GUIDANCE DOCUMENT

FOODBORNE DISEASES

OUTBREAK INVESTIGATION

Prepared by: Capability Harnessing Initiative for Food Safety Sciences (CHIFSS)

Supported by

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ON

FOODBORNE DISEASES OUTBREAK INVESTIGATION

Prepared by	:	Capability Harnessing Initiative for Food Safety Sciences (CHIFSS)
Dated	:	7th June 2022
Version	:	1.0

Published by Capability Harnessing Initiative for Food Safety Sciences (CHIFSS); Confederation of Indian Industry

Contents

Acknowledgement

CHIFSS (*Capability Harnessing Initiative on Food Safety Sciences*) expresses its sincere appreciation to the authors and reviewers of these guidelines including

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Purpose of the guidance document

An outbreak of foodborne infection can pose a significant challenge to national health and economic security. Therefore, in addition to the continued control measures to prevent foodborne infections, it is critical for the country to be prepared and in a position to respond rapidly in case of any potential illness outbreak. During the national level round table on microbiological safety of foods (2017), experts suggested the need for a comprehensive and combined guidance document that would guide key stakeholders from Health and Food Safety sector working at National and State levels, on how to coordinate, communicate and plan the actions, while handling the foodborne illness outbreak investigations and responses to food borne illnesses which have an impact on human health and economy. Further, FSSAI constituted Food Safety Risk Assessment Committee (FSRAC) for providing scientific and technical support during food safety emergency in the country dated 27th October 2020 under the order No. 1-11/INFOSAN-2019/FSSAI-2019. The FSRAC suggested food borne diseases surveillance program which then after formulated under the directives of FSSAI Section 16(5) of Food Safety and Standards Act, 2006 regarding managing and reporting of Food Borne Illness Outbreak dated 26th October 2021 File No. RCD-020001/1/2021-Regulatory-FSSAI.This guidance document is aligned with the recent FSSAI directives under Section 16(5) of Food Safety and Standards Act, 2006 including the harmonized methodologies with practical elaborative approach applicable to all, and cover under;

a) Patient and clinical aspects of investigation &

b) Microbiological sample collection for analysis of suspected food commodities

c) Process of collaboration, training and coordinated actions by different authorities in handling the outbreaks.

Given the complexity of India's food & health administration and lack of state-of-the-art technical capabilities & infrastructure and stretched capacities on the ground, such a document is expected to set clear direction, train and help stakeholders in responding quickly, pragmatically and confidently, backed by sound science.

It is proposed that both Foods Safety Standards, Authority of India and National Center for Disease Control, Ministry of health, disseminates this document to key state authorities and jointly plan extensive orientation and training of relevant staff who are engaged in responding to public health challenges (related to food consumption).

This document can be used to develop a ready reckoner for each stakeholder.

Executive summary

Foodborne pathogens cause many acute and life-threatening diseases which are worsened in the developing world. Globally, Asia and sub-Saharan Africa have the highest incidence of FBDs, along with the highest rate of deaths due to FBDs and the greatest loss of disability adjusted life years (DALYs). Unsafe food and the subsequent illnesses cost India as high as $15 billion annually and pose a preventable yet unnecessarily high economic burden. India along with China accounts for 49% of the total economic burden due to food borne diseases (FBDs) in low- and middle-income countries (LMICs) and for 71% of the total burden in Asia. The Food Safety and Standards Authority of India (FSSAI) has been actively working to streamline food safety regulations, laws and policies; and has demonstrated that better health and commercial outcomes are possible with the joint involvement of public agencies, businesses, and consumers in food safety. Of late, FSSAI has taken a series of measures including stringent packaging and labelling norms, regulation of restaurant and street food as well as inspections and sampling of food products to ensure quality of food in India. Further, FSSAI constituted Food Safety Risk Assessment Committee (FSRAC) for providing scientific and technical support during food safety emergency in the country dated 27th October 2020 under the order No. 1-11/INFOSAN-2019/FSSAI-2019 while formulating directives under Section 16(5) of Food Safety and Standards Act, 2006 regarding managing and reporting of Food Borne Illness Outbreak dated 26th October 2021 File No. RCD-020001/1/2021-Regulatory-FSSAI.

To further develop stringent control measures and increase public awareness to the FBDs, a national level round table on microbiological safety of foods (2017) was conducted by FSSAI and the suggestions and recommendations reiterated the need for a comprehensive and combined guidance document that covered both; a) patient and clinical aspects of investigation & b) Microbiological sample collection for analysis of suspected food commodities. Therefore, this document provides comprehensive guidelines and procedures for surveillance, training and reporting of food borne diseases along with the food mediated epidemics. The document provides detailed information on the responsible pathogens including bacteria and viruses, their mode of transmission and casual symptoms. This gives the basis to identify sources, vectors and types of sample collection required for the confirmation of an ailment. The most common ailments arise from bacteria and viruses causing up to 90% of the foodborne diseases in the past with a varying incubation period from

12-48 hours leading to often confusing causal symptoms such as diarrhea. The document also covers fundamental concept of food microbiology outlining food handling, sanitation, storage and cooking procedures to minimize the risk to consumers. Further, guidelines identify specific roles of participating organizations in planning and preparation of the surveillance program at National and state Level. The key national partners include Ministry of Health & Family Welfare (MOH&FW) which responding to every outbreak including the food borne disease related outbreaks along with FSSAI and NCDC under the Directorate General of Health Services, MOH&FW, Government of India (GoI). The NCDC is referred to as nodal agency for monitoring outbreaks in the country under Integrated Disease Surveillance Programme (IDSP). While FSSAI acts as a regulatory body for making food and environment safer. The health care service providers are backbone for entire program at both central and state levels in providing services to the diagnosed patients. The dissemination of the information and its implementation would not be possible without engagement of media partners and the stakeholders 'public'.

When a rising trend of illness is observed in an area, an epidemiological investigation is conducted by a Rapid Response Team (RRT) established at the district levelheaded by a District surveillance officer, to verify, diagnose and take appropriate control measures for the outbreaks. FSSAI has developed structured **Food Safety Emergency Response (FSER) system** to prevent the food safety related events and emergencies and manage/respond to such situations in timely manner. Therefore, guideline document entails system of flow of information and dissemination through the media to the public. The guidance document also provides detailed information of most common research methodologies, statistical analysis methods, common terminology, food recall procedures, sample forms, collection forms and surveillance process. Additionally, it highlights importance and role of the environment in which food is processed along with the food handlers. The document also guides on patient and food sample collection, types of collections, sources of collections such as environment of processing and food specimens.

Considering the rise in food borne diseases it is imperative that the existing surveillance network should be brought to public attention for vigilant responses from the public. In conclusion this guidance serves both the purposes of dissemination of knowledge on existing system of surveillance along with the awareness of common ailments and reporting procedures further strengthening food safety network while improving the control measures.

List of Abbreviations

CEO: Chief Executive Officer	**CFU**: Colony Forming Unit
DALYs: Disability Adjusted Life Years	**DO**: Designated Officer
DSO: District Surveillance Officer	**FAO**: Food and Agriculture Organization
FBO: Food Business Operators	**FDA**: Food and Drug Administration
FSS: Food Safety and Standard	**FSSAI**: Food Safety and Standards Authority of India
FSER: Food Safety Emergency Response system	**FSO**: Food Safety Officers
GoI: Government of India	**HACCP**: Hazard Analysis and Critical Control Points
IDSP: Integrated Disease Surveillance Program	**IHR**: International Health Regulation
INFOSAN: International Food Safety Authorities Network	**IPD**: Inpatient Department
JCC: Joint Communication Centre	**KPC**: Key Process Control
MOH&FW: Ministry of Health & Family Welfare	**NABL**: National Accreditation Board for Testing and Calibration Laboratories
NCDC: National Centre for Disease Control	**NECP**: National Emergency Contact Point
NFP: National Focal Points	**OPD**: Out Patient Department
PHC: Primary Health Centers	**PHF**: Potentially Hazardous Food
RRT: Rapid Response Team	**SSOs**: State Surveillance Officer
STEC: Shiga Toxin producing- *E. coli*	**THO**: Taluka/ Block Health Officer
UTs: Union Territories	**WHO**: World Health Organization

Chapter 1 – Food Borne Disease – Fundamental

1.1 Food borne diseases

Food borne diseases or food borne illnesses refer to the wide spectrum of illnesses that are transmitted via food as a vehicle and are a growing public health problem worldwide. They are the result of spoilage of contaminated food with microorganisms or chemicals. The contamination of food may occur at any stage in the process from food production to consumption and can result from environmental contamination, including pollution of water, soil or air. Food borne illness usually arises from improper handling, preparation, or food storage.

The most common clinical presentation of food borne disease takes the form of gastrointestinal symptoms such as acute diarrhea, vomiting, abdominal pain and/or fever; however, such diseases can also have neurological, gynecological, immunological and other symptoms. Multi-organ failure and even cancer may result from the ingestion of contaminated foodstuffs, thus representing a considerable burden of disability as well as mortality.

1.1.1 Classification of Food Borne Diseases

Food borne diseases are classified into

1. Food borne infections and
2. Food borne intoxications

Food borne infection results when foods contaminated with live, pathogenic, food poisoning bacteria are eaten. These bacteria then proliferate in the human body and eventually cause illness. Food intoxication follows the ingestion of contaminated food containing preformed toxic substances which accumulate during the growth of certain bacterial types in foods.

Causes of food borne illness

Food borne pathogens

Bacteria	Viruses	Parasites
Campylobacter jejuni *Clostridium perfringens* *Salmonella* spp. *Escherichia coli O157:H7* • *Bacillus cereus* • *Escherichia coli* with other virulence properties, such as enteroinvasive (EIEC), enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroaggregative (EAEC or EAgEC) • *Listeria monocytogenes* • *Shigella* spp. • *Staphylococcus aureus* • *Vibrio cholerae*, including O1 and non-O1 • *Vibrio parahaemolyticus* • *Vibrio vulnificus* • *Yersinia enterocolitica* and *Yersinia pseudotuberculosis* • *Clostridium botulinum* A.B.E.F toxin	• Hepatitis E • Hepatitis A • Norovirus • Rotavirus • Enterovirus	• Platyhelminthes ○ *Diphyllobothrium* sp. ○ *Nanophyetus* sp. ○ *Taenia saginata* ○ *Taenia solium* ○ *Fasciola hepatica* • Nematode ○ *Anisakis* sp. ○ *Ascaris lumbricoides* ○ *Eustrongylides* sp. ○ *Trichinella spiralis* ○ *Trichuris trichiura* • Protozoa ○ *Acanthamoeba* and other free - living amoebae ○ *Cryptosporidium parvum* ○ *Cyclospora cayetanensis* ○ *Entamoeba histolytica* ○ *Giardia lamblia* ○ *Sarcocystis hominis* ○ *Sarcocystissuihominis* ○ *Toxoplasma gondii*

Naturally-occurring toxins

- Mushroom toxins
- Mycotoxins (like aflatoxin B1, B2, G1, G2, M1, M2, ochratoxin A, fumonisin, zearalenone etc.)
- Marine toxins like:
  - Shellfish toxin, including paralytic shellfish poisoning, diarrheic shellfish poisoning, neurotoxic shellfish poisoning, amnesic shellfish poisoning
  - Ciguatera fish poisoning
  - Tetrodotoxin (Puffer fish poisoning)
- Grayanotoxin (honey intoxication)
- Phytohaemagglutinin (red kidneybean poisoning; destroyed by boiling)
- Pyrrolizidine alkaloids
- Scombrotoxin

1.1.2 Characteristics of the Important Bacterial Food Intoxications and Food Borne Diseases

Disease	Etiologic Agent	Incubation Period	Symptoms	Clinical sample for analysis
Staphylococcal food poisoning	Staphylococcal enterotoxin	1 to 6 hours; average 3 hours	Nausea, vomiting, abdominal cramps, diarrhea, and acute prostration. Temperature subnormal during acute attack, may be elevated later. Rapid recovery-usually within 1 day.	Stool, vomitus, nasal swab
Salmonellosis	Specific infection by *Salmonella* spp.	Average about 18 hours; range 7 to 72 hours	Abdominal pains, diarrhea, chills, fever, frequent vomiting, prostration. Duration of illness: 1 day to 1 week.	Stool, Rectal swab
Shigellosis (bacillary dysentery)	*Shigella sonnei, s. flexneri, s. dysenteriae, s. boydii*	Usually 24 to 48 hours; range 7 to 48 hours	Abdominal cramps, fever, chills, diarrhea, watery stool (frequently containing blood, mucus, or pus), spasm, headache, nausea, dehydration, prostration. Duration: a few days.	Stool, Rectal swab
Botulism	*Clostridium botulinum* A.B. E.F toxin	Usually 1 to 2 days; range 12 hours to more than 1 week	Difficulty in swallowing, double vision, difficulty in speech. Occasionally nausea, vomiting, and diarrhea in early stages. Constipation and subnormal temperature. Respiration becomes difficult, often followed by death from paralysis of muscles of respiration.	Blood, stool, gastric washing

Enteropathogenic *Escherichia coli* infection	*Escherichia coli* serotypes associated with infant and adult infections	Usually 10 to 12 hours; range 5 to 48 hours	Headache, malaise, fever, chills, diarrhea, vomiting, abdominal pain. Duration: a few days.	Stool, Rectal swab
***Clostridium perfringens* food poisoning**	*Clostridium perfringens*	Usually 10 to 12 hours; range 8 to 22 hours	Abdominal cramps and diarrhea, nausea, and malaise, vomiting very rare. Meat and poultry products usually involved. Rapid Recovery.	Stool, Rectal swab
***Bacillus cereus* food poisoning**	*Bacillus cereus*	Usually about 12 hours; range about 8 to 16 hours	Abdominal cramps and diarrhea, nausea, and malaise, vomiting very rare. Meat and poultry products usually involved. Rapid Recovery.	Stool, Rectal swab
***Vibrio Parahaemolyticus* food poisoning**	*Vibrio Parahaemolyticus*	Usually 12 to 14 hours; range 2 to 48 hours	Abdominal pain, server watery diarrhea, usually nausea and vomiting, mild fever, chills and headache. Duration: 2 to 5 days.	Stool
Mycotoxicosis	*Aspergillus flavus* *Aspergillus parasiticus* *Amanita sp.* *etc.*	6 to 24 hours	Nausea, vomiting, diarrhea, thirst, dilation of pupils, collapse, coma	Urine, blood, vomitus, stool
Viral food infections	*Norovirus* *Rotavirus* *Astrovirus* *Enteric adenovirus*	12 to 48 hours	Fever, vomiting, watery diarrhea	Stool, vomitus
Amoebic dysentery	*Entamoeba histolyitca*	1 to several weeks	Abdominal pain, diarrhea, constipation, headache, ulcers	Stool

Shell fish Intoxication	*Shell fish toxin*	< 1 hour	Neurological and/or gastrointestinal symptoms, paralysis	Gastric washing
Taeniasis	*Taenia solium* *Taenia saginata*	3 to 6 months	Nervousness, insomnia, anorexia, weight loss, abdominal pain, sometimes gastroenteritis	Stool, rectal swab
Chemical Intoxication	*Metallic salts* *Nitrites* *Organic phosphate* *Organic mercury etc.*	Variable (< 1 hour to >72 hours) based upon the chemical toxicant	Nausea, vomiting, headache, diarrhea, dizziness, paralysis etc.	Vomitus, urine, blood, stool

1.1.3 Transmission of Food Borne Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. The failure of food-handlers to wash hands in certain situations (such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage), wear clean disposable gloves, or use clean utensils is responsible for the food borne transmission of these pathogens.

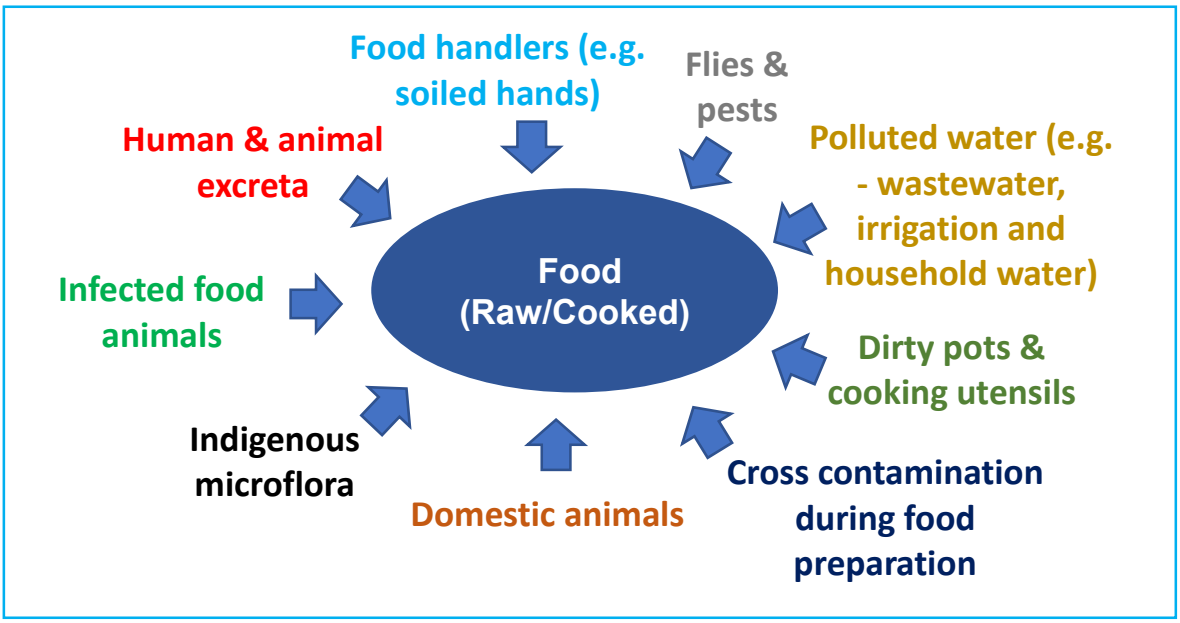


Figure 1.1 Sources for transmission of food-borne pathogens

Non-food borne routes of transmission, such as from one person to another, is also major contributor in the spread of these pathogens. Some pathogens usually cause disease when food is intrinsically contaminated or cross contaminated during production, processing or transportation, but may also be contaminated when prepared by infected persons (Fig. 1.1). Bacterial pathogens in this category often cause disease after bacteria have multiplied in food after it has been kept at improper temperatures permitting their multiplication to an infectious dose.

The period of time between the consumption of contaminated foods and the appearance of illness is called the incubation period. The incubation period can range anywhere from less than one hour to more than three days, depending on the causative organisms or the toxic product. During the incubation period, **microbes** pass through the **stomach** into the **intestine**, attach to the **cells** lining the intestinal walls, and begin to multiply there. Some types of microbes stay in the intestine, some produce a **toxin** that is absorbed into the **bloodstream**, and some can directly invade the deeper body tissues. The symptoms produced depend on the type of microbe.

The **infectious dose** is the amount of agent that must be consumed to give rise to symptoms of food borne illness and varies according to the agent and the consumer's age and overall health. Pathogens vary in minimum infectious dose; for example, ***Shigella sonnei*** has a low estimated minimum dose of < 500 **colony-forming units** (CFU) while ***Staphylococcus aureus*** has a relatively high estimate of at least 100,000 CFU's for successfully infecting human beings.

In the case of ***Salmonella*** a relatively large inoculum of 1 million to 1 billion organisms is necessary to produce symptoms in healthy human volunteers, as *Salmonellae* are very sensitive to acid. An unusually high stomach **pH** level (low acidity) greatly reduces the number of bacteria required to cause symptoms by a factor of between 10 and 100.

Table 1.1 Infectious dose of various food borne pathogens

Microorganism	Infectious dose	References
Salmonella spp.	10^4 bacteria	D'Aoust *et al.,* 2001
C. jejuni.	<1000 bacteria	Nachamkin, 2001
L. monocytogenes	>100 bacteria/g*	Swaminathan, 2001
E. coli O 157	4-20 (<50) CFU	Strachan *et al.,* 2001
Y. enterocolitica	>10^4 CFU	Robins-Browne, 2001
Virus	1-10 virus particles	Vasickova *et al.,* 2005
Giardia lamblia	10-100 cysts	Smith & Grimason, 2003

*Number in contaminated food responsible for foodborne human cases

1.2 Fundamental Concept of Food Microbiology

1.2.1 Potentially Hazardous Food (PHF)

It is a term used by **food safety** organizations to classify foods that require time-temperature control to keep them safe for human consumption. A PHF is a food that:

- Contains moisture - usually regarded as a **water activity** greater than 0.85
- Contains protein
- Is slightly basic to neutral to slightly acidic - typically having a **pH** between 4.6 and 7.5

Examples of potentially hazardous foods include

- Raw and cooked meat, or foods containing meat such as casseroles, curries and lasagna
- Poultry products such as eggs
- Dairy products such as milk, custard and dairy-based desserts
- Seafood (excluding live seafood)
- Processed or cut fruits and vegetables, such as salads
- Cooked rice and pasta

1.2.2 The top five risk factors that most often are responsible for food borne illness outbreaks are

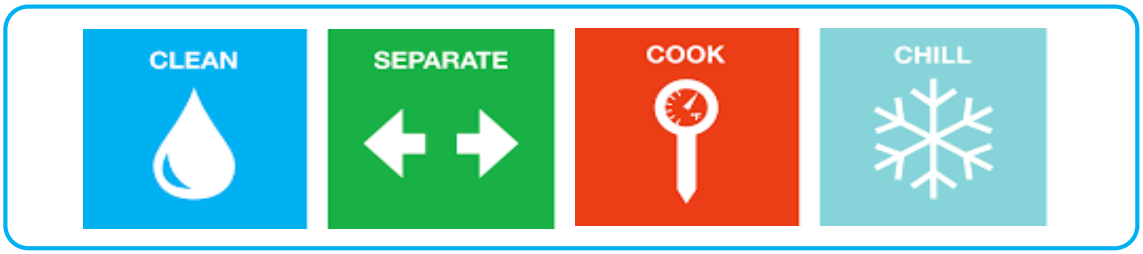
- Improper hot/cold holding temperatures of potentially hazardous food.
- Improper cooking temperatures of food.
- Dirty and/or contaminated utensils and equipment.
- Poor employee health and hygiene.
- Food from unsafe sources.

1.2.3 Food Preparation and Handling

Preparation

- Always wash hands with warm water and soap for 20 seconds before and after handling food.
- Clean all work surfaces after each use.
- Wash food surfaces with hot, soapy water, then rinse.
- Sanitize food work surfaces by spraying a safe sanitizing solution.

