- v. National Guidelines for Food Safety Emergency Response Plan of Thailand

GUIDELINES FOR INVESTIGATING AND MANAGING FOOD-BORNE ILLNESS OUTBREAKS IN INDIA



Inspiring Trust, Assuring Safe & Nutritious Food

Ministry of Health and Family Welfare, Government of India



FOOD SAFETY AND STANDARDS
AUTHORITY OF INDIA

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1. Introduction

Food safety authorities worldwide have the task of controlling and managing foodborne diseases which are of importance to national as well as international public health. As the volume and magnitude of the extensive global trade in fresh and processed food items increase, food authorities need to be able to identify and respond to incidents related to food safety and to communicate information on food safety to all stakeholders within the shortest possible time.

Many foodborne diseases had been witnessed in the recent past including cases of food poisoning due to midday meal and parties/marriages. The investigation and control of such foodborne disease outbreaks are multi-disciplinary tasks requiring skills in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology and chemistry, food safety and food control, and risk communication and management.

2. Purpose

These guidelines are intended to serve as general procedures for investigation of foodborne disease outbreaks. It is important to remember that no general guidelines will fit a specific situation perfectly, and the local environment will always make it necessary to modify investigation techniques to account for the unique characteristics of every outbreak. These guidelines have been written for state food authorities who may undertake or participate in the investigation and control of foodborne disease outbreaks.

3. Definitions

- (a) **Food Safety Incidents:** Any situation within the food supply chain where there is a risk, potential risk or perceived risk of illness or confirmed illness associated with the consumption of a food or foods.”
- (b) **Foodborne Disease:** Foodborne disease (also referred to as foodborne illness or food poisoning) is any illness that results from the consumption of contaminated food, contaminated with pathogenic bacteria, viruses, or parasites.
- (c) **Foodborne disease outbreak:** The observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.

4. Overview of Foodborne Disease

A food-borne disease is a disease that is likely to be transmitted through the consumption of contaminated food or water. Diseases resulting from the consumption of microbiological/chemical contaminated food can be commonly referred to as food poisoning or food-borne illness. Food-borne illness is caused by either chemical or biological agents. Symptoms that indicate a person is potentially suffering from a food-borne disease can include: vomiting, diarrhea, nausea, fever and abdominal cramps. A person with hepatitis A or E may also be jaundiced.

Foodborne diseases are classified into:

1. **Food borne infections:** Caused when a person eats food containing harmful microorganisms, which invade and multiply in the intestinal tract or other tissues. Examples include *Salmonella*, *Campylobacter*, *Vibrio*, and *Yersinia enterocolitica*.
2. **Food borne intoxications:** Ingestion of foods containing either poisonous chemicals or toxins produced by microorganisms in the food. Examples include bacteria such as *Clostridium botulinum*, *Staphylococcus aureus*, and *Clostridium perfringens*; chemicals such as sanitizing products; metals; seafood toxins such as ciguatera and scombroid.

The list of important pathogens causing foodborne illness, its characteristics and control measures to be taken at industrial level, establishment level and/or consumer level is attached at **Appendix-I**.

4.1 Foodborne disease outbreaks

Foodborne disease outbreaks occur when two or more (usually unrelated) people experience similar illness after eating the same food. In general terms, an *outbreak* refers to an often-sudden increase in the number of cases of an illness or disease above what is normally expected in a population in a given area (or place).

Food-borne disease outbreaks can be small and localized (occurring only in one local government jurisdiction), or large scale (affecting persons across multiple local government jurisdictions). Generally, there are two different types of food-borne outbreaks: **Point source outbreaks** are associated with a common event or venue, with people becoming ill over a short period of time. They are easy to identify if such persons report their illness and it becomes relatively easy to investigate. **Community-wide outbreaks** are not associated with a common event and involve people diagnosed with the same pathogen, which have eaten a contaminated food or ingredient that is sold at a number of food businesses. These investigations are very resource intensive, and identifying the source can be challenging.

5. Investigation of Foodborne illness outbreak

The investigation and control of foodborne disease outbreaks are multi-disciplinary tasks and different stakeholders are responsible to respond to any food borne outbreak. The responsibilities are shared between the Health authorities and Food Safety Authorities at National and State Level as the response to food borne emergencies require collaboration and cooperation at all levels.

5.1 Purpose and Objectives of an outbreak investigation

The purpose of an outbreak investigation is to stop the continuance of the outbreak and to prevent the likelihood of future outbreaks.

The specific objectives of an outbreak investigation are to:

- Identify the food business, food or ingredient associated with illness.
- Identify and control the contributory cause(s) and risk factors.
- Control the outbreak through:
 - Removing or recalling unsafe foods and ingredients
 - Eliminating unsafe food handling processes that have contributed to the outbreak's occurrence (or allowed the outbreak to continue)
- Prevent the likelihood of future outbreaks by enhancing the food business' food safety management practices,

- Educate the food business on appropriate management of food safety risks to prevent the likelihood of a re-occurrence,
- Collect information to guide further research in the prevention of outbreaks.

5.2 Foodborne Disease Outbreak Investigation Team

Investigation of an outbreak of foodborne illness is a team effort in which each member plays an essential role. It requires collaboration between Food Authorities and Health authorities for better communication and a better understanding of what is happening in regard to foodborne illness. Increased understanding of others' responsibilities would result in improved local foodborne illness investigation and control programs.

Minister of Health & Family Welfare launched Integrated Disease Surveillance Project (IDSP) in November 2004 with an objective to strengthen/maintain decentralized laboratory based IT enabled disease surveillance system for epidemic prone diseases to monitor disease trends and to detect and respond to outbreaks in early rising phase through trained Rapid Response Team (RRTs). National Centre for Disease Control (NCDC) is the agency implementing the programme. RRT has been constituted at district level to confirm and investigate public health outbreaks including Food borne Outbreaks.

The Food Safety Officers of State Food Authorities have now been made as a part of RRT and is gathered on ad hoc basis when needed.

5.3 Rapid Response Team

Once there is a threat of an outbreak or an emergency. It becomes necessary to form and activate rapid response team to address specific response tasks. At State, State Surveillance Officer (SSO) and at district level Chief District Medical Officer (CDMO) and District Surveillance Officer (DSO) are responsible to activate Rapid Response Team.