- Wash kitchen towels, sponges, and cloths often. Bacteria can live and grow on these items.
- Wash cutting boards and knives in hot soapy water. Rinse and sanitize utensils after cutting up raw meat, poultry, and fish and before using the utensils to prepare other food.
- Keep raw meat, poultry and fish and their juices away from other foods.
- Thaw food in the refrigerator, microwave oven, or under cold running water. Do not thaw food on the kitchen counter.
- Prepare all foods as close to serving time as possible.
- Cook meat, fish, poultry and eggs, until they reach a safe internal temperature and are completely cooked. Store cold foods below 4^0C and hot foods above 60^0C, if you are not serving them right away.
- Chill cooked food quickly so it spends the least amount of time possible in the "temperature danger zone". Proper storage keeps leftovers at their freshest, longer. Refrigerate or freeze all leftovers within two hours after cooking to minimize the chance of bacteria growing.



Food handling

Safe steps in food handling, cooking, and storage are essential to prevent food borne illness. You can't see, smell, or taste harmful bacteria that may cause illness. In every step of food preparation, follow the four steps of the Food Safe Families campaign to keep food safe

- Clean — Wash hands and surfaces often.
- Separate — Don't cross-contaminate.
- Cook — Cook to the right temperature.
- Chill — Refrigerate promptly.
- Refrigeration- do not clutter storage or completely fill

Food Storage

- Always refrigerate perishable food within 2 hours—1 hour when the temperature is above 90 °F (32.2 ºC).
- Check the temperature of your refrigerator and freezer with an appliance thermometer. The refrigerator should be at 40 °F (4.4 ºC) or below and the freezer at 0 °F (-17.7 ºC) or below.
- Cook or freeze fresh poultry, fish, ground meats, and variety meats within 2 days; other beef, veal, lamb, or pork, within 3 to 5 days.
- Perishable food such as meat and poultry should be wrapped securely to maintain quality and to prevent meat juices from getting onto other food.
- To maintain quality when freezing meat and poultry in its original package, wrap the package again with foil or plastic wrap that is recommended for the freezer.
- Canned foods are safe indefinitely if they are not exposed to freezing temperatures, or temperatures above 90 °F. If the cans look ok, they are safe to use. Discard cans that are dented, rusted, or swollen. High-acid canned food (tomatoes, fruits) will keep their best quality for 12 to 18 months; low-acid canned food (meats, vegetables) for 2 to 5 years.

1.2.4 Food Handler

A **food handler** is defined as a person who directly engages in the handling of **food**, or who handles surfaces likely to come in contact with **food**, for a **food** business.

Responsibilities of a food handler

Food handler are responsible for cooking, preparing, serving, packing, displaying and storing **food**. They must follow any safety instructions issued by an employer and conduct their **duties** in such as way so that they do not affect the health and safety of themselves, work colleagues, customers or their employers.

Personal hygiene is important to prevent **food** poisoning. When **handling food**, wash your hands thoroughly and often. If you are sick, do not go to work, because you can contaminate **food** more easily. **Food handlers** should be properly trained in safe **food handling**.

By **law**, **food** business operators **must** ensure that **food handlers** receive the appropriate supervision and **training** in **food** hygiene, which is in-line with the area they work in and will enable them to handle **food** in the safest way.

Food borne Disease and public health

The Food borne Disease Surveillance team works to identify and decrease the risk to the public from food borne illness. Protecting country residents from food borne illness is best accomplished through cooperation between the Food borne Disease Surveillance team, the Public Health Laboratory and Environmental Health Bureau of Consumer Protection's Food & Milk Program.

Therefore, collaborative effort between governments of developing countries, policymakers, researchers, and general public is imperative to reduce incidence of food borne diseases. Use of rapid methods for detection of food borne pathogens is required in developing countries

1.3 Importance and Reasons of Investigating Food Borne Disease Outbreak

Worldwide, food-borne diseases are a major health burden leading to high morbidity and mortality. The global burden of infectious diarrhea involves 3-5 billion cases and nearly 1.5 million deaths annually, mainly in young children. Diarrheal diseases are mostly caused by contaminated food and water. The WHO Southeast Asia Region has a quarter of the world's population, Annual burden of foodborne diseases in the WHO South- East Asia Region includes more than150 million illness,175 000 deaths and 12 million DALYs. Diarrheal diseases continue to be one of the top three leading causes of daily losses. It has the second highest burden of food-borne diseases per population among WHO regions. Globalization of the food supply has led to the rapid and widespread international distribution of foods. Travelers, refugees, and immigrants may be exposed to unfamiliar foodborne hazards in new environments. Changes in microorganisms lead to the constant evolution of new pathogens, development of antibiotic resistance, and changes in virulence of known pathogens. (WHO Guideline) It is estimated by the WHO that food-borne diseases are notified in only 10% of cases in developed countries and 1% in developing countries.

In India, the burden of food-borne disease is not known. Most food-borne diseases go unreported, only few are reported by the media, usually those with high morbidity and/or occurring in urban areas. The Integrated Disease Surveillance Programme (IDSP) network was launched in India in 2004. Aggregate analysis of IDSP data shows food-borne outbreaks together with acute diarrheal diseases constitute nearly half of all reported outbreaks under IDSP for the period 2011-19. While many food-borne diseases may be self-limiting, some can be profoundly serious and can lead to death particularly in children, pregnant women and older persons. Review of literature shows some of the emerging pathogens such as *Listeria monocytogenes*, *Yersinia enterocolitica*, *Campylobacter jejuni*, *E.coli* (STEC) 0157:H7 and *S*

sonnei have been isolated from humans, animals and food in India. (ref) Some of these organisms have developed high level of drug resistance. One hundred and sixty-six*Campylobacter jejuni* strains isolated from pediatric diarrhea cases (children < 5 years) at a Children's hospital in Kolkata, India from 2010- 2012 were tested for macrolide resistance. About 4% of the isolates were macrolide resistant by disc diffusion.*S. dysenteriae* and *S. flexneri* have been predominant Shigella spp in India responsible for causing foodborne illness. During 2002-2003, *S. dysenteriae* type 1 with an altered antimicrobial resistance pattern (100% fluoroquinolone resistant) was reported to have caused severe dysentery outbreaks in West Bengal. The severity of symptoms associated with *S. dysenteriae* type 1 is thought to be related to production of Shiga toxin type 1. *S. sonnei* is most common in industrialized countries and the disease is less severe, although it is less common in India. However, two foodborne outbreaks of *S. sonnei* have been reported in India in 2009-2010 from Kerala and Maharashtra.

During the national level round table on microbiological safety of foods (2017), experts suggested the need for a comprehensive and combined guidance document that would guide key stakeholders from Health and Food Safety sector working at National and State levels, on how to coordinate, communicate and plan the actions, while handling the foodborne illness outbreak investigations and responses to food borne illnesses which have an impact on human health and economy. Further, FSSAI constituted Food Safety Risk Assessment Committee (FSRAC) for providing scientific and technical support during food safety emergency in the country dated 27th October 2020 under the order No. 1-11/INFOSAN-2019/FSSAI-2019. The FSRAC suggested food borne diseases surveillance program which then after formulated under the directives of FSSAI Section 16(5) of Food Safety and Standards Act, 2006 regarding managing and reporting of Food Borne Illness Outbreak dated 26th October 2021 File No. RCD-020001/1/2021-Regulatory-FSSAI. This guidance document is aligned with the recent FSSAI directives under Section 16(5) of Food Safety and Standards Act, 2006 including the harmonized methodologies with practical elaborative approach applicable to all, and cover under.

a. patient and clinical aspects of investigation &
b. Microbiological sample collection for analysis of suspected food commodities
c. Process of collaboration and coordinated actions by different authorities in handling the outbreaks.

Chapter 2 – Planning and Preparation

2.1 Authorities Responsible for Investigation and Their Roles and Responsibilities

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

2.1.1 National Authorities

At the National level it is the Ministry of Health & Family Welfare (MOH&FW) which responds to every outbreak including the food borne disease related outbreaks.

National Center for Disease Control (NCDC) and Food Safety and Standards Authority of India (FSSAI) are key agencies responsible to conduct investigation of food borne disease related events. FSSAI as a regulatory authority is also responsible for law enforcement activities whenever the foodborne disease or outbreak is determined to be the result of noncompliance of Section 16(5) Food Safety & Standards Act 2006 and its regulation made thereafter.

2.1.1.1 NCDC

National Centre for Disease Control (NCDC) working under the Directorate General of Health Services, MOH&FW, Government of India (GoI) takes a leading role in supporting state health departments in surveillance and investigations of disease outbreaks including food borne diseases in the country, employing epidemiological and diagnostic tools. It also provides referral diagnostic services to individuals, community, medical colleges, research institutions and state health authorities. It investigates and recommends control measures for the outbreak of various communicable diseases in the States/UTs all over the country as well as to some neighboring countries in the Southeast Asia Region. Implementing Integrated Disease Surveillance Programme (IDSP), a systematic data collection system used for collection of information on disease trends from the states and districts.

The NCDC is the nodal agency for monitoring outbreaks in the country through the Integrated Disease Surveillance Programme (IDSP);IDSP is a decentralized state-based disease surveillance programme for generating early warning signals, early detection of outbreaks and initiating timely response. Surveillance units have been set up in more than 700 districts across India. Surveillance data is collected on weekly basis for preidentified disease

conditions. Emphasis is laid for reporting of surveillance data from all sources including public and private health facilities.

When a rising trend of illness is observed in an area, an epidemiological investigation is conducted by a Rapid Response Team (RRT) to verify, diagnose, and take appropriate control measures for the outbreak. The RRT is established at the district level which is headed by a District surveillance officer.

Role of stakeholders at Central Level

NCDC is the nodal agency to provide leadership in investigating multi-jurisdiction outbreaks in collaboration with state health authorities and other national and international partners. NCDC being a National focal point for International Health Regulations (2005) is also responsible to communicate public health risks that have the potential for cross border(spread), to WHO.

National Centre for Disease Control (NCDC) role

1. The National surveillance of acute diarrhoeal diseases including foodborne diseases and collaboration with state authorities in investigating the outbreaks.
2. The NCDC provides technical support and leadership in systematically investigating outbreaks using epidemiological approaches.
3. Training of medical officers and other public health officials to address foodborne outbreaks and control, management techniques.
4. Train and augment laboratory capacity with state agencies to process an increased volume of clinical samples.
5. Issue health related alerts to the state health departments to increase the surveillance of new or unusual clusters of illness.

2.1.1.2 Food Safety and Standards Authority of India (FSSAI)

Food safety & Standards Authority of India is a statutory body established in 2008 under Food Safety &Standards Act 2006 and works under the aegis of Ministry of Health and Family Welfare. FSSAI is mandated for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

FSSAI has been mandated by the FSS Act, 2006 for performing the following roles

1. Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
2. Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.

3. Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
4. To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
5. ***Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.***
6. Creating an information network across the country so that the public, consumers, Panchayats etc. receive rapid, reliable and objective information about food safety and issues of concern.
7. Provide training programs for persons who are involved or intend to get involved in food businesses.
8. Contribute to the development of International technical standards for food, sanitary and phyto-sanitary standards.
9. Promote general awareness about food safety and food standards.
10. Food Authority has developed a framework of national Food **Safety Emergency Response (FSER) system** which outlines the multi sectorial coordination, their roles, responsibilities and management of actions during a food safety emergency situation. The Food Safety Emergency Response (FSER) Plans 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.

The critical parameters of FSER system are

1. Identifying the emerging food safety hazards through the framework of monitoring and surveillance of production chain and the food products.
2. Assessing the risk associated with the hazard that are of national and global importance.
3. Communication and dissemination of information on the risk to all stakeholders in case of emergencies.

FSSAI will be the national emergency contact point for FSER and other agencies who have a stake in food safety will act as National focal points, the State Food Safety Commissioners, custom officers, representatives from other organizations and ministries will act as nodal officers for NFPs.

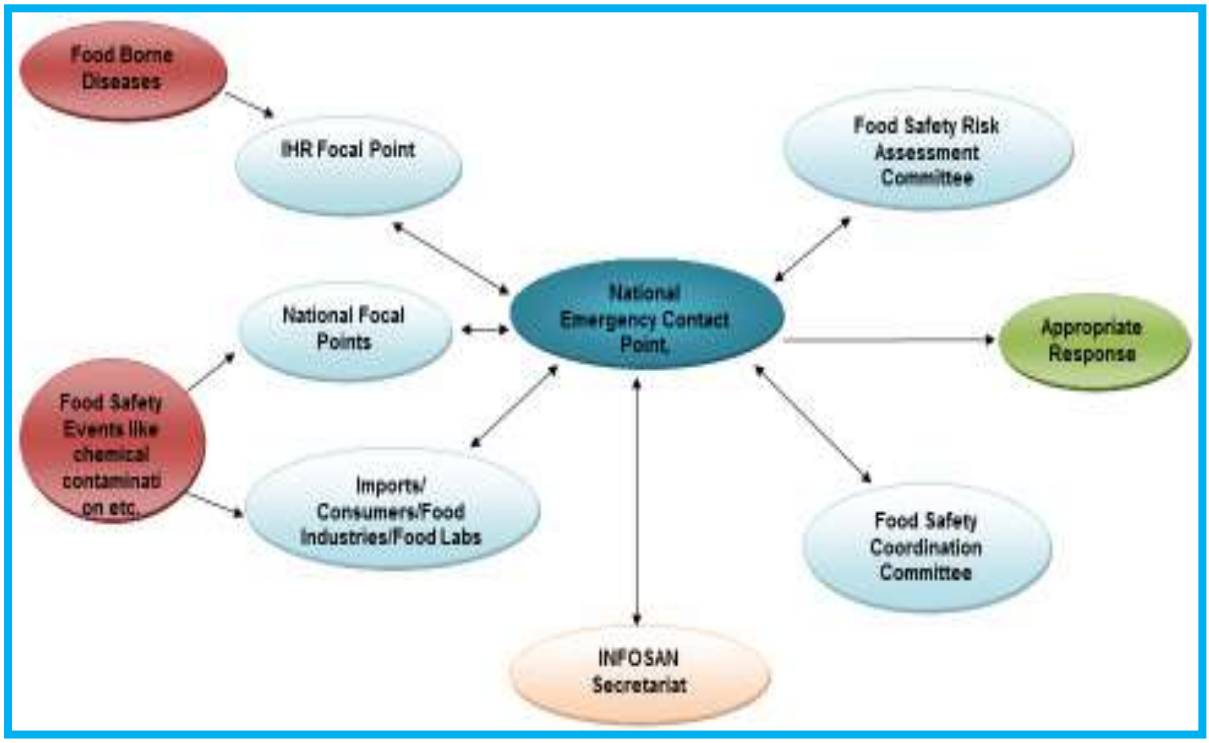
Roles and Responsibilities

National Focal Points (NFP)

1. Collaborates with and provides technical support to the National Emergency Contact Point (NECP) on food safety events and emergencies involving their respective agency.
2. Engage in sharing information with national emergency contact point and other members on food safety issues that may be relevant at the international level and beneficial to all members, such as, but not limited to risk assessments on emerging hazards, lessons learnt, identified good practices, etc.
3. Collaborates with National IHR (International Health Regulation) Focal Point on food safety events that fall under the IHR. Disseminate the INFOSAN (International Food Safety Authorities Network) Information Notes, FAO/WHO guidelines, and other important food safety information from INFOSAN within their agency, as appropriate.

The Food Safety Risk Assessment Committee will be responsible for the technical and laboratory support and provide the preliminary risk assessment data to identify the emergency situation and their levels of severity in order to support the Food Safety Coordination Committee. The Food Safety Coordination Committee will assist in providing an effective coordination of finance and resources in management of food safety emergencies.

Components in coordination of National Emergency Contact point in FSER System



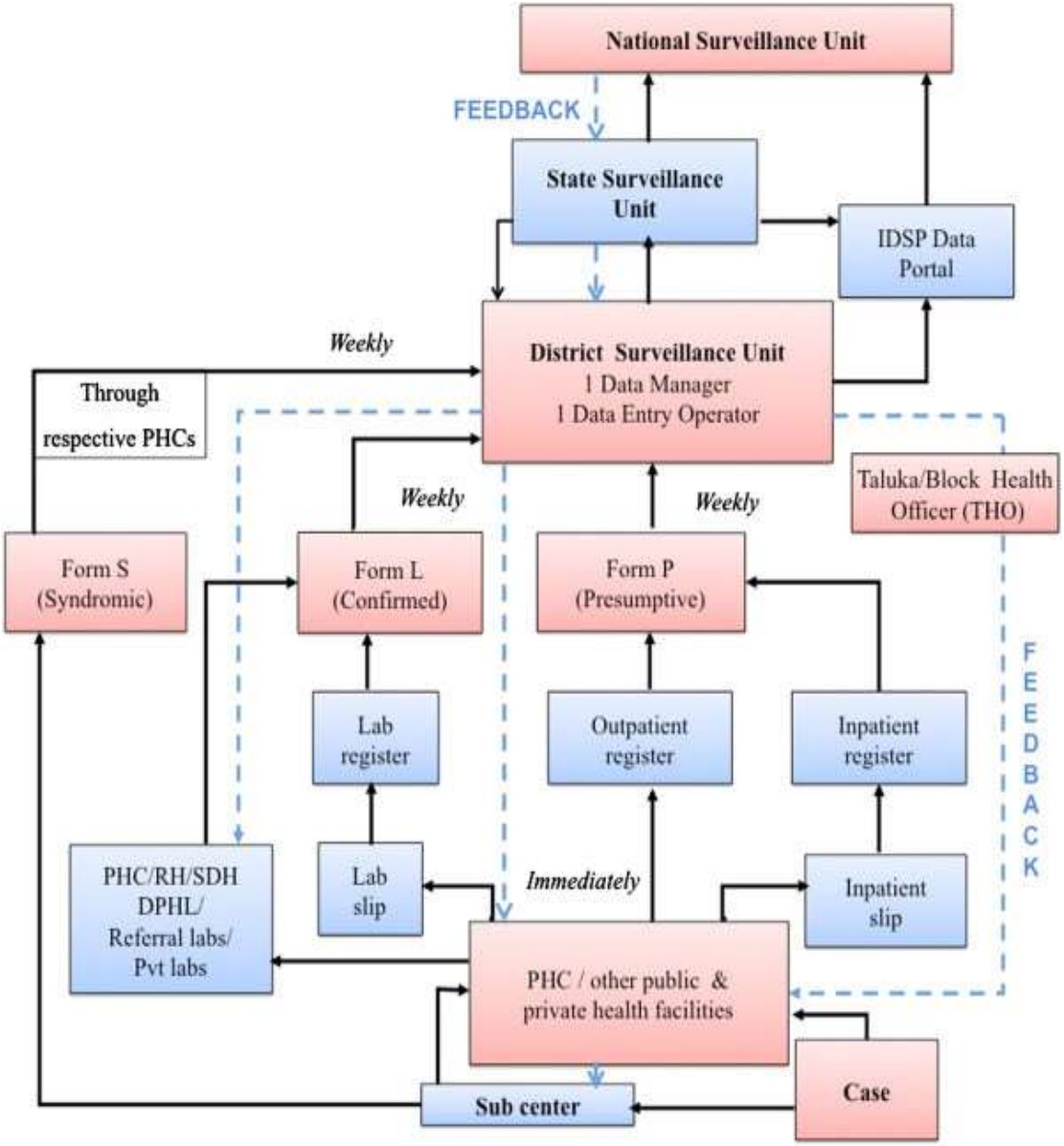


Figure 2.1 Information flow of Food Borne Disease Surveillance by IDSP.

Roles and Responsibilities of other structural components of the FSER system

State Surveillance Officer (SSOs) will be responsible for:

1. Facilitate collection of food consumption history of patients during food borne disease outbreaks and other relevant epidemiological data.
2. Facilitate collection and analysis of stool samples of patients during food borne disease outbreaks.

3. Dissemination of information/data related to the Food borne disease outbreak received from the District Surveillance Units to the Food Safety Officers in the district and FSO will further share it with National emergency contact point.
4. Share the monthly report of foodborne disease as collected under IDSP with state food safety commissioners / designated officers of State food department.

State Food Safety Commissioners will be responsible for:

1. Transmitting the data to the national emergency Contact Point and also to Food Safety Risk Assessment Committee for further analysis.
2. Reporting any food related incident to national emergency Contact Point.
3. Taking immediate actions on the decisions given by national emergency Contact Point.

Role of Stakeholders at State level

State Health Departments (State Surveillance Units under IDSP)

The State Surveillance Units in the Health departments of each State have the mandate to investigate outbreaks and are responsible to control the human illness related to the outbreaks in their state, with the help of RRT (Rapid Response Team). The State Surveillance officer is the nodal officer and has to lead or nominate a team lead for the RRT and wherever required they will work in coordination with other departments (e.g., FDA, Municipalities, local bodies, PHCs).

State Surveillance units

1. To constitute a multidisciplinary team and investigate suspected foodborne outbreaks in the local area/ state and provide mitigation and control strategies to the health departments.
2. Provide technical assistance and support to districts when requested, regarding the investigation and follow-up of foodborne outbreaks.
3. Provide training and support in proper collection of clinical samples and handling of clinical and environmental samples.
4. Coordinate with State FDA in developing a sampling plan (with inputs from epidemiological investigation) for high-risk foods regulated under FSS Act 2006.
5. Coordinate with State FDA in developing an environmental investigation plan of food manufacturing, storage and distribution chain, if required.

6. Coordinate with other departments that may be directly or indirectly involved in management of the food borne diseaseoutbreaks.
7. Define training requirements for health and food safety officials and other agencies involved with emergency response operations.
8. Report the epidemiological findings to the State and central health authorities for drawing the conclusions and decision making.
9. Training and developing centraland state public health workforce to improve food borne disease surveillance, investigation and response.
10. Awareness generation and educating the public about the outbreaks and how to reduce the risk to human health.

State Food and Drug Administration (FDA)

The State FDAs are government bodies operating under State health departments and are primarily responsible for implementing the Act and its regulations. Each state FDAs are manned by State Food Safety Commissioner appointed by the State government for efficient implementation of Food Safety and standards Act and other requirements laid down under the Act and rules and regulations made thereunder in state.

Roles and Responsibilities of State Food Safety Commissioner

1. Prohibit by order, in the interest of public health, the manufacture, storage, distribution or sale of any article of food either in the whole of the state or any area for a period of not more than one year or as mentioned in the order if found in contravention of the Act.
2. Carry out the survey of all food processing units in the state to find the compliance by such units of the standards notified for the articles of food.
3. Conduct training and awareness programs for the FDA officials and Food Business Operators on food safety.
4. Sanction prosecution for offences punishable with imprisonment under the Act.

The commissioner of food appoints Designated Officer, for each district to oversee the implementation of the Act at district level and Food Safety Officers for the local areas.