The members of the RR team are assigned with tasks appropriate to the response, such as: surveillance, sampling, product recalls, trace-backs, prohibition, disposal of contaminated materials, decontamination and disinfection, evidence gathering, quarantine, security, public education, sample analysis, or any other operational aspect of mitigating a food emergency. Generally, the team includes experts to cover all aspects of the emergency which includes District/State Epidemiologist, pathologist/clinician, microbiologist (Lab sampling), Entomologist (Vector Borne Disease), Paediatrician, Public health Nurse, Data manager/Lab Technician, Official from local bodies, and **Food Safety Officer (Food Borne Disease)**.

From here onwards, RRT will serve as foodborne disease outbreak investigation team throughout the rest of the document.

5.4 Functions of RRT in investigating Foodborne illness outbreak

RRT is gathered on ad-hoc basis when needed and composition may vary on case to case basis to deliver following functions:

- 1) To assist state health/food authorities in investigations of foodborne illness or outbreaks,
- 2) To identify causes of outbreaks through environmental investigations, laboratory analysis and epidemiologic analysis,
- 3) To track cases and complaints linked to the consumption of food, and

- 4) To make recommendations and take necessary steps for the prevention and control of foodborne illness.

5.5 Responsibilities of FSOs

- To coordinate with Rapid Response Team
- Collection of data related to food borne illness outbreak
- Visit and Inspection of the affected site
- Collection of suspected food samples
- send the samples to lab for confirmation
- to take necessary measures for control of outbreaks in consultation with state /central food authority
- Regular follow up
- Preparation of the report on the outbreak

5.6 Channel of Communication

State authorities (FSCs, DOs or FSOs) may receive information related to food safety incidents/foodborne illness outbreaks from various sources like FSSAI, health sectors (district Health facilities, DSOs, SSOs, local health bodies) or IDSP/RRT, media alert, email, news media, newspaper, consumer or from any person etc. Once the alert/information received through IDSP/RRT, DO will nominate FSO from the concerned area to work with RRT and deliver functions as mentioned above. FSO will report back on the status on the food safety incident to designated office and will prepare an interim report in line with Report format prescribed in Box 4 within 48 hrs of the incidents and send a communication on the same to FSCs and FSSAI. DO will send detailed report in the prescribed format as given in Box 4 to FSCs and FSSAI within 10 days or completion of investigation whichever is earlier of occurrence of the incident.

5.7 Process of Outbreak Investigation

In the event of a foodborne disease outbreak, the food safety officers would be required to

Box1: Consider the following points when investigating a potential foodborne illness:

1. Onset of illness- Be sure to accurately record dates and times of the onset of illness and symptom information.
2. Incubation period- Please refer to the correct incubation period range for the etiologic agent reported.
3. Exposure history- Once you know the incubation period range, then ask the case about exposure history during one incubation period range before the illness started (i.e. if the patient had Salmonella, ask about exposures during the time period 6 to 72 hours before the illness started).
4. Occupation- Asking about the case's occupation is very important to assist with determining where the case might have gotten the illness, and where there is opportunity for transmitting the illness to others. All food handling occupations are important and include positions that might not come to mind initially.

undertake the following activities as and when an alert/message received through IDSP system or consumer organisations or public or media regarding food borne disease outbreak:

- (a) Collect relevant preliminary information related to foodborne disease outbreak from RRT members. The information collected may include diagnosis/clinical report, suspected microbial infection, suspected food (food consumption history of the patient may be used), location of the food taken from, anything unusual about the meal/food
- (b) Examine/investigate the case in coordination with district/state Surveillance Officers and RRTs as soon as an alert for foodborne disease outbreak/incident is communicated and:
 - i. conduct site investigations including for operational hygiene at implicated premises
 - ii. identify potentially implicated food product and take appropriate food samples, if available, as prescribed by FSSAI time to time (draft sampling procedure is attached with it) and send the samples to the accredited laboratories for analysis along with the Form placed at **Appendix-II**. In case food samples are not available then raw materials from which food was prepared may be collected and send for analysis.
 - iii. liaise with other FSOs of the region to determine whether the implicated product is distributed in other parts of the district/state or even other states.
- (c) Take appropriate and necessary action in consultation with FSCs to ensure that the further spread of the food borne disease could be mitigated. Actions taken must be under the power delegated to the FSCs in the FSS act 2006.
- (d) Prepare brief report describing the incidents, its severity, action taken, etc. and send interim action report to DOs, FSCs, RRT members and FSSAI within 48 hours of the alert/notification received.
- (e) Maintain the record of meetings with RRT and any other concerned officers, investigations, laboratory reports, action taken, etc. from the beginning of the outbreak.

5.8 Inspection

The food business' activities and premises can be investigated to assess the likelihood of the probable cause. To assess the probable cause FSO will visit the affected site and inspect it for its design & facilities, Control of Operation, Maintenance & sanitation and Personal Hygiene. In this regard, FSSAI has developed inspection checklist for facilitating Food Safety Officers to efficiently inspect the Food Business Operators FBOs. These inspection checklists are based on revised Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 and have been developed for following sectors:

- General Manufacturing
- Milk Processing
- Meat Processing
- Slaughter house
- Catering
- Retail
- Transport
- Storage & warehouse

For more information on inspection checklist please visit [FSSAI website](#).

As every outbreak is unique, FSO will be required to apply their food safety skills and knowledge during the investigation, searching for the three major hazards which may have led to the outbreak:

1. **Contamination of food:** Cross contamination between raw and ready to eat foods, ill food handlers, inappropriate food handler hand washing, inadequate cleaning and sanitising, insufficient cooking or washing of raw product, non-potable water used in food preparation, Food contaminated during storage;
2. **Pathogen survival in food:** Insufficient time and temperature, inadequate cleaning and sanitising, inadequate reheating of foods, inappropriate pH and water activity;
3. **Pathogen growth in food (where the pathogen is bacterial):** Inappropriate time and temperature, inappropriate storage temperature, inappropriate pH and water activity;

Box 2: For information

Major components of an outbreak investigation

Irrespective of the size of the outbreak, a successful outbreak investigation involves three main investigatory components – the laboratory, epidemiological and environmental health investigations. The three investigation components may occur in sequence, or may occur simultaneously throughout the outbreak investigation.