Role of key Stakeholders District Level

District Health Authorities

Indian Public Health System has been developed over years as a 3-tier system, namely primary, secondary and tertiary level of health care.

District hospitals form the essential component, district health system form the secondary level of health care to provide curative and preventive health care services to the population in the districts.

District Surveillance units

District surveillance units are established under IDSP in each district to collect the data related to health events including the foodborne disease. These units share surveillance data with state surveillance unit. The unit is led by a district surveillance officer and comprises of a multidisciplinary team of epidemiologist, veterinarian and data managers. Public and private health facilities in the district are identified as reporting units. Each reporting unit has a nodal officer to facilitate IDSP reporting.

Role and responsibilities of District Surveillance Officer (DSO)

The DSO is responsible for establishing, maintenance, and reporting arrangement of surveillance from reporting units in the district. He/ she can identify a nodal officer for facilitating surveillance in respective units.

Role and responsibilities of Hospital Superintendent

The medical superintendent of the hospital is ultimate responsible for establishing, maintenance, and reporting arrangement of surveillance in the district Hospitals including other major hospitals. He/ she can identify a nodal officer for facilitating surveillance in respective units.

Role of Nodal Officer/s

The nodal officer will be responsible to ensure that doctors in OPD and IPD are recording the provisional diagnosis of the patients and the list of conditions that are to be reported are pasted at a place where it is easily visible to doctors sitting in OPDs for ready reference. He has to emphasize to them on how important their cooperation is in making surveillance possible in the interest of the community.

Role of Doctors

The doctors must record the provisional diagnosis in the OPD register and this information generated in routine OPDs can serve in identifying the impending outbreaks. If similar cluster cases are coming from the same locality or areas on the same day or consecutive days, one should suspect an alert.

Role of laboratory personnel

The laboratory personnel will coordinate with the nodal officer for arranging the requested specimen / sample collection supplies. They will assist in proper sample collection, handling of the sample and its transportation to the testing laboratories. They will also be receiving the initials alerts on the number, expected arrival time and suspected pathogen(s) / toxins to be tested. Once tested will provide the timely report to the doctor / nodal officer.

Food and Drug Administration at District level

Designated Officer (DO)

The State Food Commissioner by order can appoints one Designated Officer not below the rank of sub divisional officer to oversee food safety administration for each district.

Responsibility of the Designated officer

1. To issue or cancel license of food business operators.
2. To prohibit the sale of any article of food which is in contravention of the provisions of the Act.
3. To receive report and samples of articles of food from Food Safety Officer under his jurisdiction and get them analyzed in Notified Food testing laboratory in the state.
4. After receiving the report from the Food analyst, will scrutinize the report and decide as to whether the violation is punishable under the Act, and if the violation is with imprisonment also; in that case he / she shall send his recommendations within 14 days to the commissioner of food safety for sanction of prosecution.
5. To sanction or launch prosecutions in case of contraventions punishable with fine only.
6. To maintain the records of all inspections made by food safety officers and action taken by them in the performance of their duties.
7. To get investigated any complaint which may be made in writing in respect of any contravention of the provisions of this Act and the rules and regulations made there under
8. To investigate any complaint which may be made in writing against the food Safety Officer.
9. To perform such other duties as may be entrusted by the commissioner of Food Safety.

Food Safety Officers (FSO)

The Commissioner of Food Safety notifies Food Safety Officers for local areas for purpose of performing functions under the FSS Act Section 16(5).

Responsibilities of FSO

1. To take sample of any food or any substance which appear to him to be intended for sale or have been sold for human consumption.
2. Seize any article of food which appears to be in contravention of the Act or regulations.
3. Enter and inspect any place where the article of food is manufactured, or stored for sale, or stored for the manufacture or exposed or exhibited for sale. He is empowered under the Act to follow the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to search or inspection of a place by a police officer executing a search warrant issued under this code.
4. In case of perishable food items, if he is satisfied that such food is deteriorated that it is unfit for human consumption, he can seize it and give notice to the food business operator for it to be destroyed.

In addition, the Food Safety Officers as a part of RRT will, assist state and local health officials during food borne disease emergencies.

Food analyst

The commissioner of Food Safety notifies having the qualifications prescribed by the central government as food analyst for the local area assigned to him/her to perform various functions as

For legal samples

1. To inspect the sample received before analysis, to see the condition of the container and the seal on the container and in case the container is found to be in broken condition or unfit for analysis, he will inform the designated officer and put a request for sending second part of the sample.
2. Shall analyze the food samples send to him by food safety officer or any other person authorized under the FSS Act to do so.
3. Food analyst is supposed to provide the test reports within 14 days from the date of receipt of sample for analysis.

Outbreak situation

1. Coordinate with the RRT and the FSO concerned and provide assistance in receiving the preauthorized food samples submitted for testing and maintain the chain of custody documentation.
2. Provide timely test reports to the RRT and the FSC and the DO.

2.2 Rapid response team (RRT)

Following identification of an outbreak, arapid response team is activated to address specific response tasks. The team is responsible for a systematic outbreak investigation to generate evidence for public health action for outbreak mitigation and future prevention. The local health department will lead the operational management at all stages of an emergency management cycle for the local events; preparedness, prevention, mitigation, response and recovery. At the State, the responsibility will be shared by the regulatory authorities to protect the health of citizens at large. If the incident is a deliberate act, law enforcement Authorities will take a lead in enforcing the law.

The members of the RRT are assigned with tasks appropriate to the response, such as: systematic case finding and epidemiological analytic investigation to determine food vehicle and environmental risks, determining sampling approach, 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

- Epidemiologists,
- Microbiologists
- Physician specialists,
- Food Safety Authorities Officials and,
- Environmental health specialists.

The team should have appropriate representation of all the departments affected, this will help ensure a consistent communication between all stakeholders

2.2.1 Interstate coordination

When the incidents cross jurisdictional boundaries involving many other states or require support from other states, the State Surveillance Units will coordinate, communicate and share the information with local, state health departments and food regulatory officials to

facilitate incident management. The states will ensure the allocation of resources including transportation, required for emergency management.

2.3 Communication

2.3.1 Inter departmental communication

- In all food safety related emergencies, communication between departments, food industry, and all stakeholders will be critical to ensure the best possible response. RRT will be responsible to develop the communication strategies in advance of any incident and should include everyone associated with the response (local, state, National Authorities).

2.3.2 Public communication

- There has to be an established Joint Communication Centre(JCC) in which representation from all departments affected is critical to develop and disseminate clear and consistent communication with all stakeholders including, food industry, the media, affected population and general public. The JCC will prepare a communication plan to guide information content and delivery in outbreak situation, and will work together to prepare basic fact sheets, key messages and other information materials for distribution. They will also prepare and publish media materials and conduct media briefing.
- It is observed that many outbreaks end before enough information is gathered to identify the likely source and warn the public. The source also may be identified after the outbreak ends and the risk to the public is over, so there has to be consistent process of evaluating the need to warn the consumers. The information has to be extracted from the final outbreak investigation reports after the investigation ends. The report should provide valuable information for people interested in food safety topics, such as media, food safety educators, consumer advocacy groups as well as food industries and regulatory bodies who work to make our food safer.

2.4 Record Keeping

From the beginning of the outbreak and following the steps in investigation all the information, decisions made by the RRT and others involved in the investigation should be accurately recorded.

The overall principles of record keeping, is to enter accurate information and can be either handwritten, computer based or combination of both and appropriate level of confidentiality should berespected. Documenting all relevant information are useful for investigating incidents and for future reference.

Chapter 3 – Food Borne Disease Outbreak Investigation

3.1 The Epidemiological Investigation

The investigation and control of food-borne disease outbreaks require multi-disciplinary skills in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology and chemistry, food safety and food control, and risk communication and management. The investigation involves systematic surveillance by means of collection, analysis and interpretation of foodborne diseases and morbidity arising due to it. The main objective here is of prompt identification of sources, causes and prevalence of the vector causing the outbreak. In general terms, Epidemiologists refers to food borne disease outbreak as two or more cases aroused from a common source. Often term 'outbreak' is also referred to 'cluster' or 'epidemic' in some reports. The most common methodology in form of 9 steps for investigating foodborne outbreaks, as advised by WHO in their guidelines for 2015, and Section 16(5) Food Safety & Standards Act 2006 are described as.

Step 1: Detect a possible Outbreak

Detecting outbreaks requires efficient and sensitive data sources to identify triggers in the community to detect focal and widespread foodborne illnesses. In India, the main data sources for detecting foodborne disease outbreaks are

- the public;
- the media;
- surveillance data (laboratory reports, disease notifications)
- other sources like reports of clinical cases from health care providers

The public

Members of the public are often the first to provide information about foodborne disease outbreaks, particularly when they occur in well-defined populations or at local level. For convenience the local governance is suggested to develop an e-portal to address such events/complaints and decimate the information further to respective IHR focal points for further proceedings. Outbreak reports received by the public should never be dismissed without consideration.

When reports of an outbreak are received, the following information should be gathered

- the person(s) reporting the outbreak.
- characteristics of the suspected outbreak (clinical information, suspected foods)
- Epidemiological information (time of outbreak, place, number of persons involved).

The challenge in dealing with these reports is to follow up on all relevant information without wasting resources in investigating many non-outbreaks. Trained personnel should verify these reports or triggers and generate an early warning signal after verification, if there is a time, place and person clustering of illness. Additionally, the trained personnel should also collect necessary information, and conduct interview for gathering necessary information to identify possible sources, etiology and vectors. They may refer to the annexure(s), for establishing a premise of the research objectives and interview questionnaire. If any assistance (such as medical) is required, the personnel may/shall engage respective agencies at their desecration. However, it may /shall be added onto the reports submitted to IHF local points, which thereafter may be summarized or directly forwarded to NECP for further perusal. These personal are encouraged to spread awareness among public on food borne disease poisoning and vectors. They are also encouraged to assure public to avoid mass panic.

The media

Commonly, Public health authorities learn of a possible foodborne outbreak through media reports. Journalists may detect foodborne outbreaks that have been hidden from the health authorities because of their sensitive nature. Internet editions of regional or national newspaper may provide a timely and accurate picture of ongoing outbreaks. However, media reports will inevitably be inaccurate at times and should always be followed up and verified before an early warning signal is generated. This will also help public health authorities in controlling public anxiety caused by outbreak rumors in the media.

Surveillance data

Surveillance activities are conducted at local, regional and national levels by IDSP. Among the many surveillance methods for foodborne disease, laboratory reporting and disease notification may contribute importantly to outbreak detection particularly when cases are geographically scattered, or clinical symptoms are nonspecific. Other types of surveillance that may be of value in detecting foodborne disease outbreaks are hospital-based surveillance, sentinel site surveillance, and reports of death registration. As in current state the common knowledge on concepts of contact tracing in situation of food-borne outbreaks among public is still at rudimentary stage for our country, therefore IHF contact points are also encouraged to develop their local networks for assimilation of any such incidences of outbreak being faced by local pathology labs or hospitals. A good surveillance program may

shall be implemented by collaborative efforts of both service and healthcare providers along with the NECP.

Disease notification to IDSP

In India, medical practitioners are required to notify suspected foodborne disease and acute diarrheal diseases to IDSP in a weekly reporting format. Notification of cases is usually based on clinical judgement and IDSP case definitions. Most of the time confirmation by diagnostic means is not done. However, such cases should not be omitted into the weekly reports. The respective follow-ups may enable monitoring agencies to identify hidden trends linking to recurrences of food-outbreaks to a common source, thus providing basis of necessary information for further investigation and future remediation. Medical practitioners who become aware of unusual clusters of diarrheal disease or other syndromes that may indicate foodborne disease should be also required to report these promptly to public health authorities as a potential trigger for verification.

Laboratory-based surveillance

Laboratories receive and test clinical specimens from patients with suspected foodborne disease (e.g.fecal samples from patients with diarrhea). Often, positive microbiological findings from these specimens are also sent by laboratories to the relevant public health authorities and IDSP. The descriptive information from the laboratories for e.g. concerned pathogen and etiology is also encouraged. Traditional laboratory-based surveillance is "passive", i.e. dependent on laboratories to report cases to public health authorities. In some situations, such as when a potential problem is suspected, "active" surveillance may be warranted for a period; laboratories may then be actively and regularly contacted by food safety or public health authorities to enquire about recent positive tests indicative of potential foodborne diseases. Investigation of all positive cases reported by laboratories should be encouraged as common practice. Investigation reports should also be submitted to the IDSP/NECP promptly for necessary actions.

Other sources

Other sources may alert public health authorities to the occurrence of outbreaks. Often, some creativity is needed to detect outbreaks as many of these sources were created for other purposes. Examples include reports of increased absenteeism from the workplace, schools or child-care facilities, pharmacy reports of increased drug sales, e.g. of anti-diarrheal medications, and consumer complaints to health departments or food regulators.

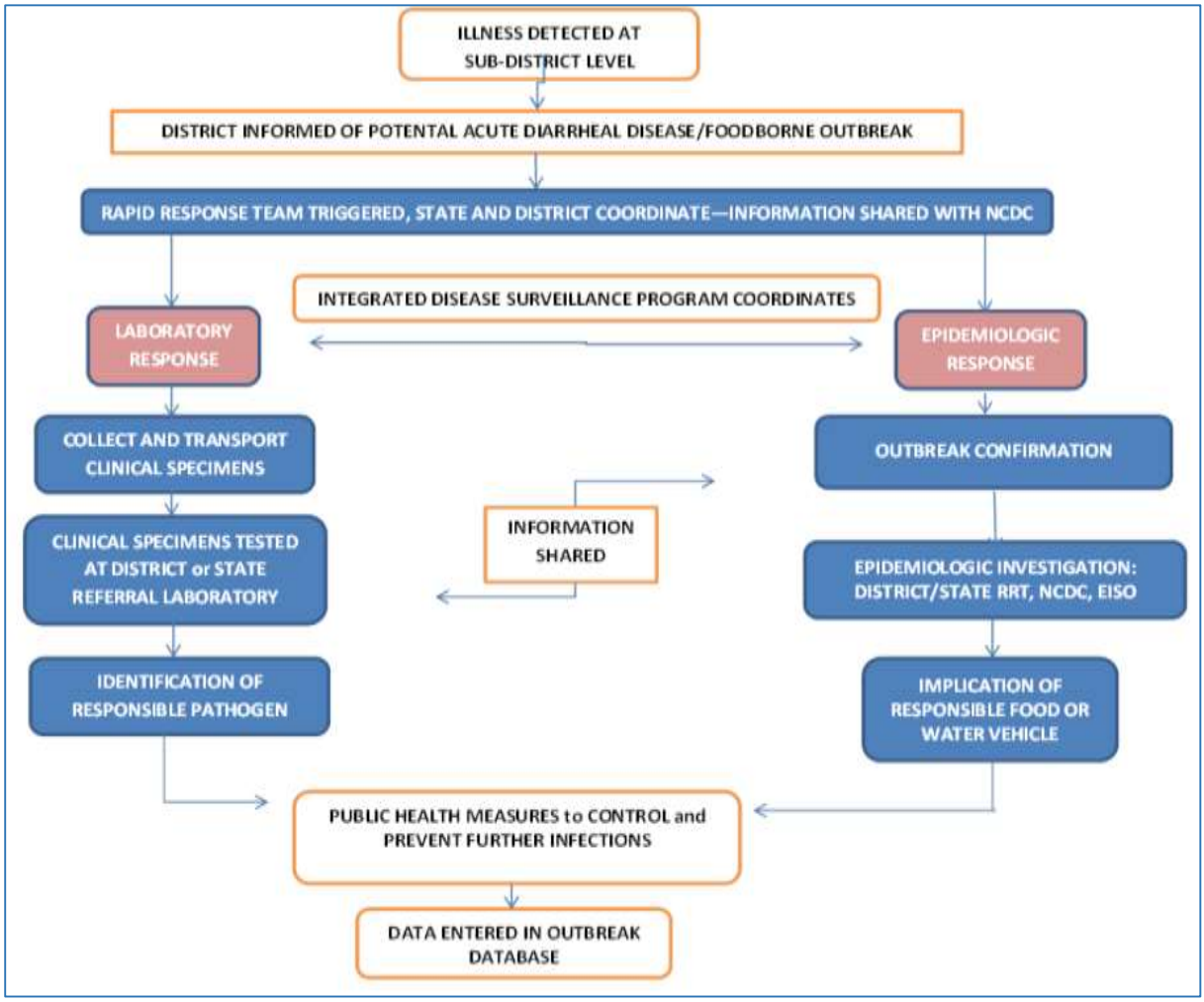


Figure 3.1: Coordinated epidemiological laboratory-based surveillance and response.

Interpreting Data Source

Foodborne outbreaks are often detected when sick people share an easily recognized potential source of infection (such as consuming meals in a marriage function, religious ceremony, party, social gatherings, common mess facility in hostel, etc.). When such events are limited to small, well-defined populations, the number of affected persons can be quickly established. The main emphasis of an investigation is on verifying that an outbreak has indeed occurred and controlling its spread.

Detecting community foodborne outbreaks from surveillance data can be more difficult. It requires the timely collection, analysis and interpretation of the data to indicate whether the number of observed cases exceed expected numbers. This requires knowledge of the background rates or traditional disease patterns in a particular population at a particular time and in a particular place, including typical seasonal changes in disease occurrence. A sudden

increase in disease occurrence may clearly point towards an outbreak (see Figure 3.2) while small changes in baseline levels can be difficult to interpret (see Figure 3.3). Even if the overall number of cases is not unusually high, a steep increase confined to a subgroup in the community or to a particular subtype of pathogen may be significant (see Figure 3.4). Local health authorities will usually know if more disease is occurring than would normally be expected. Where there is doubt, seeking additional information from other sources (e.g. absenteeism reports, telephone survey with general practitioners, checking outpatient departments of major hospitals, etc.) may help in the interpretation of surveillance data.

There are causes other than outbreaks that may lead to an increased number of observed or reported cases. These are referred to as “pseudo-outbreaks”; examples include changes in local reporting procedures or in the case definition for reporting a specified disease, increased interest as a result of local or national awareness, changes in diagnostic procedures, or heightened concern among a specific population (e.g. “psychogenic” outbreaks). In areas subject to sudden changes in population size – such as resort areas, college towns, farming areas with migrant workers – changes in the numerator (number of reported cases) may only reflect changes in the denominator (population size).

Detailed baseline epidemiological information should be collected as soon as possible, which includes, but is not limited to (alternatively annexure(s) may be used), the following:

- Information about the person(s) reporting the potential outbreak.
- Number of persons suffering from the illness.
- Date and time of consumption of food and onset of illness for each ill person.
- Specific symptoms experienced.
- Presumptive diagnosis.
- Total number of persons exposed / not exposed, both ill and not ill.
- Location where food was prepared and eaten.
- Specific food item or drink consumed, including ice.
- Other commonalities, including other shared meals or activities.
- Number of stool samples collected for testing.
- Additional information, including specific activities and medications taken before the onset of illness.

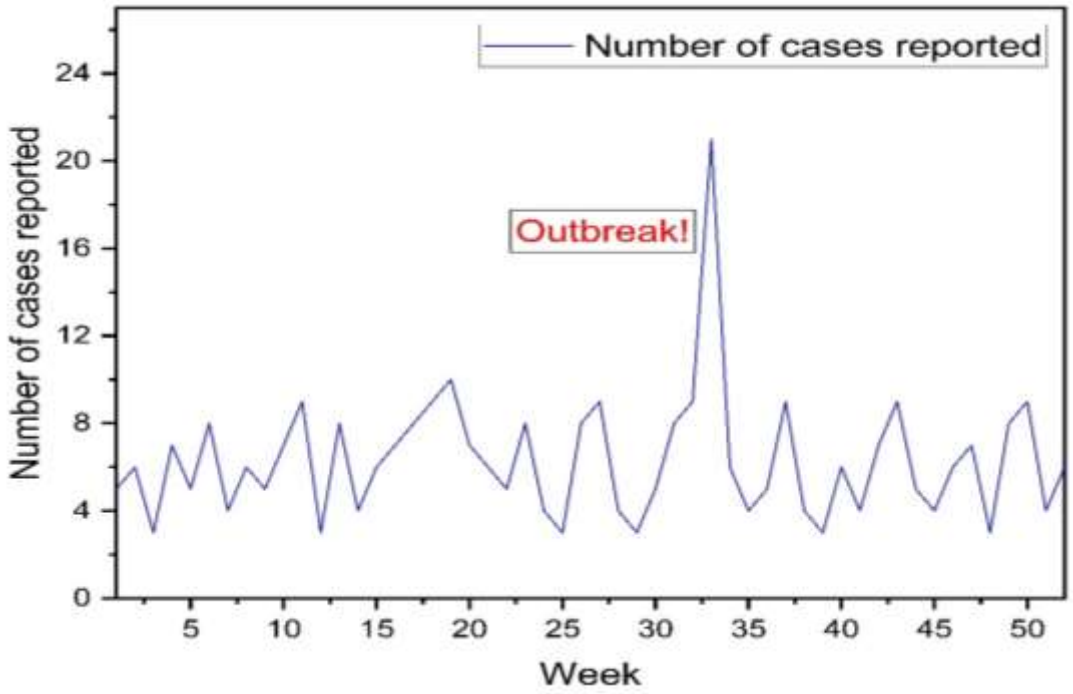


Figure 3.2: Weekly number of reported cases indicating an outbreak in 52 weeks in an arbitrary epidemic.