An **epidemiological investigation** involves investigating human cases suffering from food-borne diseases to describe the nature of the outbreak and assist in determining the source of the outbreak through statistical and descriptive studies. Steps in an epidemiological investigation normally include

- Interviewing ill cases (confirmed and suspected cases) from a notifiable disease cluster to identify a common food or food business,
- Summarising and reporting information regarding ill cases, including; age, sex, place of residence, date of illness, dates of food consumption, incubation period, duration of illness, symptoms, hospitalisation, foods consumed and food businesses attended,
- Determining, through case-control or cohort studies, if there is a statistical association between illness and the particular food(s) consumed,
- Monitoring food-borne disease databases and other information sources for new cases of specific diseases.

A **laboratory investigation** involves the laboratory testing of human faecal specimens, as well as food and environmental samples to detect the presence of a food-borne disease pathogen or toxin that caused illness or to confirm its presence in food or the environment.

An **environmental health investigation** involves an onsite investigation into the potential sources or processes that contributed to or caused the outbreak. The purpose of this investigation is to identify the environmental cause and implement immediate action to stop the continuance of the outbreak and prevent future outbreaks

5.9 Sampling

Laboratory analysis of foods for microbial or chemical contamination is time- and resource intensive and liable to a number of sampling and handling errors. Targeted sampling and laboratory analysis of foods should be directed by epidemiological and environmental

investigations. If an implicated food has not been identified at the time of sampling, a large number of specimens may be collected and stored for subsequent laboratory testing as additional information becomes available.

FSO is required to collect the all suspected food samples (please see box 2) based on the investigation information gathered on history of consumption of food of the patients and epidemiological information by RRT. The sampling procedure for chemical testing shall be followed as per the Food safety and Standards Act, 2006 and Rules/Regulations made thereunder. However, in case of microbiological sampling during emergency situation, the

Box 3: Guidelines for Determining Suspect Foods

When two or more Persons are reported ill:

- a) If the cause (organism) is **not known**, determine foods/beverages/meals common to all persons for at least 72 hours prior to the onset of illness.
- b) If the cause (organism) is **known**, determine foods/beverages/meals common to all persons which were consumed during the appropriate incubation period prior to the onset of illness.

Investigation of a suspect food

When the role of a suspect food is investigated, the complete processing and prepare history should be reviewed, including sources and ingredients, person's specific foods, the procedures and equipment used, potential sources of c time-and-temperature conditions to which foods were exposed.

Food samples that may be appropriate for collection and testing include

- Ingredients used to prepare implicated foods;
- leftover foods from a suspect meal;
- foods from a menu that has been implicated epidemiologically;
- foods known to be associated with the pathogen in question;
- foods in an environment that may have permitted the survival or growth of microorganisms

Standard Operating Procedures is placed at **Attachment-1** shall be followed read with the Food safety and Standards Act, 2006 and Rules/Regulations made thereunder.

5.10 Transportation / courier of collected samples

The sample drawn should be transported to the Laboratory for testing as quickly as possible preferably within 24hrs. Samples should be couriered either through courier services or FSO should take it personally while taking into account following points. The cost of the transportation will be borne by FSSAI.

- Dehydrated and dry foods stored without refrigeration should not be allowed to absorb any atmospheric moisture.
- Unfrozen liquid or semi-solid foods contained in unopened container should be transported to the lab in refrigerated condition (4⁰C to 8⁰C) or without refrigeration as mentioned in the label regarding storage requirements of the food products.
- Samples drawn from original packing transferred to new container should be held at 4⁰C to 8⁰C during transportation, but should not be frozen.
- Meat and meat products, poultry and fish should preferably be transferred under wet ice refrigeration to avoid dehydration at the surface of the sample.

- Frozen food products should be kept in dry ice while transportation.

5.11 Testing of samples

Most outbreak investigations will require laboratory analysis of food or environmental samples taken from the food business. The food and environmental samples can provide confirmation of the presence of a pathogen, support the likelihood of the probable cause and provide evidence to concerned officer that the outbreak was linked to the unsafe food or unsafe food handling practices. The samples should be sent immediately to the FSSAI notified labs. The role of the food laboratory in foodborne disease outbreak investigations includes

- advising on appropriate samples to be taken from food;
- performing appropriate laboratory investigations of the food to identify the suspect pathogens, toxins or chemicals;
- advising on further sampling when a specific agent is found in the food (e.g. guiding collection of clinical specimens from food-handlers);
- working with the clinical laboratory to arrange for typing or additional characterization of organisms (e.g. serotyping, phage typing, molecular subtyping) as appropriate;
- supporting epidemiological and environmental investigations in detecting the pathogen in the implicated food and understanding how the outbreak occurred.

6. Action Taken

The interpretation of the laboratory results should be completed with care. A **positive laboratory result** confirms the presence of a pathogen in the food sampled or within the food business premises. A positive result is evidence that a particular food or batch has been subjected to hazards, potentially causing the outbreak. It is important to note whether the batch sampled is the same batch of food consumed by the ill cases.

A **negative laboratory result** does not rule out an association between the food product or food business. A negative result simply represents that the food or environmental sample did not contain a pathogen at the time of collection. Often samples are collected after an outbreak is over, and the contaminated foods have been used or discarded.

FSO will take appropriate action after receiving lab analysis report of the samples. Broadly the action may be divided into two categories 1) Notification 2) Control Measures.

- 1) **Notification:** FSO will notify state and central food authorities about the outcome of analysis report of lab whether the food samples are found to be positive for the illness in question or not. It is also desirable that FSO also notify the severity of the incident to the state and central food authorities. If the case is needed to be reported to media and/or consumers then State authority in consultation with FSSAI will notify consumers on the extent of risk, measures taken by the authority, measures to be taken by the consumers (via television, radio, cable operators, internet, social media sites etc.) within 72hrs of the incident.
- 2) **Control Measures:** The primary goal of outbreak investigations is to control ongoing public health threats and to prevent future outbreaks. Ideally, control measures should be guided by the results of these investigations but as this may delay the prevention of further cases it is often unacceptable from a public health perspective.

Once investigations have identified an association between a particular food or food premises and transmission of the suspected pathogen, measures should be taken to control the source. Steps may include:

- removing implicated foods from the market (food recall, food seizure);
- modifying a food production or preparation process;
- closing food premises or prohibiting the sale or use of foods.
- Clean and sanitise the premises, equipment, fixtures and fittings and food contact surfaces,
- Enhance food safety management practices by changing processes or equipment that have contributed to, or caused the outbreak. In addition, instigate appropriate food handler training,
- Ensure ill food handlers are excluded from handling food

7. Reporting of the Incidence

There are a variety of ways to compile the information obtained during an investigation into a professional, understandable and usable document. The standard outline used to write an outbreak report is given in the **Box 4**. It can be modified to reflect the complexity of any size of outbreak. Copies of the report should be made available to all parties involved in the investigation.

8. Outbreak Communication

Effective communication is a crucial aspect of successful outbreak management. Throughout the course of an outbreak, it is important to share relevant information with:

- the general public.
- the media;
- the people directly affected;
- authorities and other professional groups;

Communication with the public: The purpose of public information in the event of an outbreak of foodborne disease is to provide: - accurate information about the outbreak; - information on implicated food products and how they should be handled; - advice on personal hygiene measures to reduce the risk of person-to-person spread.

State Food authority should periodically issue foodborne disease prevention messages or press releases to the public to reduce illness and ensure the public knows with whom to communicate (often their primary-care provider) and from where information will come during a foodborne disease outbreak.

If a major outbreak is in process or an outbreak has attracted intensive publicity, it may be necessary to establish a telephone helpline for the public. It is important that such helplines are staffed by individuals who have been trained in gathering additional information (e.g. details about cases) from callers.

Communication with the media: As the major interface between the general public and the health authorities, the media play an important role in outbreak investigation and control. Developing good relationships with the media before an outbreak occurs may be very helpful in facilitating crisis-related communication. The media may be notified of such outbreaks either officially through the FSSAI or State Food Authority media releases. In either

circumstance it is important for local government to contact the FSSAI before releasing any outbreak information to the media, to ensure any investigatory work undertaken by the FSSAI is accurately reflected in the media correspondence.

Communication with authorities and other professional groups: The most relevant authorities and professional groups include local health authorities, food, water, agricultural and veterinary authorities, and educational organizations. Whenever possible, established communication channels and regular meetings should be used as the most efficient means of keeping authorities and other professional groups fully informed. It is the responsibility of the Food Safety Commissioner to communicate with authorities and other professional groups, if needed, through appropriate means from time to time during outbreak investigation.

9. Post outbreak monitoring and review

Post outbreak monitoring includes:

- Monitoring the population at risk for signs and symptoms to ensure the outbreak has ended and the source has been eliminated;
- Monitoring the implicated foods or facilities to make sure no further contamination is occurring; Maintaining communication with the implicated facility, and tell them if additional information becomes available;
- Increasing the number of routine inspections at the implicated facility to ensure they comply with all required procedures. Old, unsafe practices often are difficult to change, and new practices might need to be used for >1 months before they become routine.

Post outbreak review includes the review process for response activities, communication methodologies, and regulatory procedures to prevent production/distribution of implicated foods, capacity & reporting of laboratories, inspection services, and effectiveness of product recall. Based on the review learning lessons from the foodborne illness outbreak, gaps may be identified which could be addressed to improve the practice of responses to outbreaks of foodborne diseases and also preparedness for resources and development systems or of structure that can be implemented by the measures more efficiently. Further, it also includes maintenance of record of such emergencies faced like product description, type of hazard and health effects observed, actions taken and their result, duration of emergency etc.

A district level and/or state level advisory committee are responsible for post incidence monitoring and review and therefore should:

- Identify the long-term and structural control measures, and plan their implementation;
- Assess the effectiveness of outbreak control measures and difficulties in implementing them;

Determining whether an Outbreak is over

Most outbreaks are considered over when two or more incubation periods have passed with no new cases. Once it is determined that an outbreak is over now than it should be determined when to remove the restrictions, if any, imposed during as control measures.

- Assess whether further scientific studies should be conducted;

- Clarify resource needs, structural changes, or training needs to optimize future outbreak response;
- Identify factors that compromised the investigations, and seek solutions;
- Identify necessary changes to current investigation and control guidelines and development of new guidelines or protocols as required; and
- Discuss any legal issues that may have arisen.

10. Evaluation by national level committee

A national level committee will be constituted to evaluate the performances of the states for responding to the foodborne outbreaks. The national level committee will comprise of officials from FSSAI, NCDC and WHO. National level committee will meet quarterly and evaluate performance through an evaluation matrix on the grade from 1 to 5 (1 being poor and 5 being exceptional).

The Commissioners of Food Safety shall present the status of the food borne illness outbreaks occurred in their states/UTs in the last quarters and action taken thereon in the meeting of Central Advisory Committee (CAC) under a standing agenda namely “the status of responses of Food borne illness outbreak. The reported Food borne disease outbreaks along with action taken by the state will be discussed in every CAC meeting.

Box 4: Format of the Report

S.No.	Particulars	Description
1.	Date and Time of Investigation	
2.	Date, Time and Place of Incidence	
3.	Name & Address of Premises/Place	
4.	Source of Information	
5.	Type of Occasion/gathering (Wedding, Religious gathering, Canteen, Mid-Day Meal, Restaurant/Hotel/Dhaba, Any Other, please specify)	
6.	If the food prepared at the place of incidence, provide details of caterer/food service establishment including License No.	
7.	If the food supplied from some other place, provide details of supplier including License No.	
8.	Possible cause of incidence	
9.	No. of person consumed food	
10.	Number of person suffered/affected	
11.	Number of deaths, if any	
12.	Symptoms noticed in affected persons	
13.	Kind of Samples collected by RRT	
14.	Outcome of laboratory test report of the samples collected by RRT	
15.	Detail of RRT (Name, designation and specialty)	
16.	Brief detail of food samples collected by FSO	
17.	Outcome of laboratory report of food samples	
18.	Gaps observed in inspection carried under schedule IV	
19.	Measures adopted to prevent the incidence	
20.	Whether FIR lodged, please give details of sections/provisions under which FIR lodged	
21.	Summary and conclusion of the investigation	
22.	Preventive actions taken to avoid such incidences in future	

Signature _____
Name _____
Designation _____
Email & Phone number _____

Characteristics of the important pathogens causing foodborne illness

(Sources: 1)WHO- Foodborne disease outbreaks: Guidelines for investigation and control and 2) Bad Bug Book: Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins)

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
1	Staphylococcus aureus	Staphylococcus aureus intoxication	1 to 7 hours	nausea, abdominal cramping, vomiting, and diarrhea. In more severe cases, dehydration, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur	meat and meat products; poultry and egg products; salads, such as egg, tuna, chicken, potato, and macaroni; bakery products, such as cream-filled pastries, cream pies, and chocolate éclairs; sandwich fillings; and milk and dairy products	All people are believed to be susceptible to this type of bacterial intoxication; however, intensity of symptoms may vary.	Food service establishment/household: Exclusion from work of food-handlers with visibly infected skin lesions (boils, cuts, etc.); nasal carriers do not need to be excluded unless implicated as the source of an outbreak. Scrupulous personal hygiene; prevention of time-temperature abuse in handling cooked/ready-to-eat foods; thermal processing, good hygiene practices during production and processing.