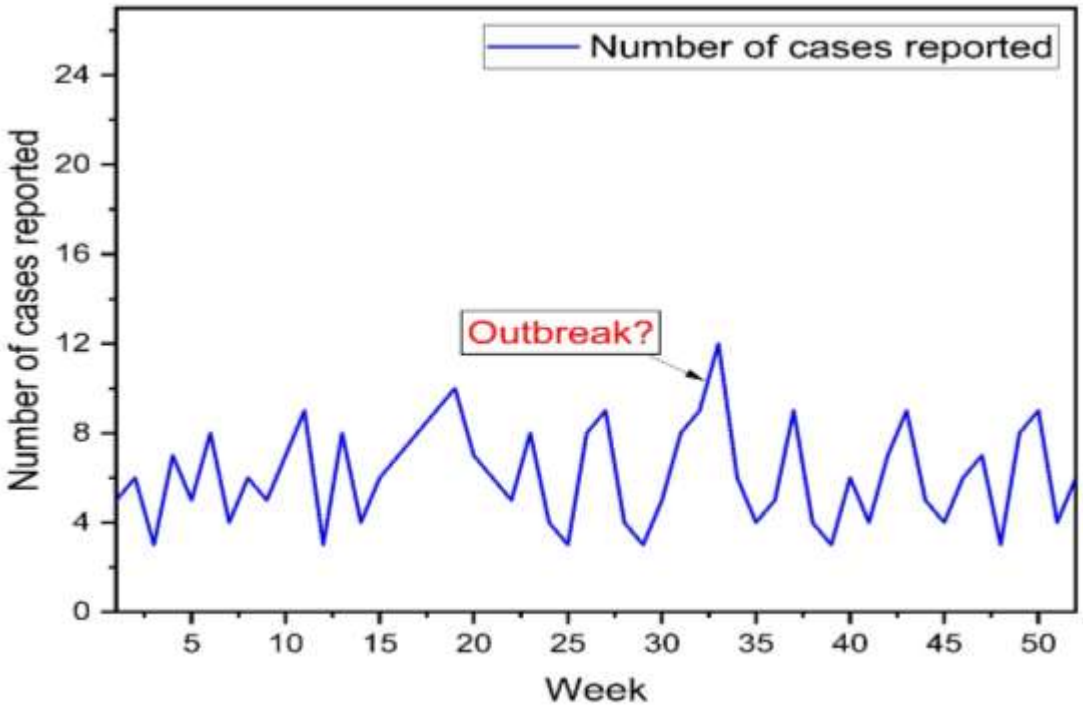


Figure 3.3: Weekly number of reported cases where it is not clear whether or not the observed number of cases in week 34 has exceeded expected numbers in an arbitrary epidemic.

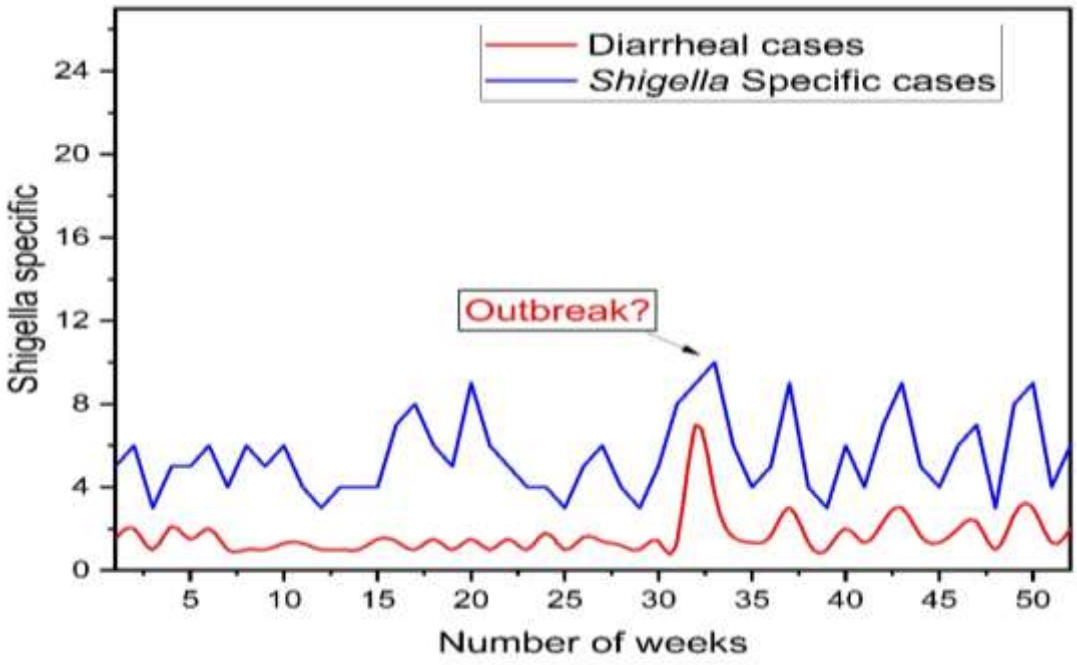


Figure 3.4: Weekly number of diarrheal cases: the outbreak of *Shigella* may have been missed without data on specific serotypes in an arbitrary epidemic.

Step 2: Verifying the outbreak and initiating investigation

After a foodborne outbreak is reported, the IDSP surveillance team will verify the report by reviewing surveillance data for any upsurge in reported cases or identify any time, place and person clustering of cases.

Once an outbreak is established, rapid response team is activated. The team should comprise of epidemiologists, medical doctors, food inspectors, and microbiologists/ lab technicians. Investigation and management of outbreaks will vary according to a number of factors including the nature and size of the outbreak, its importance with regard to the health of the public, and its economic impact. Successful investigation and control of foodborne disease outbreaks depend on working fast and responsibly, a teamwork approach, collaboration and information sharing between the RRT and the food regulator for enforcement of recommendations. When an outbreak occurs, all individuals involved in the investigation must clearly understand the course of action; time should not be lost in discussing policy matters that should have been resolved in advance.

The RRT should have clearly defined terms of reference for:

- the exact roles and responsibilities of agencies involved.
- the resources/facilities available to investigate outbreaks.

- the composition and duties of an outbreak control team, and when it should be convened.
- arrangements for information sharing with authorities at local, regional, and national.
- Conveying necessary information to public to avoid mass panic.

Step 3: Define case and conduct case investigation

Case Definition – Preliminary Assessment

Preliminary assessment of the situation

Investigation of a potential outbreak starts with the assessment of all available information; this should confirm or refute the existence of an outbreak and allow a working case definition to be established. This assessment must be initiated quickly and completed promptly in order to prevent further illnesses, and should include

- checking the validity of the information;
- obtaining reports of applicable laboratory tests that have been performed;
- identifying cases and obtaining information about them;
- Identifying linked sources and vectors for a sampling plan.
- ensuring the collection of appropriate clinical specimens and food samples.

Once the validity of the reporting source has been verified, a group of initial cases – perhaps 5 to 10 persons – should be identified and interviewed as soon as possible. This critical step helps to provide a clearer picture of the clinical and epidemiological features of the affected group. Delays in conducting these interviews can lead to recall bias or to people's inability to remember what they ate or what they did. The interviews should be open and comprehensive (annexure(s) may be used as reference) and include questions about

- demographic details, including occupation.
- clinical details, including date of onset, duration and severity of symptoms.
- visits to health care providers or hospitals.
- laboratory test results.
- contact with other ill persons.
- food consumption history.
- the respondent's thoughts on what caused their illness.
- whether the respondent knows others with the same or a similar illness.

- potential common exposures among those who have the same or a similar illness;
- date of exposure to suspected foods.

Clinical specimens (fecal samples, vomitus) from cases should be collected at the time of first contact; many of the pathogens and toxins that cause foodborne disease remain in the intestinal tract for only a short time after the onset of illness. This is the most critical step in etiological identification of foodborne illnesses.

If any of the foods that are suspected or were eaten during the potential incubation period remain available, they should also be sampled for laboratory examination and sent to designated food labs for microbiological and toxin testing.

Laboratory confirmation of these initial cases is essential to guide further investigation. If there is any doubt about the source of contamination, it may be reasonable to collect and store many samples, with subsequent testing determined by epidemiological data as they become available. If the vehicle of infection is thought to be food, the premises where the suspect food was produced, processed or handled should also be visited. It is important to visit these premises as early as possible – the amount of physical evidence of what may have caused the outbreak will diminish with time. The food safety inspector should do a hazard analysis of the food preparation and processing premises. If possible, environmental samples should also be collected for microbiological testing.

Establishing a case definition

A case definition is a set of criteria for determining whether a person should be classified as being affected by the disease under investigation. As such, it is an epidemiological tool for counting cases – it is not used to guide clinical practice. A case definition should be simple and practical and should include the following four components

- clinical and laboratory criteria to assess whether a person has the illness under investigation; the clinical features should be significant or hallmark signs of the illness;
- a defined period of time during which cases of illness are considered to be associated with the outbreak;
- restriction by “place” – for example, limiting the group to patrons of a particular restaurant, employees of a particular factory or residents of a particular town.
- restriction by “person” characteristics – limiting the group to, for example, persons over one year of age, persons with no recent diarrheal disease, etc.

Ideally, a case definition will include all cases (high sensitivity) but excludes any person who does not have the illness (high specificity). A sensitive case definition will detect many cases

but may also count as cases individuals who do not have the disease. A more specific case definition is more likely to include only persons who truly have the disease under investigation but also more likely to miss some cases.

There are no rules about how sensitive or specific a case definition should be. In the early stage of an outbreak investigation, the aim is to detect as many cases as possible; this requires a sensitive case definition (e.g. a person with three or more loose stools in a 24-hour period). At a later stage, the clinical picture is often clearer, and the diagnosis is laboratory-confirmed; this allows the use of a more specific case definition (e.g. laboratory-confirmed Salmonella infection), which may then be used to conduct further analytical studies. Criteria included in a case definition cannot be tested as risk factors in subsequent statistical analyses.

Because a single case definition that suits all needs is rare, it is quite common for case definitions to change during an investigation or for different case definitions to be used for different purposes. Many investigators use the following (or similar) case definitions in parallel

- **Confirmed cases –** have a positive laboratory result (isolation of the causative agent or positive serological test). This case definition has high specificity, e.g. gastrointestinal illness with microbiological confirmation of *E. coli*$_{O157}$
- **Probable cases –** have the typical clinical features of the illness but without laboratory confirmation, e.g. bloody diarrhea or hemolyticuremia syndrome without microbiological confirmation.
- **Suspected cases –** have fewer or atypical clinical features. This case definition has high sensitivity, e.g. non-bloody diarrhea without microbiological confirmation

Ways to find cases of illness

The cases that prompt an outbreak investigation often represent only a small fraction of the total number of people affected. To determine the full extent of the problem and the population at risk of illness, an active search for additional cases should be undertaken.

Methods for finding additional cases will vary from outbreak to outbreak. Many foodborne disease outbreaks involve clearly identifiable groups (for example, persons all attending the same wedding party), so that case-finding is relatively straightforward. In other outbreaks, particularly those involving diseases with a long incubation period and/or with mild or asymptomatic illness, case-finding may be quite difficult. Directly contacting physicians, hospitals, laboratories, schools or other populations at risk may help to identify unreported cases.

In some cases, public health officials decide to alert the public directly. For example, in outbreaks caused by a contaminated commercial food product, announcements in the media can alert the public to avoid the implicated product and to see a medical practitioner if they have symptoms typical of the disease in question.

Cases themselves may know other people with the same condition – particularly among household members, work colleagues, classmates, friends or neighbors.

If an outbreak affects a restricted population (e.g. students in a school or factory workers) and if a high proportion of cases are unlikely to be diagnosed, a survey of the entire population can be conducted. Questionnaires may be administered to determine the true incidence of clinical symptoms.

Finally, a review of laboratory surveillance data can help to find people with similar infections, assuming the cause of the outbreak is known. Cases that may be epidemiologically linked to an outbreak can often be identified through a unique subtype or biochemical or molecular feature of the causative organism, which may be particularly helpful in an outbreak caused by a widely distributed food product that crosses jurisdictional or even international boundaries.

Implement control and preventive measure

Usually most of these outbreaks are self-limiting. Precautions and prevention are aimed at preventing future outbreaks. Investigators should respond and implement appropriate public health action as soon as possible including, but should not be limited to, the following:

- Removal of contaminated food.
- Exclusion and restriction of persons who are at high risk of spreading illness, including food handlers, day care attendees and providers, and persons involved with direct patientcare.
- Emphasizing hand hygiene.
- Closing the food establishment, if implicated.
- Spreading awareness about food contaminates and necessary practices to ensure safety for e.g., washing or undercooking.

Step 4: Generate Hypothesis

Generate Hypothesis about the cause

Careful description and characterization of the outbreak is an important first step in any epidemiological investigation. Descriptive epidemiology provides a picture of the outbreak in

terms of the three standard epidemiological parameters – time, place and person. This can direct immediate control measures, inform development of more specific hypotheses about the source and mode of transmission, suggest the need for further clinical, food or environmental samples, and guide the development of further studies. With the initial information from case interviews, the laboratory and the environmental inspection, it is often possible to describe the event in simple epidemiological terms and to form preliminary hypotheses about the cause of the outbreak. Apparent "outliers" or unusual cases – for example, the only case who resides in a different town, the oldest case, the youngest case – can often provide useful clues for generating hypotheses.

Conduct Interviews: with the help of meticulously designed questionnaire

Once cases are identified, information about them should be obtained in a systematic way by use of a standard questionnaire. This contrasts with the preliminary phase of the investigation during which the interviews may be more wide-ranging and open-ended to allow for generation of hypotheses. Questionnaires may be administered by an interviewer or may be self-administered. Sometimes patients themselves will not be interviewed but their parents, spouses or caregivers may provide data; the sources of information should always be recorded on the questionnaire (some sample questionnaires of interest are annexed). Regardless of the disease under investigation, the following types of information should be collected about each case.

Identifying information – name, address, contact details (e.g. daytime telephone number, work address) – to allow patients to be contacted with additional questions and to be notified of laboratory results and the outcome of the investigation. Names will be helpful in checking for duplicate records, and addresses may allow mapping of cases. When identifying information is recorded, issues of confidentiality must always be addressed in accordance with prevailing laws and regulations.

Demographic information – age, date of birth, sex, race and ethnicity, occupation, residence, etc. – to provide the "person" characteristics of descriptive epidemiology that help to define the population at risk of becoming ill.

Clinical information – to identify cases, verify that the case definition has been met, define the clinical syndrome or manifestations of disease, and identify potential etiologies:

- Date and time of first signs and symptoms;
- Nature of initial and subsequent signs and symptoms;
- Severity and duration of symptoms;

- Medical visits and hospital admission.
- Treatment
- Outcome of illness

Risk factor information – to allow the source and the vehicle of the outbreak to be identified. This type of information will need to be tailored to the specific outbreak and the disease in question. Generally, the questionnaire will address both food-related and personal risk factors.

Food-related risk factors

- Detailed food history
- Sources of domestic food and water supply
- Specific food-handling practices, cooking preferences
- Eating away from home
- Demographic information to identify implication of living conditions

Personal risk factors

- Date and time of exposure to an implicated food or event (if known)
- Contact with people with similar clinical signs and symptoms
- Information on recent travel (domestic and international)
- Recent group gatherings, visitors, social events
- Recent farm visits
- Contact with animals
- Attending or working in a school, child-care facility, medical facility
- Working as a food handler
- Chronic illness, immunosuppression, pregnancy
- Recent changes in medical history, regular medications
- Allergies, recent immunizations

Depending on the suspected etiology and local patterns of food consumption and availability, enquiries should be conducted about any foods that could be a potential source of contamination in the outbreak. It is important to collect a thorough history of food

consumption for the entire suspected incubation period (which is often 3 to 5 days before illness for many common foodborne pathogens). An accurate and thorough food history will often require direct questions about specific foods as well as open-ended questions. Data should also be collected on the number and size of meals eaten, and the source and handling of suspected foods should be noted. If the pathogen is known, questions can focus on foods and other risk factors known to be associated with the particular pathogen. For information about the types of foods that are commonly associated with certain pathogens.

Knowledge of the incubation period of the pathogen can point to the most likely period of exposure or identify an unusual event or a suspect meal. If certain foods are known to be associated with the pathogen, specific questions should be asked about them (although enquiries should not be limited to these foods).

If the pathogen is not known but the clinical details suggest a short incubation period, information should be gathered about all meals eaten during the 72 hours before the onset of illness. Most people cannot remember all foods eaten over a 72-hour period; add a calendar, the menu of a suspect meal, or a list of foods to the questionnaire that may help their recall of relevant items.

In protracted outbreaks, when investigating illnesses with incubation periods longer than 72 hours (e.g. hepatitis A, typhoid fever, listeriosis) or when a person does not remember specific foods eaten, questions should be asked about food preferences, i.e. foods usually eaten or routine dietary habits. Information should also be obtained about foods purchased during the incubation period of the disease under suspicion.

Collected Information usage

Once the first questionnaires have been completed, the information they contain should be collated promptly to provide insight into the distribution of clinical symptoms and other factors among cases. The data can be summarized in a line listing, with each column representing a variable of interest and each row representing a case. New cases can be added conveniently to the list and updated as necessary. A line listing can be created directly by copying relevant information from the questionnaires or from a computerized database into which case data have been entered. Many types of computer software are available for this purpose, some of which are available free of charge, including Epi Info and Epi Data . While entering data, their consistency and quality should be critically evaluated. If feasible, the respondents may be re-contacted to clarify illegible or ambiguous responses on the questionnaire.

Analyzing data

Clinical details

The percentage of cases with a particular symptom or sign should be calculated and arranged in a table in decreasing order. Organizing the information in this way will help in determining whether the outbreak was caused by an intoxication, an enteric infection or a generalized illness. For example

- If the predominant symptom is vomiting without fever and the incubation period is short (less than 8 hours), intoxication by, for example, *Staphylococcus aureus,Clostridium perfringens or Bacillus cereus* is likely.
- Fever in the absence of vomiting and an incubation period of more than 18 hours' points to an enteric infection such as *Salmonella, Shigella, Campylobacter or Yersinia*.

Time

The time course of an outbreak is usually shown as a histogram with the number of cases on the y-axis and the date of onset of illness on the x-axis. This graph, called an **epidemic curve**, may help in

- Confirming the existence of an epidemic.
- Forecasting of the further evolution of the epidemic.
- Identifying the mode of transmission.
- Determining the possible period of exposure and/or the incubation period of the disease under investigation.
- Identifying outliers in terms of onset of illness, which might provide important clues as to the source.

To draw an epidemic curve, the onset of illness must be known for each case. For diseases with long incubation periods, day of onset is sufficient. For diseases with a short incubation period – such as most foodborne diseases – day and time of onset are more suitable.

If the disease or its incubation time are unknown, several epidemic curves with different units on the x-axis can be drawn to find one that portrays the data best. The pre-epidemic period on the graph should be shown to illustrate the background or "expected" number of cases or the index case. If the outbreak has a known source (e.g. a particular food served at a common event such as a wedding), the epidemic curve can also be labelled with this information.

The shape of an epidemic curve is determined by

- The epidemic pattern (point source, common source or person-to-person spread);
- The period of time over which persons are exposed;
- The incubation period for the disease.

In **common-source outbreaks**, a single source of pathogen results in exposure of persons at one point in time (point source), at several points in time (intermittent common source) or over a continuous period (continuous common source). An epidemic curve with a steep up slope, a more gradual down slope and with a width approximating the average incubation period of the pathogen indicates a **point-source outbreak** (see Figure 3.5A).

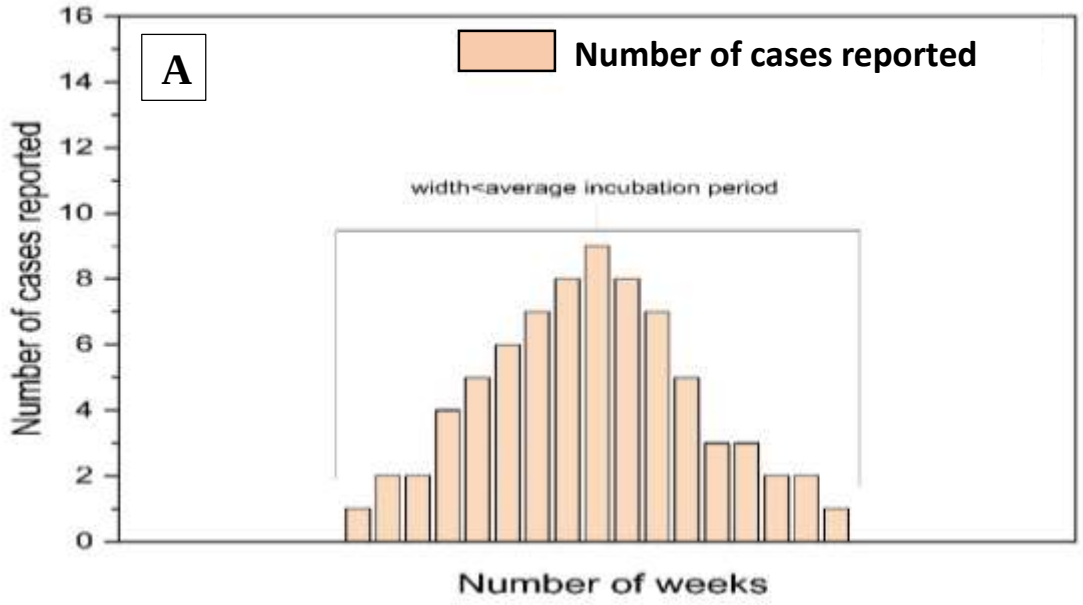
If there is a single source of pathogen but exposure is not confined to one point in time, the epidemic is either an **intermittent common-source** or a continuous **common-source outbreak**. In both these types of epidemics, onset will still be abrupt, but cases will be spread over a greater period of time than one incubation period, depending upon how long the exposure persists (Figure 3.5B, 3.5C).

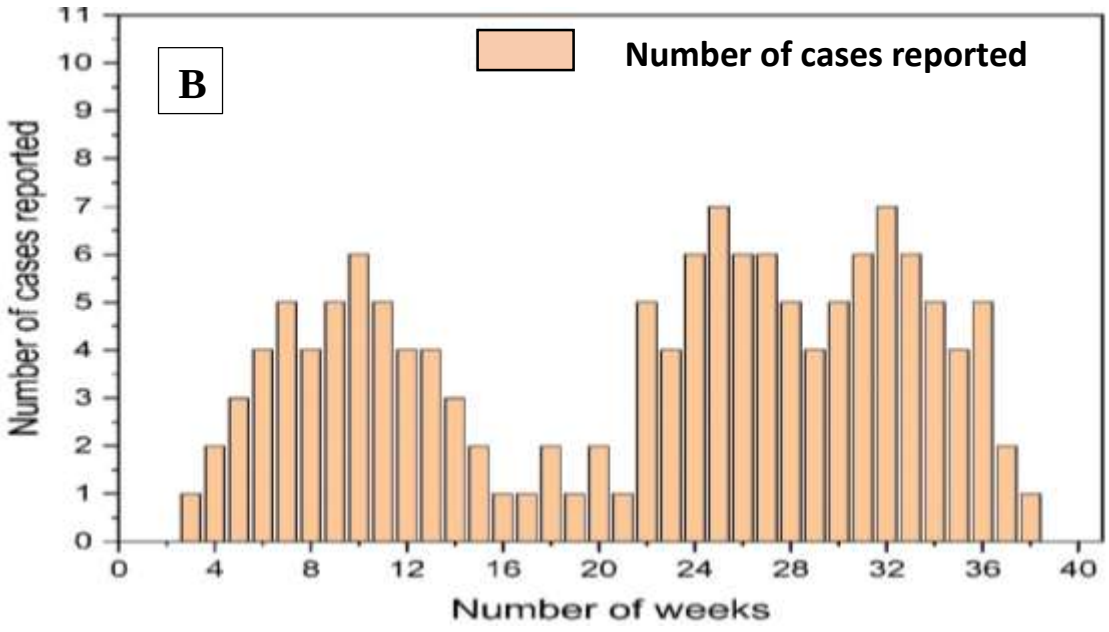
A **propagated epidemic** is caused by the spread of the pathogen from one susceptible person to another. Transmission may occur directly (person-to-person spread) or via an intermediate host. Propagated epidemic curves tend to have a series of irregular peaks reflecting the number of generations of infection. The time between the peaks may approximate the average incubation period of the pathogen (Figure 3.5D).