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
2	Bacillus cereus	B. cereus food Poisoning: a) diarrheal type of illness b) vomiting (emetic) type of illness	a) Diarrhoeal syndrome: 6-15 hours b) Emetic syndrome: 0.5-6 hours	a) Diarrhoeal type: acute diarrhoea, nausea and abdominal pain. b) Emetic type: acute nausea, vomiting and abdominal pain and sometimes diarrhoea.	starchy products such as boiled or fried rice, potato, pasta, and cheese products; spices, dried foods, milk, dairy products, vegetable dishes, sauces, puddings, soups, casseroles, pastries, and salads Many outbreaks (particularly those of the emetic syndrome) are associated with cooked or fried rice has been kept at ambient temperature	All people are believed to be susceptible to B. cereus food poisoning	Effective temperature control to prevent spore germination and growth. Food storage at >70 °C or < 10 °C until use Good hygiene practices during production and processing.

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
3	Salmonella	Salmonellosis	6 to 72 hours	Nausea, vomiting, abdominal cramps, diarrhea, fever, headache	meats, poultry, eggs, milk and dairy products, fish, shrimp, spices, yeast, coconut, sauces, freshly prepared salad dressings made with unpasteurized eggs, cake mixes, cream-filled desserts and toppings that contain raw egg, dried gelatin, peanut butter, cocoa, produce (fruits and vegetables, such as tomatoes, peppers, and cantaloupes), and chocolate.	Anyone, of any age, may become infected with Salmonella	<p>Industrial:Effective heat-processing of foods of animal origin including pasteurization of milk and eggs; irradiation of meat and poultry thermal processing; good hygiene practices during production and processing; vaccination of egg-producing flocks.</p> <p>Food service establishment/household:Safe food preparation practices, including thorough cooking and reheating of food and boiling of milk; adequate refrigeration; prevention of cross-contamination; cleaning and disinfection of food preparation surfaces; exclusion of pets and other animals from food-handling areas.</p> <p>Consumers particularly vulnerable groups, should avoid raw and undercooked meat and poultry, raw milk, raw eggs and foods containing raw eggs.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
4	Campylobacter jejuni	Campylobacteriosis	2 to 5 days	Fever, diarrhea, abdominal cramps, and vomiting	improperly handled or undercooked poultry products, unpasteurized ("raw") milk and cheeses made from unpasteurized milk, and contaminated water; vegetables and seafood; nonchlorinated water, such as that found in ponds and streams	Children younger than 5 years old and young adults 15 to 29 years old	<p>Industrial: Heat treatment (pasteurization/sterilization of milk); hygienic slaughter and processing procedures; irradiation of meat and poultry; treatment of water; good hygiene practices during production and processing.</p> <p>Food service establishment/household: Heat treatment of milk (boiling); thorough cooking of all meat; washing of salads; prevention of cross-contamination of contact surfaces; personal hygiene in food preparation (hand-washing after contact with animals); keeping pets away from food-handling areas.</p> <p>Consumers should avoid eating raw or partially-cooked poultry or drinking raw milk</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
5	Listeria monocytogenes	Listeriosis	a few hours to 2 or 3 days	Influenza-like symptoms such as fever, headache and occasionally gastrointestinal symptoms.	raw milk, inadequately pasteurized milk, chocolate milk, cheeses particularly soft cheeses), ice cream, raw vegetables, raw poultry and meats (all types), fermented raw-meat sausages, hot dogs and deli meats, and raw and smoked fish and other seafood.	pregnant women, persons immunocompromised, cancer patients	<p>Industrial: Heat treatment of milk (pasteurization, sterilization) with measures to ensure that processing contamination risks are reduced. For ready-to-eat, high-risk processed foods, reduction of all cross-contamination risks after processing; processing; good hygiene practices during production and processing.</p> <p>Food service establishment/household: Use of pasteurized or heat-treated (boiling) milk and products made from pasteurized or heat-treated milk; refrigeration of perishable foods and consumption within a short space of time. Pre-cooked refrigerated foods should be thoroughly reheated before consumption. Avoidance of certain high risk foods, e.g. soft cheese, ready-to-eat meat such as pâté and raw milk and raw milk products during pregnancy.</p> <p>Consumers, particularly pregnant women and other vulnerable individuals, should avoid eating</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
							<p>raw foods of animal origin, e.g. raw meat, raw milk. Pregnant women should also avoid foods that support growth of Listeria, e.g. soft cheese, pre-prepared salad, cold, smoked or raw seafood.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
6	enterotoxigenic E. coli (ETEC)	Escherichia coli infection	1-3 days; as short as 10-12 hours	ETEC mediates its effects by enterotoxins. Symptoms include diarrhoea from mild to a severe, cholera-like syndrome), abdominal cramps and vomiting sometimes leading to dehydration and shock.	ground (minced) meat, raw milk, and vegetables	-	Industrial: Treatment of drinking water; effective sewage disposal system and treatment of irrigation water; thermal processing; good hygiene practices during production and processing. Food service establishment/household: Specific control measures based on prevention of direct and indirect contamination of food and water with faecal matter; thorough cooking and reheating of food; good personal hygiene.
7	enterohemorrhagic E. coli (EHEC)		3-8 days, median of 4 days	abdominal cramps and watery diarrhoea that may develop into bloody diarrhoea (haemorrhagic colitis). Fever and vomiting may also occur.			For EHEC infection, control measures include: Industrial: Irradiation of meat, or thorough heat processing of meat; pasteurization/sterilization of milk; treatment of wastewater used for irrigation.
8	enteropathogenic E. coli (EPEC)		1-6 days; as short as 12-36 hours	EPEC adheres to the mucosa and changes its absorption diarrhoea, abdominal pain and fever.			Food service establishment/household: Thorough cooking of meat; boiling of milk or use of pasteurized milk; hand-washing before preparation of food.