A **mixed epidemic** involves both a common source epidemic and secondary propagated spread to other individuals. Many foodborne pathogens (such as norovirus, hepatitis A, *Shigella*, and *E. coli*) commonly exhibit this mode of spread.

Calculate incubation periods

The incubation period is the interval between ingestion of food contaminated with enough pathogens or toxins to cause illness and the first sign or symptom of the illness. Incubation periods will vary with individual resistance and with the different amounts of pathogens/toxins ingested and their uneven distributions in food.


A
Number of cases reported
width<average incubation period
Number of cases reported
Number of weeks
0
2
4
6
8
10
12
14
16


B
Number of cases reported
Number of cases reported
Number of weeks
0
1
2
3
4
5
6
7
8
9
10
11
0
4
8
12
16
20
24
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32
36
40

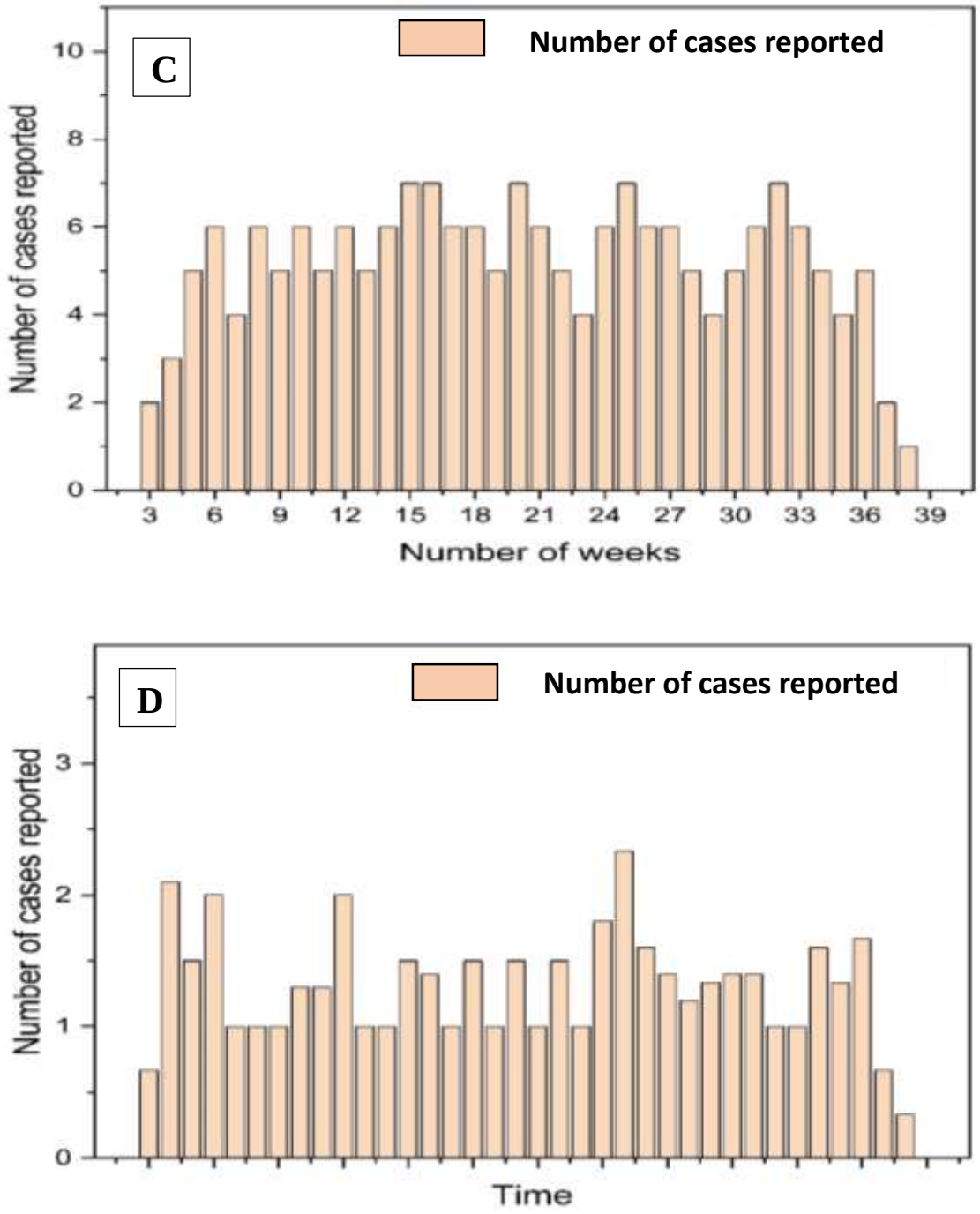


Figure 3.5: Examples of types of epidemic curves; A. Point Source; B. Intermittent common source; C. Continuous common source; D. Propagated (person-to-person) in an arbitrary epidemic.

It is often best to characterize outbreaks using the *median* incubation period. Unlike the mean (or average), the median is a measure of central tendency which is not influenced by very short or very long incubation periods. For details of how to calculate the median, see Annex 10(Statistics).

If the time of exposure and the time of onset of illness are known, individual incubation periods can be calculated directly and summarized by calculating the median.

If only the time of onset of illness is known and the shape of the epidemic curve suggests a point-source outbreak, inferences about the average incubation period and thus the suspected time of exposure may be drawn from the epidemic curve

- Identify the median time of onset of illness.
- Calculate the time between occurrence of the first and last case (width of the epidemic curve).
- Count back this amount of time from the median to obtain the probable time of exposure (see Figure 3.6).

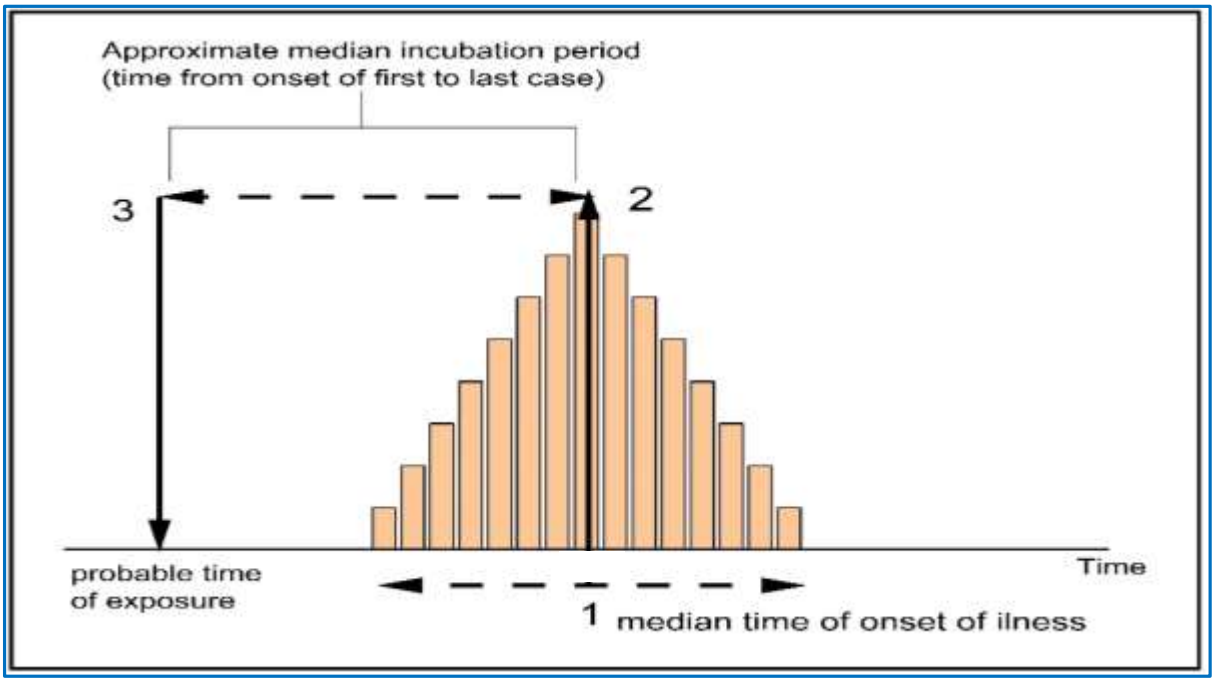


Figure 3.6: Determining the median incubation period and probable time of exposure in a point-source outbreakin an arbitrary epidemic**.**

If the organism and the time of onset of illness are known and the shape of the epidemic curve suggests a point-source outbreak, the probable time of exposure may be determined from the epidemic curve as shown in Figure 3.7

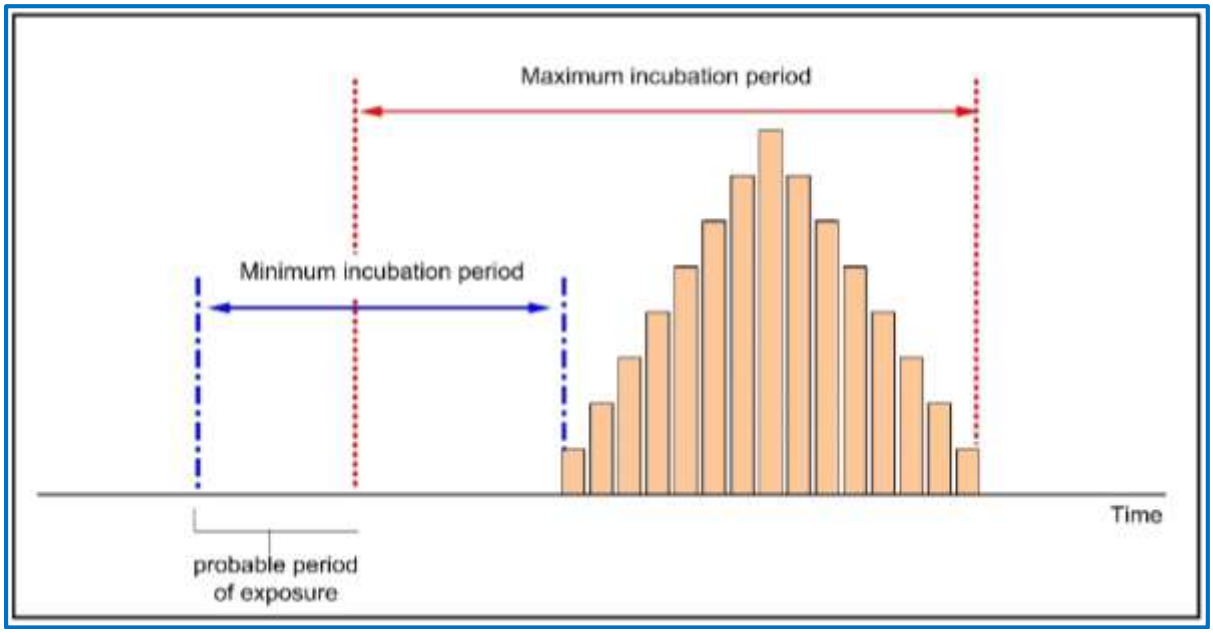


Figure 3.7: Determining the probable period of exposure in a point-source outbreak with known pathogenin an arbitrary epidemic**.**

If the pathogen and onset of illness are known, the range of time during which the exposure probably occurred can be calculated as follows:

- Look up the minimum and the maximum incubation period for the disease (see Section 6).
- Identify the last case of the outbreak and count back on the x-axis one maximum incubation period.
- Identify the first case of the epidemic and count back the minimum incubation period.
- Ideally, the two dates will be similar and represent the probable period of exposure.
- Alternatively, identifying the peak of the epidemic and counting back one average incubation period can determine the probable time of exposure. This method is useful in ongoing outbreaks in which the last cases have not yet appeared.
- These methods cannot be used if secondary spread is involved, or exposure is prolonged.

Place

Assessment by "place" provides information on the geographical extent of the foodborne outbreak and may reveal clusters or patterns that provide important clues about its cause.

Geographical information is best displayed by the use of maps; the types most commonly used in outbreak situations are spot maps and area maps. These can be produced by hand or by using sophisticated geographical information systems. A **spot map** is produced by placing a dot or other symbol on the map showing where a case lives, works or may have been exposed. Different symbols can be used for multiple events at a single location. On a spot map of a community, clusters or patterns may reflect water supplies or proximity to a restaurant or to a grocery.

Person

The purpose of describing an outbreak by "person" characteristics is to identify features that are common to cases as a clue to etiology or sources of infection. Age, sex, ethnicity and occupation are among the numerous characteristics that can be used to describe the case population. If a single or specific characteristic emerges, this often points towards the population at risk and/or towards a specific exposure. For example, it may be apparent that only certain students in a school became ill, or only workers in a single factory or a group of people who attended a local restaurant were involved. Nevertheless, even if it appears that only a single group of people was at risk, it is important to look carefully at the entire population to be sure that no other groups are affected. Certain groups of people may be more susceptible to disease or more likely to seek medical attention for their symptoms, for example people who live in a city where medical care is readily available. Sometimes cases in a particular group are more likely to be detected and reported than cases in other groups, and premature conclusions about the population affected could therefore be misleading.

Determining who is at risk of becoming ill

A measure of disease frequency is important in characterizing an outbreak, and the commonest such measure in epidemiology is a rate. Rates adjust for differences in population size and thus allow comparison of the occurrence of disease in various subgroups. Calculating rates of disease requires knowledge both number of cases and of the number of people in the population group(s) in which the disease may occur in each period (often referred to as the denominator). This population group is called the population at risk and is usually defined based on general demographic factors. For example, if the disease affects only children aged 5 to 14 years, the population at risk is the children in this age group living in the outbreak.

Excluding population groups in which the disease does not occur helps the investigation to focus only on those affected, leading to clearer findings, and allowing more effective intervention and control activities. If only a certain ethnic group within a region is involved, for example, the investigation may focus on food items specific to that group.

The attack rate is commonly used in disease outbreak investigations and is a key factor in the formulation of hypotheses. It is calculated as the number of cases in the population at risk divided by the number of people in the population at risk.

Sometimes it may be impossible to calculate rates because the population at risk is not known. In such situations, the distribution of cases themselves may help in formulating hypotheses.

Step 5: Test Hypothesis

Formal testing of a hypothesis may be unnecessary if it is strongly supported by epidemiological, laboratory or food data, but if such support is lacking or important questions remain unanswered, further studies may be needed. For example, descriptive epidemiology will often explain the source of the outbreak and the general mode of transmission but not reveal the specific exposure that caused the disease. Analytical epidemiological studies are then used to test the hypotheses.

Develop explanatory hypothesis: with studies to explain an outbreak

At this stage of the investigation the data need to be summarized and hypotheses formulated to explain the outbreak. Hypotheses should address the source of the agent, the mode and vehicle of transmission, and the specific exposure that caused the disease. They should also be

- plausible;
- supported by the facts established during the epidemiological, laboratory and food investigations;
- able to explain most of the cases.

While it is important to consider what is already known about a disease, an unlikely or unusual hypothesis should not be automatically discarded.

Epidemiological Studies

Analytical epidemiological studies frequently involve comparisons of the characteristics of a group of well persons with those of ill persons to quantify the relationship between specific exposures and the disease under investigation. The two types of analytical studies most used in outbreak investigations are cohort studies and case–control studies.

The value of a comparison group for identifying specific exposures is illustrated by the example of a school outbreak of gastroenteritis, in which 30 cases are identified. Interviewing all 30 cases about their food consumption shows that all ate vanilla ice cream purchased from

a street-vendor one day before illness. Enquiries about consumption of other foods show that no other food item was consumed by as many cases as vanilla ice cream.

Comparing the 30 cases with a group of 60 healthy students from the same school reveals that all the healthy students also ate vanilla ice cream purchased from the same street-vendor. Comparison of other exposures, however, reveals that most of the 30 cases had lunch in the school canteen the day before illness while most of the healthy students did not. This difference indicates that food from the school canteen is the more likely vehicle for the outbreak than vanilla ice cream; the finding that all cases had eaten vanilla ice cream merely reflects its popularity among the students.

Retrospective cohort studies

Retrospective cohort studies are feasible for outbreaks in small, well-defined populations in which all exposed and all non-exposed persons are identifiable. These studies compare the occurrence of disease among those who were exposed to a suspected risk factor with occurrence among those who were not.

Case–control study

In many circumstances, not clearly defined "cohort" of all exposed and non-exposed persons can be identified or interviewed. In such situations – when cases have already been identified during a descriptive study and information has been gathered from them in a systematic way a case–control study can be an efficient study design.

In a case–control study, the distribution of exposures among cases and a group of healthy persons ("controls") are compared with each other. The questionnaire used for the controls is identical to that administered to the cases, except those questions about the details of clinical illness my not pertain to the controls.

Vomitus/Stool Testing

Stool Specimens: Stool samples should be collected in Clean, dry, leak-proof screw cap container and tape Proper collection and transport of stool specimens requires the appropriate transport medium (modified Cary-Blair medium) and encouraging ill persons to submit a stool specimen.

Method of collecting a rectal swab from infants/debilitated patients

- Label the specimen tube/container containing the appropriate transport medium.
- Moisten a swab in sterile saline.
- Insert the swab tip just past the anal sphincter and rotate gently.

- Withdraw the swab and examine to ensure that the cotton tip is stained with faeces.
- Place the swab in the labelled sterile tube/container containing the appropriate transport medium.
- Break off the top part of the stick without touching the tube and tighten the screw cap firmly.
- Place in a sealed bag and send to laboratory immediately.

Handling and transport: Stool specimens should be transported at 4-8°C. Bacterial yields may fall significantly if specimens are not processed within 48hrs of collection. Shigella are particularly sensitive to elevated temperatures.

Vomitus / gastric aspirate can also be tested for organisms and toxins and should be collected as soon as possible after onset of illness. Instruct the patient to vomit directly into a sterile specimen container, such as a screw-capped bottle (or a urine specimen container). If this is not possible, ask the patient to vomit in a clean container, bowl or plastic bag and transfer the vomitus to the screw-capped container with a clean spoon. Place the cap securely on the container and seal the lid with tape.

Step 6: Identify point of contamination and food vehicle implicated in the outbreak

Data from the epidemiological analytic study along with results of clinical specimens and environmental samples is useful for identifying a link between foodborne illness and contaminated food vehicle or processes that may have introduced contamination into the food such as improper storage or cross-contamination while serving food etc.

Step 7: What if no link of food to illness

When Rapid Response Team cannot link a food to an illness, the RRT should generate a new Hypothesis and do another analytic study.

Step 8: Control of Outbreak

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. At the same time, specific interventions – such as recalling a food product or closing food premises – can have serious economic and legal consequences and must be based on accurate information. Thus, the implementation of control measures

is often a balancing act between the responsibility to prevent further cases and the need to protect the credibility of an institution.

Choosing outbreak control measures

Control of source

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.

Control of transmission

If a contaminated food product cannot be controlled at its source, steps need to be taken to eliminate or minimize the opportunities for further transmission of the pathogen. Depending on the situation, appropriate public advice may be issued during a period of hazard, for example

- boiling of microbiologically contaminated water or avoidance of chemically contaminated water;
- advice on proper preparation of foods like following WHO “Five Keys to Safer Food” guidelines
- advice to dispose of foods;
- emphasizing personal hygiene measures.
- Exclusion of infected persons from work and school

Outbreak Communication

Information to the public should include

- actions that consumers should take to prevent further exposure and illness.
- name and brand of the food product (including labelling) being recalled.
- the nature of the problem, the reason for recall of the product, and information about how the problem was discovered.
- name and location of the producing establishment and point of contact;
- locations where the product is likely to be found.

- numbers, amounts, and distribution.
- a description of common symptoms of the illness associated with the suspected pathogen or contaminant;
- appropriate food-handling information for consumers;
- actions that consumers should take if illness occurs.

Sometimes important new information becomes available after the initial release is published. This may necessitate a correction or update, or a complete revision and simultaneous removal from circulation of the first release.

Issuing a press release is of little use when consumers have not seen the product package or cannot identify the product directly, as in the case of products shipped to restaurants and large institutions. Efforts then should concentrate on issuing general food safety advice to the public.

Step 9: Decide when an outbreak is over

End of Outbreak

Review of outbreak

The Rapid Response Team (RRT) should formally decide when an outbreak is over and issue a statement to this effect.

A structured review should follow all outbreaks for which a Rapid Response Team is convened and should include a formal debriefing meeting with all parties involved in the investigation. The aims of debriefing are to

- Ensure that control measures for the outbreak are effective;
- Identify long-term and structural control measures and plan their implementation;
- 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;
- Change current guidelines and develop new materials as required;
- Discuss legal issues that may have arisen;
- Arrange for completion of the final outbreak report.

A “brainstorming” session, held in an open and positive environment, may produce additional valuable suggestions and ideas not addressed during the formal debriefing. Consideration should be given to using an external facilitator for the review sessions.

Outbreak report

An interim report should be made available by the RRT 2 to 4 weeks after the end of the investigations, followed by a written final report. The final report should be comprehensive, protect confidentiality and be circulated to appropriate individuals and authorities. The report should follow the usual scientific format of an outbreak investigation report and include a statement about the effectiveness of the investigation, the control measures taken and recommendations for the future.

Future studies, research

Further studies may be conducted after completion of the initial investigations, particularly if new or unusual pathogens were involved or additional information for risk assessment of a particular pathogen is required. The need to catch up on routine work delayed by the outbreak investigation often makes it difficult to conduct such follow-up studies. Nevertheless, it is important that these opportunities be considered following each outbreak – either by RRT members themselves or by others who may be in a better position to do this. Details of the outbreak may also be published in an international journal in order to inform the scientific community at large.

Economic evaluations of outbreaks and associated control efforts can be important in assessing the cost-effectiveness of outbreak investigations and food safety measures. Foodborne outbreaks will incur costs to

- health care providers (diagnostic and curative services);
- the population (medication, time missed from school or work, reduced activity as a consequence of long-term sequelae, death);
- the food industry (closure, adverse publicity, recall, litigation);
- agencies, laboratories and other persons and organizations involved in the investigation, response and control activities.

Costs associated with outbreaks can be enormous and quantifying them may help to increase the commitment of the food industry and other agencies to food safety.