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
9	enteroinvasive E. coli (EIEC)		1-3 days; as short as 10–18 hours.	EIEC causes inflammatory disease of the mucosa and submucosa by invading and multiplying in the epithelial cells of the colon. Symptoms include fevere, abdominal pain, vomiting and watery diarrhoea (in <10% of cases stools may become bloody and contain mucus).			<p>Consumers should avoid eating raw or partially cooked meat and poultry and drinking raw milk.</p> <p>Exclusion from work/school: Until 48 hours after first normal stool for cases not in risk groups. For cases in risk groups 1-4 and for contacts in risk groups 3-4 until microbiological clearance obtained (2 negative faecal samples taken at intervals >48 hours).</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
10	Clostridium botulinum	Botulism	12-72 hours	Vomiting, diarrhea, blurred vision, double vision, difficulty in swallowing, muscle weakness. Can result in respiratory failure and death	Improperly canned foods, especially home-canned vegetables, fermented fish, baked potatoes in aluminum foil. Honey is a common vehicle of transmission of infant botulism. (Several outbreaks have occurred as a result of consumption of uneviscerated fish, garlic in oil and baked potatoes)	All people are believed to be susceptible to botulism	<p>Toxin destroyed by boiling – spores require a much higher temperature.</p> <p>Industrial: Heat sterilization; use of nitrites in pasteurized meat; thermal processing good hygiene practices during production and processing.</p> <p>Food service establishment/household: Acid-preservation of food at low pH (<4.6); thorough cooking of home-canned food (boil and stir for 15 minutes); refrigerated storage of food, particularly vacuum-packed, fresh or lightly cured/smoked food.</p> <p>Consumers should avoid giving honey or foods containing honey to infants; discard swollen cans.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
11	Clostridium perfringens	Perfringens food poisoning	8– 24 hours	Intense abdominal cramps, watery diarrhea	Meats, poultry, gravy, dried or precooked foods, time and/or temperature-abused foods	Institutional settings (such as school cafeterias, hospitals, nursing homes, prisons, etc.), where large quantities of food are prepared several hours before serving, are the most common circumstance in which C. perfringens poisoning occurs. The young and elderly are the most frequent victims of C. perfringens poisoning.	<p>Food service establishment/household: Adequate cooling and cool storage of cooked products. Meat-based sauces and large pieces of meat should be cooled to <10 °C within 23hours; thorough reheating of stored food before consumption; Preparation of quantities as required when no refrigeration is available; thermal processing; good hygiene practices during production and processing.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
13	Shigella	Shigellosis or Bacillary dysentery	1-3 days, up to 1 week for S. dysenteriae	Abdominal cramps, fever, and diarrhea. Stools may contain blood and mucus	uncooked foods that have received extensive handling, such as mixed salads and vegetables, water and raw milk. Cooked foods that are not reheated after contact with an infected food handler	All people are susceptible to shigellosis, to some degree, but children 1 to 4 years old, the elderly, and the immunocompromised are most at risk.	<p>Industrial: Treatment of drinking water; effective sewage disposal system; thermal processing; good hygiene practices during production and processing.</p> <p>Food service establishment/household: Safe food preparation practices, including careful hand-washing with soap and water; thorough cooking and reheating of food before consumption; disinfection of food preparation surfaces; thorough washing of all fruits and vegetables.</p> <p>Exclusion from work/school: Groups 1, 2 and 4 should not handle food or provide child or patient care until two successive stool specimens (collected at least 24 hours apart and no less than 48 hours after cessation of antimicrobials) are free of Shigella.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
14	Vibrio	cholera, a gastrointestinal illness.	a few hours to 3 days	Profuse watery diarrhoea, which can lead to severe dehydration, collapse and death within a few hours unless lost fluid and salt are replaced; abdominal pain and vomiting.	Undercooked or raw seafood such as molluscan shellfish (oysters, mussels, and clams), crab, lobster, shrimp, squid, and finfish	infection is more likely to occur among people in impoverished areas, poorly developed areas, and areas with a high population density. Cholera is most severe in children suffering from malnutrition	<p>Industrial: Safe disposal of excreta and sewage/wastewater; treatment of drinkingwater (e.g. chlorination, irradiation); heat treatment of foods (e.g. canning); high pressure treatment; good hygiene practices during production and processing.</p> <p>Food service establishment/household: Personal hygiene (hand-washing with soap and water); thorough cooking of food and careful washing of fruit and vegetables; boiling drinking-water when safe water is not available.</p> <p>Consumers: should avoid eating raw seafood. Oral vaccines have recently become available in some countries. Although no country or territory currently requires vaccination against cholera as a condition for entry, local authorities may require documentation of vaccination.</p>

S.No.	Name of Pathogen	Common Name of Illness	Onset of symptoms	Typical signs and symptoms	Typical food vehicles or associated foods	Target Population	Specific control measures
15	Hepatitis A	Hepatitis	25-28 days (range 2-6 weeks).	Loss of appetite, Diarrhea, abdominal discomfort, nausea and vomiting, followed by symptoms of liver damage (passage of dark urine, pale stools, jaundice).	Raw fruit and vegetables, bakery products, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with an infected food handler; shellfish from contaminated waters	All people are considered susceptible to HAV infection	<p>Industrial: Treatment of water supply; safe sewage disposal.</p> <p>Food service establishment/household: Good personal hygiene, particularly thorough hand-washing with soap and water before handling foods and abstinence from handling food when infected; thorough cooking of shellfish; thermal processing; good hygiene practices during production and processing. An effective vaccine is available and vaccination of professional food-handlers and travellers should be considered. Immune-serum globulin is effective in preventing illness if administered within 14 days of exposure to hepatitis A, and can be used for pre-exposure prophylaxis in travellers who cannot be vaccinated.</p> <p>Exclusion from work/school: All cases (including those in risk groups 1-4) for 7 days after onset of jaundice and/or symptoms</p>