Steps if number of illnesses increases or if it is a multistate outbreak

If number of illnesses increases or if it is a multistate foodborne outbreak three main strategies can be adopted

- **Quickly detect outbreaks** by monitoring nationwide surveillance systems that track diseases.
- **Gather the evidence linking** the outbreak to a likely food or animal source.
- **Communicate to consumersand retailers** about the source of the outbreak to prevent additional illnesses.

3.2 The Product and Environmental Investigation

3.2.1 Conducting food product and establishment investigation

The investigation and control of foodborne disease outbreaks are multi-disciplinary tasks requiring skills in the areas of epidemiology, food microbiology and chemistry, food safety and food control, and risk communication and management. Many outbreaks of foodborne disease are poorly investigated, if at all, because these skills are unavailable or because a field investigator is expected to master them all single-handedly without having been trained.

Environmental and food investigation

Environmental investigations (often also referred to as food or sanitary investigations) are conducted in parallel with epidemiological and laboratory investigations to find out how and why an outbreak occurred and, most importantly, to institute corrective action to avoid similar occurrences in the future. The specific objectives of an environmental investigation during a foodborne disease outbreak include

- identifying the source, mode and extent of the food contamination;
- assessing the likelihood that pathogens survived processes designed to kill them or to reduce their numbers;
- assessing the potential for growth of pathogens during food process storage;
- identifying and implementing corrective interventions.

Examples of records that may be useful in an investigation include

- menus, recipes or product formulations
- purchasing and inventory records
- shipping records and other documentation relating to the source of an implicated product;
- Hazard Analysis and Critical Control Points (HACCP) plans and records;

- records of corrective action;
- flow diagrams
- floor plans of the establishment;
- complaint records;
- cleaning records;
- food laboratory testing results;
- past inspection records;
- personnel records

Investigation of food establishments

During a foodborne disease outbreak, investigation of a food establishment will often require

- interviewing managers;
- interviewing any employees who may have had a role in the processing or preparation of suspected foods;
- a review of employee records (to determine whether some were out ill during the period of interest);
- a review of the overall operations and hygiene;
- food and environmental sampling;
- a review of food worker health and hygiene, including specimens for analysis;
- an assessment of the water system and supply;

Investigation of a suspect food

When the role of a suspect food is investigated, the complete processing and preparation history should be reviewed, including sources and ingredients, persons who handled the specific foods, the procedures and equipment used, potential sources of contamination, and time-and-temperature conditions to which foods were exposed.

Product description

The suspect food should be fully described in terms of

- all raw materials and ingredients used (menus, recipes, formulations);
- sources of the ingredients;
- physical and chemical characteristics, including pH, water activity (a_w);
- use of returned, reworked or leftover foods in processing;
- intended use (e.g. home use, catering, for immediate consumption, for vulnerable groups).

Observation of procedures from receipt to finish

Observations must cover the entire range of procedures, focusing on actual processes and work practices and including cleaning methods, schedules, personal hygiene of food-handlers and other relevant information. The temperature history (temperature and duration) of the suspect food should be recorded as completely as possible, including the conditions in which the food was stored, transported, prepared, cooked, heat-processed, held warm, chilled or re- heated. Observation of food-handling practices may be valuable for small-scale operations and in the domestic setting as well as in commercial operations.

Interviewing food-handlers

All food-handlers who were directly involved in producing, preparing or handling suspect foods should be interviewed. Information should be obtained about the exact flow of the suspect food, its condition when received by each food-handler, the manner in which it was prepared or handled, and any unusual circumstances or practices prevailing during the relevant period. Recent illnesses of food-handlers (before, during or after the date of the outbreak exposure) and times of absence from work should also be noted. Specimens for microbial analysis should be obtained from any food-handlers who are ill. If any employee is found to be infected with the agent of concern, it is essential to determine whether he or she is a potential source of the problem or is infected because of having eaten the same food.

At every step of the process, data should be evaluated with respect to contamination, growth/proliferation and survival factors associated with the suspected pathogen(s).

Formulating risk questions

The investigating team should decide on the key questions to be answered. This helps to define the scope of the assessment and ensures that all the relevant information is collected. Clearly defined questions help identify priority activities to be conducted as part of the risk assessment. A risk question is similar to a research question and typically focuses on

- who is likely to be affected?
- the likely exposure to a hazard
- when,why and how a population might be adversely affected by exposure to a hazard

Hazard analysis in an outbreak situation should also be able to address the following questions at each step of the processing of potentially implicated foods

- Could pathogens have been introduced at any stage
- Could pathogens already present have been able to grow at any stage

- Could pathogens have survived processes designed to kill them

This analysis also includes observation of the food-handling environment, assessing such factors as the location and availability of sinks and appropriate hand-washing facilities, and determining whether separate areas are maintained for the preparation of raw and ready-to-eat foods.

Environmental samples

The purpose of collecting environmental samples is to trace the sources of, and evaluate the extent of contamination that may have led to, the outbreak. Samples may be taken from work surfaces, food contact surfaces of equipment, containers, and other surfaces such as refrigerators, door handles, etc. Environmental samples may also include clinical specimens (such as faecal specimens, blood or nasal swabs) from food workers and water used for food processing. Raw poultry, pork, beef and other meats are often contaminated with Salmonella, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Clostridium perfringens, Staphylococcus aureus, Escherichia coli* O157 and other pathogens by the time they come into processing areas or the kitchens. If any of these agents is suspected in an outbreak, meat scraps, drippings on refrigerator floors and deposits on saws or other equipment can be helpful in tracing the source of contamination. Swabs can also be taken from tables, cutting boards, grinders, slicing machines and other utensils that had contact with the suspect food. However, as these pathogens are often present in such raw products, their detection does not automatically imply that they were the cause of the outbreak. Other situations in which tracing contamination to raw foods may be important and should be considered include

- The pathogen is uncommon, newly emerging or re-emerging or causes serious disease (e.g. E. coli O157).
- It can be expected that foods will be eaten raw or lightly heated (e.g. shellfish, fresh vegetables, shell eggs).
- Little is known about a pathogen and there is a need to advance knowledge about its ecology.
- Unlicensed or illegally sold foods were involved.
- It is suspected that foods were adulterated.
- The source of contamination is unusual.
- A new or unusual vehicle is involved

In such situations, a “traceback”, or tracing of the implicated food backwards through its distribution and production channels to its place of origin, is commonly performed. The purposes of such tracebacks include

- Identifying the source and distribution of foods in order to alert the public and remove the contaminate

Product from the marketplace.

- comparing the distribution of illnesses and distribution of product in order to strengthen an epidemiological association (sometimes referred to as an “epi” traceback);
- determining the potential route or source of contamination by evaluating common distribution sites, processors or growers.

Traceback investigations may lead to the identification of an ongoing public health threat and a consequent need to take appropriate actions, such as recall of foods, closing of a establishment, confiscation of foods, or warning consumers of a potential risk. Investigators should be prepared to coordinate activities closely with other appropriate agencies and organizations to ensure a prompt and effective response as necessary.

Successful investigation and control of foodborne disease outbreaks depend on working fast and responsibly. When an outbreak occurs, all individuals involved in the investigation must clearly understand the course of action; time should not be lost in discussing policy matters that should have been resolved in advance.

Typical steps in the investigation of a foodborne disease outbreak include

- establishing the existence of an outbreak
- verifying the diagnosis
- defining and counting cases
- determining the population at risk
- describing the epidemiology
- developing hypotheses
- evaluating the hypotheses
- undertaking additional epidemiological, environmental and laboratory studies, as necessary.
- implementing control and prevention measures.
- communicating findings.

3.2.2 Food Trackback Investigation

3.2.2.1 Role of industry in Trackback Investigation

Traceability is a visibility application that enables foodservice trading partners to track and trace product throughout the supply chain. It involves each trading partner collecting and maintaining product information that supports, at the very least, "**one up/one down**" visibility of the product's movement through the distribution channel.

Traceability is a way of responding to potential risks that can arise in food and feed, to ensure that all food products in the country are safe for citizens to eat.

Parties in the Supply Chain often play multiple roles in the traceability process. Supply chains are complex; there is not one simple scheme that could describe who is involved in the Supply Chain from upstream to downstream for all industry sectors. Yet there are typical roles for all involved in the supply chains.

By the time any item is purchased, consumed or used, it may have gone through a number of events and transformations. Each event or transformation may have involved a number of different parties. Every party has a responsibility to manage traceability and can use the generic traceability framework to achieve this goal.

Maintain the traceability is a responsibility of both the Traceable Item Source and Traceable Item Recipient. In the case of product recall, two levels of responsibility can be distinguished

- **Primary responsibility:** Typically, importers, producers, processors, manufacturers, or distributors, retailers and providers who are responsible for the specification and content of products, withdrawal and / or recall and notification. They are each responsible within the limits of the activities under their control.
- **Secondary responsibility:** Typically, transporters, carriers, ship owners, storage companies, and logistics providers who work on behalf of the organizations with primary responsibility. However, those with secondary responsibility must create, capture, record and share data about their traceability activities.

Traceability management involves the association of a flow of information with the physical flow of traceable items. Each player must perform different roles within the supply chain, but all players must follow the basic agreed-to steps of the traceability process. In order to achieve traceability across the supply chain, all Traceability Partners must achieve internal and external traceability.

An effective traceability system is how a food business operator can track and trace food through the food chain. In the event of a food incident, without a traceability system, a food

withdrawal/recall could be more difficult, extensive and time consuming than otherwise necessary. This can damage the food business operator and sometimes damage an entire sector of the food industry. Food business operators are therefore reliant on each other to have efficient and effective traceability systems in place.

Food business operators are responsible for establishing food traceability systems that, as a minimum, comply with the Food Safety & Standards Act and the Rules and Regulations made there under. However, to ensure the highest standards of food safety and public health protection, food must be traceable throughout the entire food chain. Therefore, every food business operator, at every step in the food chain, has a role to play in the traceability of food. Consequently, food business operators should pay particular attention to the effective and efficient transfer of accurate traceability information to their immediate customers. The interconnectivity of traceability systems throughout the food chain is so important for the protection of the consumer and protection of the food industry, that it is highly recommended that food business operators determine that their immediate suppliers and immediate customers also have effective traceability system in place prior to establishing trading relations.

Food industry trade bodies may also have a role in developing more specific detailed guidance for the food sector that they represent. All food business operators must have systems capable of identifying the traceability information required in the applicable food law. These systems must be able to provide information to the competent authorities on demand as and when needed.

3.2.2.2 Recall procedure

Introduction

Food on sale for human consumption must be wholesome, unadulterated, uncontaminated, properly labelled and fit for human consumption. Violation of the provisions in these regards may lead to regulatory action against the concerned FBO under the Act, or rules and regulations made thereunder.

Food Recall

Food recalls are an appropriate method for removing or correcting marketed food products and their labelling that violate the laws administered by the regulatory authority. Recall can be defined as an action to remove food products from market at any stage of the food chain, including that possessed by consumer, which may pose a threat to the public health or food that violate the Act, or the rules or regulations made thereunder. Recall of food product is in the common interest of the industry, the government and in particular the consumer. Recalls

afford equal consumer protection but generally are more efficient and timelier than formal administrative or civil actions, especially when the product has been widely distributed.

Manufacturers and/or distributors should initiate a recall at any time to fulfil their responsibility to protect the public health from products that present a risk of injury or gross deception or are otherwise defective. Firms may also initiate a recall following notification of a problem by Food Authority or a state agency, in response to a formal request by authority, or as ordered by Authority.

Purpose of this guideline

The purpose of this guide is to provide an overview of how to develop a recall plan and how to implement that plan in the event of a recall. It will assist in identifying products which are unsafe that violate the Act, or the rules or regulations made thereunder and enable recall of the product(s) from the marketplace.

Role of the Food Authority

The Food Authority's main role in a recall is to monitor the progress of the recall and assess the adequacy of the action taken by the FBO in this regard. After a recall is completed, the Food Authority will make sure that the product is destroyed or suitably improved. Where the recall is related to serious defects in the manufacturing process, the concerned authority may review the license of the FBO concerned.

The Food Authority will publicize the recall when it is of the opinion that the public need to be alerted about a health hazard or that clarification of the situation needs to be made to allay public worries.

In cases of public health emergencies, the Food Authority may, depending on the available evidence, alert the public before a decision on recall has been reached.

Role of the industry

Food Business Operators (FBO) carry the prime responsibility of implementing the recall, and for ensuring compliance with the recall procedure at its various stages including follow-up checks to ensure that recalls are successful and that subsequent batches of the food products are safe for human consumption.

If a food business operator considers or has reason to believe that a food which has processed, manufactured, distributed or imported is not in compliance with the food safety requirements, it shall immediately initiate procedures to recall the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the

consumer, the operator shall effectively and accurately inform the consumers of the reason for its recall, and if necessary, recall food product from consumer that have already supplied to them.

A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be unsafe for the consumers. FBO shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, with national law and concerned authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Food business operators shall collaborate with the concerned authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Food recall plan

All food business operators as prescribed in the regulation 7 of Food Safety and standards (Food Recall Procedure) regulations, 2017 must have an up-to-date recall plan as provided in Annex (Model recall Plan)- I. At the time of recall being carried out, the FBO shall submit their detailed recall plan to the CEO, FSSAI. A brief step by step procedure and its description are as below.

Assemble the Recall Management Team

Notify the authority

Identify all products to be recalled

Detain and Segregate all products to be recalled which are in your firm's control

Prepare and distribute the information of recall including Press Release

Prepare the Distribution List

Verify the effectiveness of the recall

Control the recalled product(s)

Decide what to do with the recalled product(s)

Fix the cause of the recall if the problem occurred at your facility

Conducting a recall plan

Step 1: Assemble your Recall Management Team

At the very beginning of the recall the FBO should initiate the formation of recall management team and assign the recall duties to each person and should ensure that all members of the recall management team are informed of the decision to conduct a recall and each member knows their responsibilities during the recall.

The team should include people responsible for

- Decision making
- Quality assurance / technical advisory
- Media communication
- Complaint investigation
- Contacting accounts
- Sharing details of distributors (for tracing) to whom via product has been already retailed out.
- Food Authority Contact
- Legal Counsel

Step 2: Inform the Authority

Inform the concerned regulatory authority at the earliest opportunity, after an incident is identified that may lead to a recall and should be updated throughout the process. The information should include the following

- a detailed description of the nature of the problem
- the name, brand, size, lot code(s) affected
- details of complaints received and any reported illnesses
- the distribution of the product - local or national
- when was the product distributed (specific dates)
- label(s) of the product(s) which may be recalled
- the total quantity of product manufactured and distributed
- the name of your firm's contact with the authority
- the name and telephone number(s) for your firm's after-hours contact

The detailed information is given under Schedule I of FSS (Recall Procedure) Regulations, 2017

Step 3: Identify all products to be recalled

It is the responsibility of FBO to ensure that all products which need to be recalled are identified. In addition to those products directly affected by the problem, the FBO should

- Determine if any other codes, brands or sizes of the same product are affected
- Determine if any other products are affected

Step 4: Detain and segregate products to be recalled which are in your firm's control

The FBO should ensure that all products to be recalled that are in your firm's control are not distributed and;

- Determine the locations of the recalled product(s) e.g. on-site, at the plant, off-site storage
- Determine the amounts at each location
- Identify and segregate products to prevent distribution

Step 5: Prepare and distribute the information of recall

Informing the Consumer: - Depending on the extent of the recall, the company concerned should inform the consumer of the recall at the earliest possible moment. Information dissemination may take the form of a press release, letter to the concerned parties or paid advertisement in the media. Sufficient telephone hotline service should be made available to deal with enquiries.

Information within the Food Chain: - The FBO shall inform everyone in the food chain from the raw material vendor to the supplier and any other relevant retailer or trade association of the affected food by written communication, phone, e-mail, fax, or a combination of thereof.

The press release, letter or advertisement shall be in the form of 'Food Recall Notice' and shall contain the following information, namely

- Name of the Food Business Operator recalling the food
- Name of the food, brand name, pack size, batch and code number, date of manufacture, used by date or best before date
- The contamination or violation in the food or reason for such recall
- "do not consume message"
- Health warning and action
- The places or outlets where the food is found

- The action to be taken by the consumer
- Contact number for queries

The FBO must

- Complete the press release within two hours after being notified of the recall
- Submit a draft of the proposed Press Release, if required, to the concerned Authority for approval
- Arrange for translation of the press release for concerned region

Step 6: Prepare the distribution list

Keeping accurate distribution records allows to limit the recall to the specific accounts that received the product being recalled. Using the distribution record system, produce a **product and lot code specific** distribution list which

- Identifies the accounts that received the recalled product
- Lists the accounts names and addresses, contact names and telephone numbers
- Identifies the type of account e.g., manufacturer, distributor, retailer

Step 7: Verify the effectiveness of the recall

The food business operator should determine whether the recall is progressing effectively and submit periodic status reports to the concerned authority to inform the progress of the recall. FBO shall submit the periodic recall status report once in a week or as otherwise specified by the concerned authority. To conduct an effective recall, the FBO should maintain the food distribution records which include Name and address of suppliers and distributors, date of purchase of raw material, batch code, lot number and complete traceability from Raw material to finished good.

The FBO must;

- verify that all accounts have stopped distributing and selling the recalled product(s) product(s)
- verify that the recalled product(s) have been returned

Step 8: Control of the recalled product(s)

The product is to be recovered to a central site, or in the case of widely distributed product, to major recovery sites. The recovered product must be stored in an area which is separated from any other food product. Accurate records are to be kept of the amount of recovered product and the batch codes of the product recovered.

It is the responsibility of the FBO to ensure that recalled products do not re-enter the market.

- Separate and clearly identify recalled product(s)
- Reconcile quantities and monitor returned product(s)
- Record the recalled product(s) in Recalled Product Records document

Step 9: Decide what to do with the returned product

After recovery, products may be corrected or reprocessed before release to the market if it is fit for human consumption. Otherwise, the product is to be destroyed. The action to be taken on the recalled product should be approved by the competent Authority

- Decide on the action to be taken on the recalled product e.g., correction, re-export, destruction
- Find out if the Authority wants to witness/verify that the action has been taken
- Verify that the action has been effective
- Record the action taken for each product in your Recalled Product Records document

Step 10: Fix the cause of the recall

As the manufacturing firm that produced the unsafe product, it is your responsibility for ensuring that all reasonable steps are taken to prevent similar recalls in the future.

put controls in place or revise existing controls to prevent similar problems in the future**, it**

Chapter 4 – Laboratory Analysis

The laboratory investigations are integral part of food borne disease surveillance program. They are the confirmatory tests conducted on suspected food items along with the specimens, such as stool, blood and urine. The protocols and method of laboratory analysis are vast and require expertise knowledge along with the regulatory guideline's setup for them. These guidelines are regularly modified to meet the pre-requisite standards and can be easily obtained from the www.fssai.gov.in ; www.iso.org ; or bis.gov.in. For which the list of recognized laboratories by Food Safety & Standards Act 2006under sections16(5),98 and 43(1) are annexed under annexures 4 and 5, respectively. However, the surveillance program essentially requires collection of the sample in field for analysis at the lab for which the standard practices and guidelines are detailed in this section.

4.1 General guidelines for food sample collection during an outbreak investigation and testing

Food samples

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.

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.

If a packaged food item is suspected of being involved in an outbreak, it is particularly important to collect unopened packages of that food – ideally, from the same lot. This can help to establish whether the food was contaminated before its receipt at the site of

preparation. If no foods are left from a suspect meal, samples of items that were prepared subsequently but in a similar manner may be collected instead, although findings from these tests must be interpreted with care. Any ingredients and raw items that are still available should also be sampled. Storage areas should be checked for items that may have been overlooked; even food retrieved from garbage containers may provide information useful in an investigation.

The circumstances in which samples were collected, the names of the suppliers and distributors, and coding information on packaged foods should be recorded so that the distribution channels of the product can be determined if necessary.

Laboratory investigations

Most foodborne outbreaks are microbiological in origin and their investigation will usually require a microbiology laboratory. Outbreaks caused by chemically contaminated food also occur, although they are much less common than microbiological events. Symptoms resulting from both microbiological and chemical contamination can be similar and may be difficult to distinguish, even by laboratory tests. While the general principles of investigation apply to both types of incidents, it is important to involve a chemical laboratory from the beginning if a chemical cause seems likely.

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);
- Supporting epidemiological and environmental investigations in detecting the pathogen in the implicated food and understanding how the outbreak occurred.

4.2 Chain of custody procedures food samples

Key Steps in the Chain of Custody Process

Step 1—Developing Key Control Points

After analyzing the manufacturing process, it is necessary to develop key control points. A key control point is an area with a combination of products. The key process control (KPC) shows where contamination or mixing of materials can occur. In an ideal world, all products are fully tested and certified prior to manufacturing. However, the reality of any

manufacturing operation suggests that these KPCs are points of vulnerability. Once KPCs are developed, tracking and quality assurance can start to drive a uniform marking system.

Step 2—Product Identification and Uniform Marking System

The simplest way to ensure there is no mixing of certified and uncertified materials is to create a marking and identification system that is fail-safe for even the simplest of operators. The marking system needs to be clear in every part of the process and include raw materials, work in process, finished goods, distribution, and logistics to cover the entire supply chain. A separation strategy for certified and uncertified materials would require different locations to segregate the materials. The marking system must be clear throughout the entire manufacturing process, including raw materials, work in process, finished goods and distribution/logistics. It is essential to have some policies and regulations around the third parties that will carry out the logistics and warehousing of the components.

Step 3—Record-Keeping and Document Programs

A chain of custody program requires detailed records and record systems to track all the activities of the product down to the lot, batch, minute and second of the manufacturing process. The documentation process will keep track of all this supply chain activity from the first producer through the end consumer. Some heavily regulated industries such as the pharmaceutical and aerospace industries can lead the way, as they have this process already in place.

Step 4—Assigning Responsibility, Authority and Accountability with Assurance of Compliance

Organizations need to invest in people with the responsibility, authority and accountability for the design, implementation and monitoring of the chain of custody process, certification, documentation, and compliance. Compliance will be a key element to the process. Additional undertakings include developing the process, policies and procedures, and training the internal organization.

Step 5—Auditing

The chain of custody process requires rigorous internal and external processes to drive compliance and ensure product and process integrity. Many organizations are not currently equipped to audit the supply chain, inside and out. The audit is key to the success of the program. Companies will have to add new staff to document control and manage the audits of the supply chain, ensuring compliance. Under a self-regulated or federally regulated program, government agencies will also have to develop additional processes, procedures and testing programs as well as increase their capital, human and technological resources.

Step 6—Supply Chain Integration

Supply managers will also have the burden of developing a certification process for the downstream integration of the chain of custody processes. Suppliers require procedures, processes, compliance monitoring and education. This is quite an undertaking for any organization. We have been identifying the need for integration and management of the supply chains, which will be forced through the chain of custody process.

Annexures

Annexure 1: Model Recall Management Plan

Recall Plan Template

(Insert FBO Name)

Recall plan

In the event, that if any of our products, that presents a threat to the public health or food that violate the Act and Rules and Regulations made there under __ (**Insert name of FBO**) ___will protect public health by facilitating the efficient, rapid identification and removal of unsafe food from the distribution chain and, by informing consumers of the presence in the market of such food.

There is a documented recall procedure in place, and this will be periodically tested to ensure that it is comprehensive and fit for purpose in its ability to remove an unsafe food from consumers and/or the distribution chain.

Recall Procedure

Introduction

This procedure states the action/s **__(Insert name of FBO)__** will take to effectively manage the food recall in case the food does not meet the requirements of the hygiene, safety and quality of food as well as protect the health of consumers. An effective product recall will ensure that the unsafe or food that violate the Act and Rules and Regulations made there under is contained and either destroyed or rendered safe.

We will refer to and follow instructions when required which are laid out in the following documents

- Food Safety and Standards (Food Recall Procedures) regulation, 2017
- FSSAI Website (www.fssai.gov.in)
- Guidelines for food recall plan

Roles and Responsibilities

It is our __(**Insert name of FBO**)__responsibility to effectively organise and manage the recall of food that presents a threat to the public health or food that violate the Act and Rules and

Regulations made there under and to formulate a broad level recall plan as per FSSAI guideline on recall plan.

The recall co-ordinator for the site is **__(insert name)__**who has been given authority from management to make recall decisions on behalf of __(**Insert name of FBO**)__. When a recall is initiated, our actions in recalling the affected food/s need to be co-ordinated with the **___(insert the name of concerned Authority)____**

We shall notify **___(insert the name of concerned Authority)____** as soon as a recall is likely to be initiated. It is our responsibility to manage the recall by clarifying the food safety issue and the exposure (who and where risk exists), and to provide details on distribution and the method of recall.

The Recall management team

The recall management team is responsible for the management of all recall activities and to adhere to this procedure. Duties of the recall management team are to

- assess the overall problem.
- notify the relevant regulatory authority.
- evaluate the hazard in the food and the extent of contamination.
- determine a strategy to be followed.
- make decisions about product still in manufacture or in storage.
- notify insurers.

The recall co-ordinator **__ (insert name) __** will initiate the formation of a recall management team and will co-ordinate actions with **__ (insert the name of Concerned Authority) __**and our marketing and distribution agents. Committee members will include personnel from across our **__ (Insert name of FBO) __**

(Insert name of FBO) RECALL PLAN

Company name : _____

Address : _____

Phone No : _____

Products produced : _____

Recall Management Team				
Name	Alternate Person	Business Phone	After Hours Phone	Responsibilities During Recall

Recall Actions & Documentation

The recall management team shall reference and follow the actions outlined in the Safety and Standards (Food Recall Procedures) regulation, 2017 when we become aware a product may be unsafe or food that violate the Act and Rules and Regulations made there under. We will ensure that records of all actions and decisions and who was responsible are recorded and retained.

Decision to Recall

The decision to recall will be submitted to **___(insert the name of Concerned Authority)____**

Notification of a product recall

If the decision is taken to initiate a recall, we will notify

- Senior management of **__ (Insert name of FBO) __**, supply chain personnel
- Food Authority.
- Anyone that has received our product, including distributors, wholesalers, retailers and caterers.
- Consumers, via the media contacts included on our contact list.

The contact list must contain the contact details for the following

- The products recall committee and senior management and key company personnel.
- Suppliers of all ingredients.
- Downstream Food Business Operator and business customers.
- Sources of technical advice and support including laboratory facilities.
- Regulatory Authorities.

Regaining control of affected stock

The recovered product/s will be stored in an area that is separated from any other food products. Accurate records will be kept of the amounts recovered and the codes of the product/s. If the recovered product/s is unfit for human consumption, it may be destroyed

or denatured under the supervision of the company management and/or the regulatory authority where legally required.

If the food safety risk can be safely removed from the recovered product/s through relabelling or reprocessing this may be done once it is clear that public health will be protected.

Recall Status report

Periodic status reports will be submitted to the CEO, FSSAI after the notification of the recall for assessing the progress of the recall.

The frequency of such reports will be determined by the relative urgency/gravity of the recall and will be specified by the concerned food authority for each recall. However, in any case the reporting interval shall not be more than 1 week.

The recall status report should contain information specified under Schedule II of Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

Post recall report

Recall management team will submit post recall report to the CEO, FSSAI after the completion of the recall to assess the effectiveness of the recall.

In addition, ...(**insert the name of FBO**) ... will investigate the reasons that led to such recall and will take action to prevent recurrence of the problem.

Termination of a recall

.....(**insert the name of FBO**) ... may request termination of the recall by submitting a written request to the CEO, FSSAI along with the latest recall status report stating that the recall was effective.

The recall will be terminated when the concerned food authority determines that all reasonable efforts have been made in accordance with the recall strategy and it is reasonable to assume that the food product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled food product. Written notification that a recall is terminated will be issued by the Food authority to the company.

In case of unsatisfactory reports, the concerned food authority may consider further action like stepped-up inspection, seizure or any other legal action, against the .....(**insert the name of FBO**) ....

Follow up action

We……. (**insert the name of FBO**) ... will submit an interim report as soon as recall is completed to the regulatory authorities within an agreed timeframe of the closure of the recall in any case not later than thirty days after the completion of a recall. The final report will include the elements outlined in the FSS (Food Recall Procedure) Regulations, 2017.

Annexure 2: Case Study in Applied Epidemiology

Investigating an Outbreak of Unusual Disease in Cuddalore, Tamil Nadu

Instructor Guide

Learning Objectives

After completing this case study, the participant should be able to

- **Define an outbreak**
- **Enlist steps in an outbreak investigation**
- **Examine line list and use descriptive information to generate hypothesis regarding potential risk factors**
- **Hypothesis generation for rare exposures**
- **Evaluate hypothesis epidemiologically**
- **Compare food specific attack rate to identify possible food vehicle.**

Acknowledgement

This case study is based on an investigation of an actual outbreak that occurred in Cuddalore, Tamilnadu in 2015. The investigation was conducted by Dr Janardhan Nayak, EIS Officer Batch 2014.

This case study was written by Dr. TanzinDikid, NCDC, with review by Dr. Richard Dicker, US CDC.

Format of this activity

This practicum comprises of an instructor guide and a participant copy. It is intended to be separated into sections by a facilitator, for constant, guided, interactive discussion between trainees as new information arises. The facilitator will initiate discussion on each section after allowing the trainees to go through the questions. This instructor's guide has example responses. This practicum may be attempted in one day or split into sections to be attempted on different days.

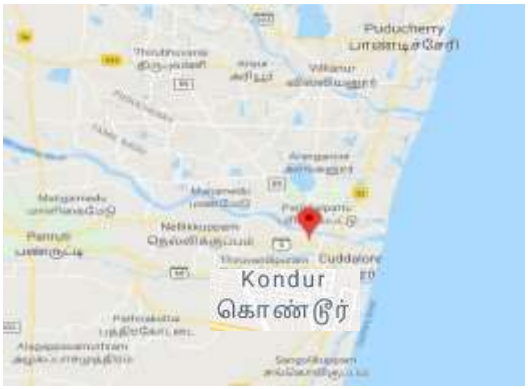
Prerequisites

This case study is prepared as a follow up to lectures on 1. Study designs; 2. Measures of risk and association; 3. Investigating an outbreak; 4. Hypothesis generation.

Participants are expected to be familiar with

- Descriptive and analytical study.
- Chronology of systematically investigating an outbreak and hypothesis generation
- Rate, ratio, proportion, measures of association

Section 1. Early information



At 8:00 pm on 4 April 2015, the District Surveillance Unit, Cuddalore learned that 64 persons of Kondur village had been admitted at the Government District Hospital, Cuddalore with complaints of vomiting and giddiness. The Central Surveillance Unit was informed the same night.

Kondur Village is in Cuddalore District, Tamilnadu. According to Census India 2011, Kondur Village had a population of 12,506 residents, of whom 1,087 were children 0-6 years old.

The District Rapid Response Team (RRT) investigated and coordinated case management with treating physicians. Two EIS Officers joined the RRT on 5 April. The RRT quickly determined that all the affected persons were residents of Kondur village and were suffering from vomiting, giddiness and paraesthesias. The physicians were managing the cases symptomatically.

Question 1: Is this an outbreak?

Answer 1

An outbreak is defined as the occurrence of more cases in a place (or population) and time than is normally expected. For new or rare diseases, even a single suspected case may prompt an outbreak investigation. Here 64 persons of one village (a cluster of cases) have been admitted to hospital with similar complaints of vomiting, giddiness and paresthesia's. A cluster of cases seems unusual. However, it has to be put in the perspective of the denominator or the population size. For example, a cluster of 4 cases of cancer in a neighborhood may sound alarming but may well be within the expected level of cancer occurrence. Here the denominator or the population size of the village is known and revealed later.

Question 2: What factors play a role in deciding whether to investigate a possible outbreak?

Answer 2

The decision regarding whether and how extensively to investigate a potential outbreak depend on a variety of factors. These usually include some factors related to the health problem, some related to health department and some external factors.

Factors related to the problem itself include severity of illness, number of persons affected, and availability of information regarding etiology / causative agent, source and mode of transmission and at-risk individuals / groups.

Factors related to health department include outbreaks when the number of affected or exposed persons is large, when the disease is severe (serious illness with high risk of hospitalization, complications or death), when effective control measures exist, and when the outbreak has the potential to affect others unless prompt control measures are taken. For example, NCDC has been sending teams to investigate AES cases in May-June every year from 2011-15 in Muzzafarpur, Bihar as the disease affects young children and is potentially fatal unless timely management is given. More so, over the years there has been intense media and political scrutiny into the matter.

At the State or National level unusual presentation of disease or a new or rare disease may prompt an investigation than occurrence of a common disease or a disease with well-known mode of transmission and control measures. A case in point was the first outbreak of Crimean Congo Hemorrhagic Fever (CCHF) reported in January 2011 from Gujarat and investigated by NCDC. Although the number of affected cases was small, the severity and presentation of the cases was alarming enough for the state to request an investigation by the central RRT

Section 2. Developing a case definition and finding cases

The District Rapid Response Team conducted a house-to-house survey of the areas from 6 to 8 April. Results of the survey showed that, on 4 April 2015, 199 persons reported onset of nausea, vomiting, giddiness, abdominal pain/ cramp, diarrhoea, paraesthesia of lip, gum and mouth, fever, dizziness and headache.

The RRT decided to develop a working case definition before they began to look for cases.

Question 2.1: What is a case definition?

Answer 2.1

A case definition is a tool for classifying someone as having or not having a disease under evaluation. A workable case definition includes clinical criteria and lab criteria (where available) along with restrictions by time, place and person. The case definition should NOT include the risk factor or exposure under evaluation. The clinical criteria should be based on simple and objective measures. In an outbreak situation, when the diagnosis is uncertain, epidemiologists may resort to classifications based on certainty of the diagnosis, such as (from most certain to least certain) confirmed, probable, and possible case definitions.

Question 2.2: Formulate a case definition for this phase of the investigation.

Answer 2.2

Instructor Note: Assign participants to work in groups of 3. After 5 minutes, ask different groups to present and justify their case definitions.

A reasonable case definition could be:

Clinical: "nausea, vomiting or giddiness in a person of any age" or "watery diarrhoea of more than 3 episodes in a day"

Time: "on 4th April 2015"

Place: "in village Kondur"

Person "a person of any age"

Caution: When developing a case definition, be careful about ANDs and ORs. "Nausea OR giddiness" (either one) would include more people than "nausea AND giddiness" (requires both).

Whatever case definition is used, it is important that the case definition be applied consistently to all persons under investigation.

Question 3: What case-finding strategy would you use?

Answer 3

After developing a case definition, it is important to apply it systematically to record cases. Methods for case finding will vary depending on the community setting and disease in question. As this outbreak appears to have affected residents living in one particular village it is reasonable to conduct a house-to-house survey to find additional cases.

Other methods used for case finding could be direct contact with selected physicians, hospitals, laboratories where affected patients are likely to visit, conducting serological, culture surveys or molecular mapping. If the disease is transmitted person to person, contact tracing can be an effective method of case finding.

Question 4: Which variables would you include in a data collection tool? Limit your list to no more than 10 variables.

Answer 4

Instructor Note 1: *Direct participants to work in their same groups of 3. After 5 minutes, ask different groups to present and justify their lists.*

Instructor Note 2*: Before designing a data collection tool that will be used with potentially hundreds of respondents, it would be useful to talk with a few cases and with the local authorities to determine if any mass events (e.g., banquet, religious gathering, sports event) occurred. These "hypothesis-generating" interviews can help focus the data collection tool.* Typically, a data collection instrument has 5 or 6 categories of variables — personal identifiers, socio-demographic variables, clinical features, risk factors and other so-called epidemiologic variables, reporter / data collector information, and, depending on the type of disease (particularly if the disease is spread by person-to-person contact), potential contacts.

Variables could include:

Personal identifiers

- Name
- Address or other locating information
- Telephone number

Socio-demographic information

- Birth date and/or age
- Sex
- Occupation
- Other demographic characteristics (tribe, religion etc)

Clinical information

- Any illness on 4 April 2015?
- If yes,
  - Time of onset
  - Yes/no checklist for each of the following
    nausea, vomiting, giddiness, abdominal pain/ cramp, diarrhoea, paraesthesia of lip & gum and mouth, fever, dizziness and headache, other (specify)
  - Went to hospital? Hospitalized?
  - Duration of symptoms

Risk factor information

- Exposure to any recreational drugs
- Attendance at mass gathering
- Exposure or witness to case before becoming ill (a feature of mass hysteria)
- Food / water

Reporter / Data Collector Information

- Name or initials or code
- Date of interview

The District RRT planned to collect the data on paper data collection forms.

Question 5: After data collection has occurred, what are options for organizing the data for review and analysis?

Answer 5

Depending on the number of forms collected and the number of cases, the data could be organized into a line list or into an electronic database.
A line list (also called a line listing) is a database comprised of rows and columns. Each column represents an important variable such as name, gender, time of onset, etc. Each row represents a case. The line list can be compiled on a sheet of paper or on an electronic spreadsheet such as MS Excel.

The data can also be entered into software such as Epi Info. In Epi Info, data entry screens mimic the data collection tool. The data can be collected on paper forms and then entered into Epi Info later, or the response can be entered directly onto tablets during the interviews, bypassing paper altogether.

Section 3. Finding Cases

The RRT formulated an operational case definition of "nausea or vomiting or giddiness and paraesthesia's in a person of any age in Kondur village on 4th April 2015". The RRT conducted a house-to-house survey of 303 households that included 1410 village residents.

Question 6: Are all four symptoms required to be considered a case?

Answer 6

No. Although the case definition is not entirely clear because of the placement of the ORs and ANDSs

(nausea OR vomiting OR giddiness) AND paraesthesia's (could have been reworded as paraesthesia's PLUS any one of the following – nausea, vomiting, or giddiness)

vs.

Nausea or vomiting or (giddiness and paresthesias)

Either way, no more than two symptoms are required.

The survey identified 199 persons with signs and symptoms consistent with the case definition. The RRT put the data into a line list, similar to the following

Table 1. Example of line list of first 2 cases, Cuddalore outbreak, April 2015

Case No.	Onset date	Onset time	Address	Age	Gender	Occupation	S/S reported	Exposure A (Y/N)	Hospitalization status (Y/N)
1	4th April	5.00 PM	Gali No. 4, Kondur village	35	M	Fisherman	Nausea, vomiting	Y	Y
2	4th April	3.30 PM	Gali No. 6, Kondur village	19	F	Housewife	Giddiness, vomiting	Y	Y

Of the 199 cases, 150 (75%) were farmers by occupation. No recent common feasts or party had occurred in the village. 56 of 199 cases gave history of drinking toddy (local beer). None had a history of using any recreational drugs. Only 2 of 199 had a history of exposure to any pesticides while spraying their fields. Symptom onset began between 4.45 -11.00 pm. The RRT analysed the data by time, place and person.

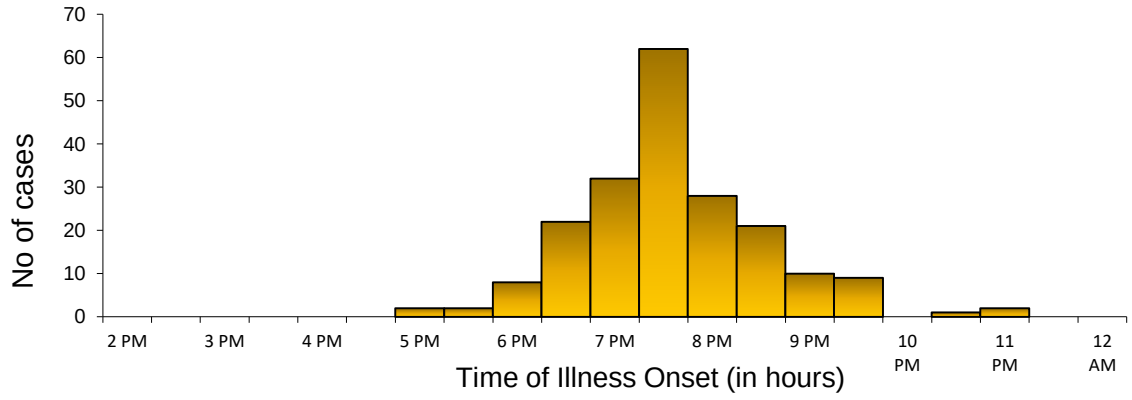


Fig 1. Distribution of cases according to time of illness, N=199

Table 2. Distribution of cases on the basis of age group and gender

Age group (years)	Population, n=1410	Cases, n=199	Attack Rate %
0–5	123	21	17
6–15	286	50	17
16–45	767	103	13
46–60	173	21	12
>60	61	4	7
Female	700	105	15

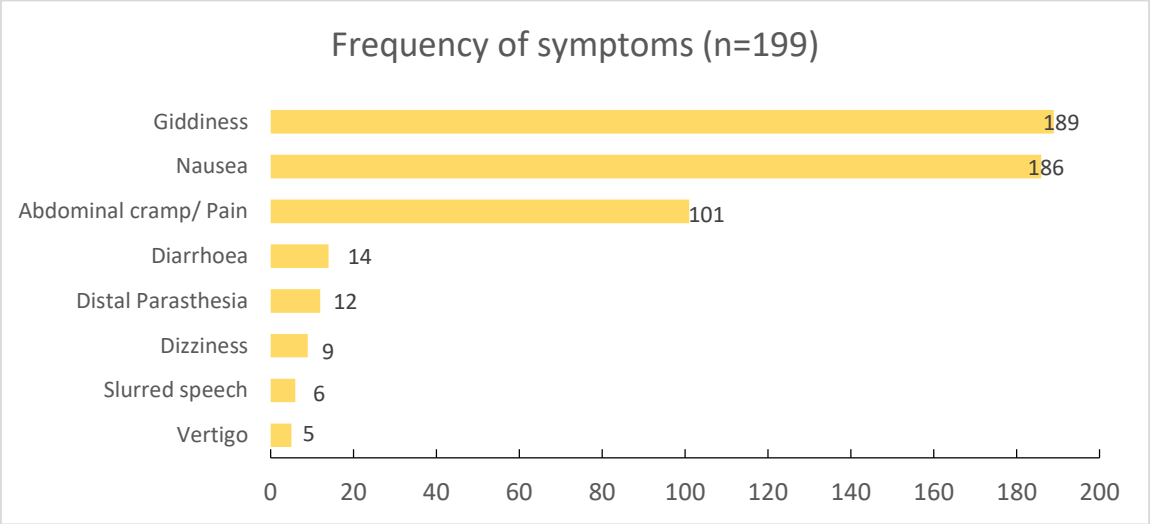


Figure 2. Distribution of cases on the basis of clinical profile

Question 7: Summarize the descriptive epidemiology.

Answer 7

Overall attack rate was 199 / 1410 = 14%.

Onset of symptoms occurred over a 6-hour period from 5 pm to 11 pm, with a peak at 7:30 pm.

Cases occurred in every age group, with slightly lower attack rate among those over age 60. Males were affected more as compared to females.

Almost all cases had giddiness and vomiting, about half had nausea, other symptoms were relatively uncommon.

Section 4. Hypothesis generation

The RRT's next step was to generate one or more plausible hypotheses.

Question 8: Which parameters should a plausible hypothesis address?

Answer 8

Hypothesis should address

- Agent
- Source of agent
- Mode of transmission
- Exposures that increase risk of disease

Question 9: In an outbreak situation, what methods does an epidemiologist use to generate a robust hypothesis?

Answer 9

Field epidemiologists must review clinical, laboratory and epidemiological features of the disease Subject matter knowledge on agents (causes), common exposures, and modes of transmission is used to generate plausible hypothesis. EIS Officers or FETP fellows should know where to look for and find this information.

However, there will be times when your hypothesis will require more analytical techniques. These could be review of outliers in time, place, person distribution, in-depth interviews with patients and local authorities.

Question 10: In what type of outbreak situations would you consider using less common ways of obtaining information for hypothesis generation?

Answer 10

In unusual outbreaks with rare exposures or modes of transmission, epidemiologists can consider using open-ended interviews, focus groups or key informant interviews to obtain information for hypothesis generation.

Question 11: Summarize the descriptive epidemiology you have learned so far.

Answer 11

Time: The affected persons fell sick over a short period of time.

Place: All affected persons were from same village but not necessarily localized to any part of village or around any water source.

Person: The illness has affected all age groups and is equally distributed between both genders. The illness is reported most frequently by fishermen and clam eaters.

The RRT's review of descriptive data suggested a point source outbreak with short incubation period. A close examination of the reported symptom profile showed that nausea, vomiting and giddiness, and upper GI symptoms were predominant complaints. Some neurological symptoms, including parasthesia of lip and gums, were also reported. One team did in-depth interviews with 27 affected residents. The other team spoke with health department officials, food department officials, and private practitioners.

Health department officials and private practitioners noted that cases with similar symptoms were reported from this area in the past and were possibly linked to dietary exposure. The affected village has an adjoining coastline. Commercial ships dock at a nearby area. There were no major industries around. Results of in-depth interviews with 27 cases were summarized as follows

The RRT decided to conduct in-depth interviews with patients and local authorities. They also decided to limit the reference period for possible exposures to within 3 days. They divided themselves into teams.