Food Analysis Request Form (Form I)						
Description of Food Sample						
Sample Collected by	_____				Phone Number	
Date of Sample Collection		DO code	_____	Sample Code	_____	
Sample Type	Food	_____	Swab	_____	Other	_____
Name of the Food Products		Nature of the food	<ul style="list-style-type: none"> • Cooked • Raw • Ready To Eat • Frozen • Other (please specify) 		<ul style="list-style-type: none"> • Solid • Semi Solid • Liquid 	
Temperature at the time of sample collection		Storage Condition				
Food Establishment/Source						
Name and type of food establishment						
Address						
Phone No.						
Reason for Collection	Product Information, if applicable					
Suspected foodborne outbreak		Manufacturer Brand	_____			
Routine Surveillance		Code/lot no	_____			
Consumer Complaint		Batch No	_____			
Other (Please Specify)	_____					
Food Analysis Requested (Check the following that applies)						
Microbial contamination in Food		Chemical contamination in Food		Container analysis		
<i>Listeria</i>		Aflatoxins		Coliform count		
<i>Salmonella</i>		Mycotoxin		<i>E. coli</i> count		
<i>Shigella</i>		Scombroid poisoning		Other (please specify)		

<i>E. coli O157:H7</i>		Ciguatoxin					
<i>E. coli O104:H4</i>		Shellfish toxins					
<i>Staphylococcus aureus</i>		Lead					
<i>Clostridium botulinum</i>		Cadmium					
<i>Clostridium perfringens</i>		Mercury					
<i>Bacillus cereus</i>		Other (please specify)					
<i>Campylobacter</i>							
<i>Cryptosporidium</i>							
<i>Cyclospora</i>							
<i>Y. enterocolitica</i>							
<i>Yeast/Mold</i>							

Standard Operating Procedures for Microbiological Sampling During Food-Borne Illness Incidences

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1. Purpose

To lay down the procedure of sampling of food and water samples.

2. Scope

- 2.1. This procedure is applicable for sampling of foods and water samples from various locations like cafeteria, food courts, kitchens, food processing units, pack houses etc. for microbiological analysis by Food Safety Officer (FSO).
- 2.2. For the purpose of sampling food products may also be categorized as cooked, raw, frozen, refrigerated, perishable, solid dried, and semi-solid, viscous, liquid, fragile.

3. Responsibility

- 3.1. FSO will be responsible to follow the SOP accordingly and to maintain the record as per SOP.
- 3.2. Designated Officer (DO) will be responsible to ensure the implementation of this SOP.

4. Food Sampling for Microbiological Analysis

4.1. General Requirements for Food sampling

- The reliability of the analysis and interpretation of the results exclusively depend on the process of sampling/sample preparation. Hence it is very important that the sample should be uniform, homogenous and a true representative of the entire Lot/Batch size.
- Samples must be protected against extraneous contamination and improper handling especially at temperatures that may significantly alter the micro flora.
- The sample for microbiological examination should be collected in clean sterilized bottles/container/disposable, pre sterilized bag or pouches.
- All the sampling equipment's used like Can cutters, spatulas, cotton swabs, aluminium foil, knife, spoons, scalpels etc. should be sterilized before use.
- The sampler must keep their hands away from the mouth, nose, eyes and face. During sampling, hands should be sanitized with Isopropyl alcohol (IPA) and sterilized hand gloves should be used.
- Do not touch the inside of the sterile container lip or lid. Do not allow the open lid to become contaminated.
- Sampling should be done under aseptic conditions as far as possible and care should be taken to see that good sanitation and hygienic conditions are maintained. Samples shall be drawn in a clean sterile wide mouth, screw tight bottles, Nasco bags, gamma irradiated or ETO sterile zip lock bags.
- Whenever possible, samples of products in original unopened containers or packages should be drawn and send to laboratory without any delay.
- In case of liquids the sample shall be properly mixed before sampling.
- Cooked food samples should not be reheated.
- The total amount of sample drawn should not be less than 150- 200 gm or the quantity should as per the test requirement.

- As soon as the samples are collected they should be preserved in ice pack. Samples should be surrounded by ice pack from all sides or dry ice as required.
- Samples of dry foods or non-perishable food items shall be stored in such a manner that temperature does not vary duly from the normal temperature.
- Samples drawn shall be transported to the laboratory for testing as quickly as possible, preferably within minimum 1- 2 hrs. or maximum within 24 hrs.
- Sample container should be closed with the stopper or sealed air tight immediately after drawing the samples
- Sterile container/bags used for sampling should not be over filled or punctured by any wire closure.
- While using sample containers, one environmental control sample comprising of empty container being exposed to the same conditions as those under which the sample is being collected should also be taken accordingly.
- Depending upon the nature and type of food, the sample containers such as pouches, bags, bottles, glass, metal containers, cans and jars should be selected.
- Each and every sample container should be marked with full details of the sampling in a manner depicted in the sampling plan.
- All the samples in which there is possibility of microbial growth should be held in ice, dry ice or freezing mixture depending upon the type/nature of food and should be transported to the laboratory under refrigerated conditions.
- The sample should be transported to the laboratory under the specified storage conditions only.
- Frozen or refrigerated products should be transported in insulated containers of rigid construction.
- Frozen samples should be collected and transported in its original frozen form.
- Dehydrated and dry foods may be shipped and stored without refrigeration and should not be allowed to absorb any atmospheric moisture. All these materials should be stored in a clean, cool and dust free place until required for analysis.
- Refrigerated products should not be frozen, unless otherwise specified.
- The storage conditions for the food products should be maintained as specified below.

Sr. No.	Product	Storage Condition Temp. (Deg. C.)	Storage Period
1	Frozen & Refrigerated Foods	Freezer & Refrigerator	One Week
2	Highly Perishable Foods	Freezer	One Week
3	Liquid Food	Refrigerator	One Week
4	Semi Solid or viscous Foods	Refrigerator	One Week
5	Fragile Foods	27 ± 2 deg. C.	One Month
6	Solid Dry Foods	27 ± 2 deg. C.	One Month

4.2 Sampling Plan for Food Samples

4.2.1 Sample Container, Sampling Device and Instruments

- Clean dry sterile, leak proof containers of wide mouth stainless, steel cans with tight fitting lids, jars, Glass bottles or disposable plastic bags of capacity minimum 200gm.
- Sterile spoons, pipettes, swabs forceps, tongs, scoops and spatula.
- Sterile scissors, chisel & knives.
- Label or marker.
- Insulated box Capable of chilling sample to 10C to 50C for a few hours.
- Sterilizing Equipment: Disinfectant (70% IPA).

4.2.2 Size and Number of samples:

The food sample should be taken as per parameter to be tested and as per the extant Food Safety and Standards Rules and Regulations. The sample size should be minimum 200gm or 200ml. Sample should be representative of the whole lot/batch/container and homogenized.

4.2.3 Sampling Procedure:

Hands should be cleaned with disinfectant before sampling and sterilized hand gloves should be used. The sample should be collected in the original unopened container or otherwise transfer representative portions from open container using sterile spoon knife or spatula. The sampling equipment should be sterilize using IPA before taking samples and aseptic conditions should be maintained as far as possible.

A Preparation of sampling appliances and containers

(a) Sampling appliances:

- For liquid products: Stainless steel tubes, dippers, glass pipette or any suitable sterile container available.
- For solid and semi-solid products: Drills triers, spoons, scalpels, spatula, scoops, knives made up of stainless steel
- For sample containers use wide mouth glass jars and bottles of 50 or 100 ml or large capacities as per requirements and they should be closed by glass stoppers or screw caps.
- Stainless steel cans with tight fitting lids, sterile stomacher bags may be used depending on the type of products

B Drawing samples:

- (a) Small packages or containers:** In case of all types of foods and food products sold in sealed containers (bottles, tins, cans, cartons etc.), the original unopened containers should be selected randomly and send to the laboratory.
- (b) Large and bulk containers:** Samples of unfrozen food and food products in the form of liquid, semi liquids, jellies, powder or grains of uniform consistency held in large tins, cans, bags etc. should be drawn in the following manner:
- After cleaning and sterilizing the site by flaming or IPA, open the lid aseptically as far as possible or pierce holes of convenient size on the top of the container (use sterile knife or any other sharp sterile instrument)

- With the help of sterile spoon, scoops, tier tubes or pipette take equal quantities of materials from different part of the container and transfer to the sterile container.
- In case of liquid samples, the material should be properly mixed with the help of sterile dipper or other equipment before drawing the samples.
- Samples should be drawn from each container of the selected lot and transfer to separate sterile container
- The total amount of sample to be drawn from each container should be minimum 200g or 200ml.

(b.1) Sampling procedure for specific products:

Frozen Foods

- Open the cans aseptically and remove little frozen material from the surface at 3 different areas using sterile chisel.
- Drill 3 cores at these places from top to bottom of the container.
- Transfer the sample to the chilled sample container with a sterile spoon and should be kept in frozen condition by packing it in an insulated box with dry ice.
- Drill a fourth hole for examination of odour.

Whole fruits, shell eggs, Fish and Oysters

- A representative no. of fruits, eggs, fish and oyster should be selected at random from different containers using aseptic precautions.
- Transfer the samples to sterile jars, cartons or cans, poly bags.

Fresh meat and meat products

- In case of meat and meat products, to get true micro flora it is necessary to take representative samples from the surfaces as well as deeper portion surfaces.
- Scrap out thin portions from various positions on surfaces using sterile scalpel, knife or spatula and transfer to a sterile sample container or in sterilize poly bags.

Dehydrated and dried foods

- Open the container aseptically.
- With sterile spoon draw portion from all parts of each container selected from the lot.
- Transfer the sample to sterile glass jar or can having tight fitting lids.
- If the sample contains big lumps of solids, then use sterile triers or scoop for drawing out cores of the sample.

Cooked Food Products

- Remove the covering on the product with the help of sterile forceps/scissor.
- Sterile Poly bags should be used for collecting samples

- Aseptically collect sufficient sample in the labelled sterile container.

4.2.4 Labeling:

All sample containers should be marked or labeled immediately before or after sample is taken. The labels have to be well coded. The sample should be marked as:

- a. Sample name
- b. Nature and Type of sample
- c. Sample Batch or code number, if applicable
- d. Identification No
- e. Sample Quantity
- f. Sampling location
- g. Temperature at the time of sampling
- h. Sample drawn by
- i. Date and time of sampling
- j. Transportation and storage condition

4.2.5. Transportation and Storage:

The sample drawn should be transported to the Laboratory for testing as quickly as possible preferably within 24hrs.

- Dehydrated and dry foods stored without refrigeration should not be allowed to absorb any atmospheric moisture.
- Unfrozen liquid or semi-solid foods contained in unopened container should be transported to the lab in refrigerated condition (4⁰C to 8⁰C) or without refrigeration as mentioned in the label regarding storage requirements of the food products.
- Samples drawn from original packing transferred to new container should be held at 4⁰C to 8⁰C during transportation, but should not be frozen.
- Meat and meat products, poultry and fish should preferably be transferred under wet ice refrigeration to avoid dehydration at the surface of the sample.
- Frozen food products should be kept in dry ice while transportation.

5. Collection of Water Sample for Microbiological Examination (As per guideline of IS: 1622 – 1981 & APHA)

- Hands should be cleaned with disinfectant before sampling and new sterilized hand gloves should be used.
- Bottle should be sterilized as per protocol APL/ QUAL/005/02, then wrapped with aluminium foil or sterilized disposable plastic bottle.
- Sampling Procedure – Bottle should be kept stoppered until it is required for filling. The stopper should be removed with care to eliminate foiling. Cap should be removed and held in one hand and after collecting sample bottle should be stoppered immediately.
- Size of the sample – The volume of the sample should be taken in sufficient amount for carrying out all the tests required (not less than 500 ml). The sampling bottle should not be filled up to the brim and 2.5 cm space should be left for effective shaking of the bottle.

- Preservation and Storage – The initial time limit for starting an analysis should be one hour but not more than 6 hours after collection of water sample.
- Identification Data – Sample label should contain all related information regarding the test.
 - Date and time of sampling
 - Type of sample
 - Sample code
 - Sampling location
 - Temperature at the time of sampling

6. Precautions

- The samples should be representative of whole lot and the number of units to be selected from a lot shall depend upon the size of lot.
- If there is wide variation between different units e.g. when a consignment is from different manufacture, then every unit should be sampled.
- In the case of products in bulk or in large containers representative sample should be drawn in a protected place not exposed to damp air, bright light, dust and transferred to sterile containers under aseptic conditions as far as possible.
- All precaution should be taken, to protect the samples, the sampling instrument and sampling containers against adventitious contamination at the time of drawing of samples, opening containers and transferring samples.
- Sampling appliance should be cleaned and sterile.
- Examination of the samples should be supplemented with inspection of the premises, processing equipment and personnel hygiene.
- The samples should be transported to the laboratory as quickly as possible.