Exposures	N=2727	%
Occupation		
Farmer/ Farm labour	9	(33)
Fisherman	19	(70)
Semiskilled (plumber/ electrician)	1	(3.7)
Factory/ Shipyard worker	1	(3.7)
Drinking water		
Bore well # 1	5	(18.5)
Bore well #2	7	(26)
Unprotected well	4	(15)
Private underground water	10	(37)
Water from overhead tank # 1	1	(3.7)
Water from overhead tank # 2	0	(0)
Milk		
Cold milk	2	(7.4)
Hot milk	21	(77)
Untreated milk	4	(15)
Phirni (ice cream)	3	(11)
Sea food		
Fresh fish	18	(66.6)
Dried fish	8	(30)
Lobster	3	(11.1)
Crab	9	(33.3)
Clam	25	(92.5)
Pesticide handling		
Yes	12	(44.4)
H/o substance use or toddy use		
Yes	09	(33)
H/O attending a feast or party		
Yes	06	(22)

Question 12: Develop a hypothesis based on this evidence.

Answer 12

Hypothesis The outbreak was a point-source outbreak caused by exposure to a single agent with a short incubation period. The symptoms and occurrence among fishermen and clam eaters, suggest shellfish poisoning.

Section 5. Hypothesis testing

After analysing results of the descriptive data and hypothesis generating interviews in the previous section, the RRT hypothesized that "eating clams was associated with the reported illness".

Typically, hypothesis in a field investigation are evaluated using a combination of environmental evidence, laboratory science, and epidemiology. Clam samples were collected from local vendors and their source of clam harvesting was traced back.

Environmental testing by marine biologists identified the clams as Meretrix meretrix species. They were not able to isolate any toxin from the clams or the sand and water collected from the clam-harvesting site. The water was found to be heavily contaminated with E.coli and Bacillus sp.

Results of the stool sample collected were negative for Vibrio cholera, Salmonella sp. and Shigella sp.

Question 13: Apart from an epidemiologic study, what other lines of inquiry can contribute meaningfully to this investigation?

Answer 13

Epidemiology can implicate vehicles and guide appropriate public health action. Laboratory evidence can confirm the findings. Additional environmental studies with an inter-disciplinary team comprising of marine biologists, toxicologists, ecologists and food department would be particularly helpful in this case to explain the mode of contamination of clams. In this setting, a case-control study seems like a reasonable choice.

Section 6. Case-Control Study Design and Analysis

Question 14: What are important factors to keep in mind while selecting controls?

Answer 14

Conceptually, controls must not have the disease in question but should represent the population from which the cases come, i.e., they are similar to cases except in their disease status. In this way, controls are comparable to the source population of the cases and may well differ from the general population with respect to a number of characteristics including level of exposure. Methodology used for selection of controls should ensure random selection to prevent any selection bias.

Both cases and controls were asked about consuming clams on 4th April 2015. The two-by-two table results are shown in the following table.

Table 3. Clam Consumption by Case-Control Status, Kondur Village Outbreak, April 2015

Exposure	Cases	Controls	Total
Ate clams	65	11	76
Did not eat clams	0	54	54
Total	65	65	130

Question 15: Calculate the proportion of cases and proportion of controls exposed to clams.

Answer 15

Cases: 65 / 65 = 100%

Controls: 11 / 65 = 17%

Question 16: What is an appropriate measure of association for the data from this type of study? How will you calculate it?

Answer 16

The odds ratio is the appropriate measure of association for a case-control study design. As population at risk or the extent of the denominator is usually not known while deciding to undertake a case control study, direct calculation of attack rates and rate ratio is not possible.

The formula for the odds ratio is (a x d / b x c). For the data in this table, the odds ratio would be calculated as 65 x 54 / 0 x 11. However, because the value in cell c is 0, the odds ratio is not calculable. (*Epi Info reports the odds ratio as undefined.*)

Different methods ("fudge factors") have been suggested for dealing with this situation. Perhaps the most common is to add 1 to each cell. This procedure can be justified on Bayesian grounds so it is not completely arbitrary, but you also have covariates, which complicates matters.

Using this method, the odds ratio is (66 x 55) / (12 x 1) = 302.5, with 95% CI= 38.1–2400.1, and P-value < 0.0001.

Epilogue

In addition to the epidemiological investigation, the investigator (JN) also conducted in-depth interviews with the local women. They reported that consumption of clams is very common in this coastal village as it is a readily available source of nutrition. For some, it is also considered therapeutic for common ailments. The usual practice is to consume scooped flesh and soup after heating in oil and discard the shell. Clams are purchased fresh from local vendors on the day of preparation itself.

In this instance local women recalled the clams "smelling weird" when they purchased it on 4th April. When local vendors were interviewed, they noted that clams are commonly harvested from nearby Pennai River. However, on this fateful day clams were harvested from a different site in the hope of getting larger sized clams.

Marine biologists from the nearby University revealed that dumping of anthropogenic wastes, run off from agricultural lands and rivers, coastal upwelling are the major factors resulting in blooming of microalgae that produce toxins. These marine toxins are heat-stable and water-soluble. Shellfish, being filter feeders, tend to accumulate these toxins. Blooming of microalgae is seasonal in nature and some water bodies with high anthropogenic activity around it are more susceptible to it.

Of 10 health practitioners interviewed, 7 (70%) reported that they had seen patients in their practices with some sort of seafood-origin food poisoning. But they were not aware of neurological symptoms being associated with food poisoning or of its fatal nature.

The investigator recommended the following to the local health authorities

- **Creating awareness among the local population regarding safe clam harvesting sites and avoiding the practice of eating of clams (shellfish) during the season of algal bloom.**
- **Training for all level service providers to strengthen their knowledge on early identification and management of shellfish poisoning.**
- **Initiation of surveillance for seafood (shellfish) poisoning.**

Although laboratory results were indeterminate for any microbial or toxic etiology, confirmation of the etiology of the outbreak was not possible. The systematic epidemiological and environmental investigation provided a scientific basis for recommendations and appropriate public health action.

This investigation also underscores the importance of a coordinated and timely effort by a multidisciplinary team of epidemiologists, marine biologists and the food safety department led to containment of this outbreak of shellfish and prevention of new ones.

Annexure 3: List of Referral Laboratories notified by FSSAI

S. No.	Name of Laboratories	Name of the Director	Email id	Contact Details
1.	Central Food Laboratory, 3 Kyd Street, Kolkata- 700016	Dr. A.K. Adhikari	cflcal@gmail.com	033-22291309
2.	Food Safety & Analytical Quality Control Laboratory, C/o Central Food Technological Research Institute, Mysore-570013	Dr. Alok Shrivastava (Chief Scientist and Head)	csc@cftri.res.inaloksriva@yahoo.com	0821-2514972
3.	State Public Health Laboratory, Stavely Road, Cantonment Water Works Compound, Pune-411001	Mr. Hemant Kulkarni	cflpune123@yahoo.in	020—26330509
4.	National Food Laboratory, Ahinsa Khand-II, Indirapuram Ghaziabad-201014	Sh. G.P. Sharma	frslindia1971@gmail.com	0120-2650950, 09999239370 (Accountant – Mahesh)
5.	Indian Institute of Horticultural Research, Hessaraghatta lake post, Bangalore-560089	Dr. M.R. Dinesh	Director.IIHR@icar.gov.in	080-28466353
6.	Quality Evaluation Laboratory, Spices Board, Palarivattom P.O. Kochi-682025	Chairman – Dr. A. Jayathilaka Secretary – Suresh Kumar PM	sbqelkochi@gmail.comsbqel@indianspices.com	0484-2333610 (ext 329)
7.	Quality Evaluation Laboratory, Spices Board, Chuttugunta Center, GT Road, Guntur-522004		sbzognt@gmail.com	0863-2338571
8.	Quality Evaluation Laboratory, Spices Board, Plot No. R-11, Sipcot Industrial Complex, Gummidipoondi, Thiruvallur Dt., Chennai-601201		sbqelchennai@gmail.com	044-27921342
9.	Quality Evaluation Laboratory, Spices Board, First Floor, Banking complex II, Sector 19A, Vashi, Navi Mumbai-400703		sbqelmumbai@gmail.com	022-27841116, Extn. No. 21
10.	Centre for Analysis and Learning in Livestock in Food (CALF), National Dairy Development Board (NDDB), Anand-388001, Gujarat	1.Rajesh Nair, Director, (CALF) Board 2. Rajiv Chawla Scientist-III (CALF)	rajeshnair@nddb.coop rchawla@nddb.coop,	02962-226311,7574835057 02692-226652 (Ext 652)

11.	CSIR-Indian Institute of Chemical Technology, Uppal Road, Tarnaka, Hyderabad - 500007	Dr. S. Chandrasekhar	director@iict.res.in	040- 27193030
12.	National Research Centre on Meat, Chengicherla, Boduppal, Hyderabad – 500092	Dr. V.V. Kulkarni	nrcmeat_director@yahoo.co.in	040 2980 1672/73/74,29804541
13.	Indian Institute of Food Processing Technology, Food Safety and Quality Testing Laboratory, Pudukkottai Road, Thanjavur – 613005, Tamil Nadu	Dr. K. Singaravadivel	director@iicpt.edu.in	04362-226676
14.	ICAR- Central Institute of Fisheries Technology, Indian Council of Agricultural Research, Willingdon Island, CIFT Junction, Matsyapuri P.O., Cochin – 682029, Kerala	Dr. Ravishankar CN	cift@ciftmail.org, aris.cift@gmail.com	0484 – 2666880, 2667727
15.	ICAR-National Reasearch Centre for Grapes, P.O. Manjiri Farm, Solapur Road, Pune - 412307	Dr. S.D. Sawant (Director)	director.nrcg@icar.gov.in	020-26956002
16.	Pesticide Formulation and Residue Analytical Centre, National Institue of Plant health Management, Rajendranagar, Hyderabad - 500030	Dr.CherukuriSreenivasa Rao, (Director)	dirpmniphm-ap@nic.in	+91 40 24010106, +91-9441026576
17.	Punjab Biotechnology Incubator, Mohali SCO7 & 8, Phase---5, SAS Nagar, Mohali -160059, Punjab	Dr. AjitDua (CEO)	pbti2005@yahoo.com	0172-5020891/95 09915514974
18.	CSIR-Indian Institute of Toxicology Research Vishvigyan Bhawan, 31, Mahatma Gandhi Marg Lucknow - 226 001, Uttar Pradesh, India	Professor (Dr.) Alok Dhawan	director@iitrindia.org	+91-522-2217497

Annexure 4: List of 74 State Food Testing Laboratories continuing under Section 98 of FSS Act, 2006

S. No.	State/UT	Name & Address of the Laboratory	NABL Accreditation
1.	Andhra Pradesh	Regional Public Health Laboratory, Govt Hospital Complex, PeddaWaltair, Visakhapatnam – 530017	No
2.	Assam	State Public Health Laboratory, BamuniMaidam, Guwahati 21, Assam	No
3.	Bihar	Combined Food & Drugs Laboratory, Agamkuan, Patna- 800 007	No
4.	Chhattisgarh	State Food Testing Laboratory, Near Mahila Police Station, Opp. Nagar Nigam Office, Kalibari, Raipur	No
5.	Delhi	Combined Food & Drugs Laboratory, Directorate of PFA, NCT of Delhi, A-20, Lawrence Road, Industrial Area, Delhi- 110035	NABL Accredited
6.	Goa	Food and Drug Laboratory, Directorate of Food & Drugs Admn. DHANWANTARI, Opp, the Shrine of Holy Cross, Bambolim – Goa – 403202	No
7.	Gujarat	Public Health Laboratory, Urban Health Centre Bldg, Nr. Lal Bungalow, C.G. Road, Navarangpura, Ahmedabad 380009	NABL Accredited and FSSAI Notified
8.		Food and Drugs Laboratory, Near Polytechnic College, Nizampura, Vadodara – 390 002	NABL Accredited and FSSAI Notified
9.		Regional Food Laboratory, New Lotus Ring Road, Nr. Mahakali Temple, Opp. District Panchayat Staff Quarters, Bhuj, Kutch - 370001	NABL Accredited and FSSAI Notified
10.		Regional Food Laboratory, University Road, Nr. Forensic Lab, Opp. Kidney Hospital, Rajkot, Gujarat - 360005	NABL Accredited and FSSAI Notified
11.		Public Health Laboratory, Surat Municipal Corporation, 304 Ambedkar Shopping Centre, Mann-Darwaja, Ring Road, Surat - 395003	No
12.	Haryana	District Food Laboratory, Civil Hospital, Karnal – 132001	No
13.		State Food, Water and Excise Laboratory, Govt. of Haryana, Ground Floor, Sector – 11 D, Chandigarh	No
14.	Himachal Pradesh	Composite Testing Laboratory, Kandaghat, Distt. Solan, Himachal Pradesh	No
15.	Jharkhand	State Food & Drug Laboratory, Namkum, Ranchi Tata Road, Ranchi – 834010	No
16.	Jammu & Kashmir	Public Health Laboratory, PatoliMangotrian, Jammu	No
17.		Public Health Laboratory, Nr. CD Hospital, Dalgate, Srinagar	No
18.	Karnataka	State Food Laboratory, Public Health Institute, Sheshadri Road, Bangalore- 560 001	No
19.		Divisional Food Laboratory, Ummerkhayan Road, Tilak Nagar Mysore-570001	No

20.		Divisional Food Laboratory, Vaccine Institute Premises, Tilakwadi, Belgavi-590006	No
21.		Divisional Food Laboratory, Old Hospital Compunf, Kalaburagi-585105	No
22.		BBMP Food laboratory, Dasappa Hospital Compund, N R Square, S. J. P Road, Bangalore-560002	No
23.	Kerala	Regional Analytical Laboratory, Kakkanand, P.O. Ernakulam, Kochi	NABL Accredited and FSSAI Notified
24.		Regional Analytical Laboratory, Malaparamba, Kozhikode – 673009	NABL Accredited and FSSAI Notified
25.		Government Analyst Laboratory, Vanchiyoor P.O Red Cross Road, Thiruvananthapuram - 695035	NABL Accredited and FSSAI Notified
26.	Madhya Pradesh	State Food Laboratory, Controller Food and Drug Administration, Idgah Hills, Bhopal - 462001	No
27.	Maharashtra	Food & Drugs Administration Laboratory, FDA Plot no. 341, Bandra Kurla Complex, Bandra (East), Mumbai-400051	NABL Accredited and FSSAI Notified
28.		Regional Public Health Laboratory, Nizam Bunglow, Cantonment Area, Aurangabad - 431002	No
29.		District Public Health Laboratory, Dhobhi Ghat Building, General Hospital Compound, Jalgaon – 425001	No
30.		District Public Health Laboratory, 330/2, B, Y.P. Powar Nagar, Bendre Building, Kolhapur - 416002	No
31.		District Public Health Laboratory, Solapur	No
32.		District Public Health Laboratory, Ahmednagar	No
33.		Municipal Laboratory, Room No. 49, 2nd Floor, G North Ward Office, J.K. Sawant Marg, Dadar, Dadar West, Mumbai-400028	No
34.		Public Health Laboratory, Konkan Bhawan, 6th Floor, CBD Belapur, District Thane, New Mumbai - 400 614	No
35		District Public Health Laboratory, New Civil Hospital Compound, Nashik – 422002	No
36.		State Public Health Laboratory, Stavely Road, Cantonment Water Works Compound, Pulgate, Near St. Mary's School, Pune - 411001	NABL Accredited and FSSAI Notified
37.		District Public Health Laboratory, Vasantdada Co-op. Industrial Estate, Madhavnagar Road, Nr. R.T.O., Sangli – 416416	No
38.		District Public Health Laboratory, Satara	No
39.		Regional Public Health Laboratory, Mental Hospital Compound, Chindwada Road, Nagpur- 440 029	No
40.		District Public Health Laboratory, Opposite Irvin General Hospital, Amravati-444601	No

41.		District Public Health Laboratory, Nanded	No
42.		Food and Drug Administration Laboratory, Aurangabad	No
43.		Food and Drug Administration Laboratory, Nagpur	NABL Accredited
44.	Manipur	State Public Health Laboratory , R. D Wing Complex, Lamphet, Imphal, Manipur -795004	No
45.	Meghalaya	Food Testing Laboratory, Pasteur Institute Shillong -793001	No
46.	Nagaland	Food Health Laboratory, Paramedical colony, Kohima, Nagaland	No
47.	Odisha	State Public Health Laboratory, In front of Ram Mandir, Convent Square, Bhubaneswar - 751001	No
48.	Pondicherry	Public Health Laboratory, Indira Nagar ,Gorimedu, Puducherry-605006	No
49.	Punjab	State Food Laboratory, Kharar , Distt. SAS Nagar	No
50.	Rajasthan	Food Safety and Standards Laboratory, E-1, Behind Kamla Nehru T.B. Hospital, Jaipur Road, Ajmer	No
51.		State Public Health Laboratory, Mini Swasthya Bhawan, Mandir Marg, Sethi Colony, Behind Mental Hospital, Jaipur – 302004	No
52.		RegionalPublic Health Laboratory, C-27, Railway Road, Jodhpur - 342001	No
53.		Food Safety and Standards Laboratory, Rajiv Gandhi Hospital Campus, Alwar – 301001	No
54.		Public Health Laboratory, Maharana Bhopal Cancer Hospital, Near Dhobighat, Udaipur	No
55.		Food Analysis and Public Health Laboratory, Near IAM hall, Near blood bank, MBS Hospital, Nayapura Kota, Rajasthan	No
56.		Public Health Laboratory, P.B.M. Hospital Premises, Bikaner (Rajasthan)	No
57.		Public Health Laboratory, Banswara (Rajasthan)	No
58.	Sikkim	State Food Laboratory, ChewatarSingtam - 737134	No
59.	Tamil Nadu	Food Analysis Laboratory, No.219, Race Course Road, Coimbatore - 641018	No
60.		Food Analysis Laboratory, King Institute Campus, Guindy, Chennai - 600032	No
61.		Food Analysis Laboratory, Gandhi Nagaram, Near Gandhi Musiam, Poor Home Campus, Madurai – 625 020	No
62.		Food Analysis Laboratory, Kamaraj Nagar Colony Post, Salem – 636014	No
63.		Food Analysis Laboratory, Medical College Road, Near Membalam, Thanjavur - 613001	No
64.		Food Analysis Laboratory, No.5, Old Police Hospital Road,Palayamkottai, Tirunelveli – 627002	No
65.	Telangana	State Food Laboratory, Nacharam Industrial Area, Hyderabad – 501507	NABL Accredited and FSSAI Notified

66.	Tripura	Regional Food Laboratory, Pandit Nehru Office Complex, Agartala - 799006	No
67.	Uttar Pradesh	Regional Public Analyst Laboratory, HB Training Campus, Halwai Ki Bageechi, Agra	No
68.		State Government Laboratory, UP Behind Nehru Batika, Sector C, Aliganj, Lucknow – 226020	NABL Accredited and FSSAI Notified
69.		Regional Public Health Laboratory, Shivpur, Varanasi – 221003	No
70.		Regional Public Analyst Laboratory, Medical College compound, meerut-250004	No
71.		Regional Public Analyst Laboratory, BRD Medical College Compound, near ANM training centre Gorakhpur-273013	NABL Accredited
72.		Regional Public Analyst Laboratory, Rani Lakshmi Bai Medical college Compound , Jhansi-284128	NABL Accredited and FSSAI Notified
73.	Uttarakhand	State Food and Drug Laboratory, Rudrapur, Uttarakhand	No
74.	West Bengal	West Bengal Public Health Laboratory, 2, Convent lane, Kolkata-700015	NABL Accredited

Remarks: State Food testing laboratories of FDA Nagpur, Gorakhpur, Kolkata and Delhi are NABL Accredited and their FSSAI Notification is under process.

Annexure 5: List of FSSAI Notified Food Testing Laboratories under Section 43 (1) of FSS Act, 2006

S. No	Name and Address of the Laboratory
A	**NORTHERN REGION**
	Delhi
1.	Apex Testing and Research Laboratory, New Delhi B-90, Shardapuri, Ramesh Nagar, Near Mother Diary, New Delhi-110015
2.	AGSS Analytical & Research Lab (P) Ltd, Delhi C-37/2, Lawrence Road, Industrial Area, Delhi 110035
3.	Arbro Pharmaceuticals Private Limited, Delhi 4/9, Kirti Nagar Industrial Area, New Delhi-110015
4.	Avon Food Lab PrivateLimited, Delhi C-35/23, Lawrence Road Industrial Area, Delhi 110035
5.	Bharat Test House, Delhi 454/2, Timber Market Azadpur Commercial Complex, Delhi-110033
6.	Delhi Analytical Research Laboratory, Delhi Plot No. 2, Timber Block, Jhilmil, Industrial Area, New Delhi – 110095
7.	Delhi Test House, Delhi A-62/3. G.T.Karnal Road, Industrial Area, Opp. Hans Cinema, Azadpur, NewDelhi-110033
8.	Fair Quality Institute (Food Analysis & Industrial Research Quality Institute), New Delhi Plot No. 635, IInd Floor, Opp Metro Pillar No. 512, Main Rohtak Road, Mundka, New Delhi-110041
9.	FICCI Research and Analysis Centre, New Delhi Plot No - 2A, Sector-8, Dwarka, New Delhi - 110077
10.	ITL Labs Private Limited, Delhi B-283-284, Mangolpuri, Industrial Area,Phase- I, Delhi- 110083
11.	Quality Services & Laboratories, New Delhi Plot No 10, Second Floor, D.S.I.D.C, Scheme-III, Okhla Industrial Area, Phase – II , New Delhi – 110 020
12.	Shriram Institute for Industrial Research, Delhi 19,University Road, NewDelhi-110 007
13.	Sigma Test and Research Centre, Delhi BA –15, Mangolpuri Industrial Area, Phase – II, Delhi -110 034
14.	Shree Krishna Analytical Services, New Delhi SKAS Pharma Pvt. Ltd., A-5/4, Mayapuri Industrial Area, Phase –II, New Delhi
15.	Sophisticated Industrial Materials Analytical Labs Private Limited, Delhi A-3/ 7 Mayapuri Industrial Area, Phase-II, New Delhi - 110064
16.	Spectro Analytical Labs Limited, Delhi E-41, OkhlaIndustrialArea,Phase- 2, New Delhi–110020
17.	Standard Analytical Laboratory (ND) Private Limited, Delhi 69, Functional Industrial Estate, Patparganj, Delhi – 110092
18.	Research Institute of Material Sciences Pvt Ltd, Delhi Plot No. 22 & 23, Ranaji Enclave, NangliSakrawati, New Delhi – 110043
19.	Centre for Environment and Food Technology Pvt. Ltd., New Delhi 17, DLF Industrial Area, 1st & 2nd Floor, Moti Nagar, New Delhi110015

	Haryana
20.	Alpha Test House, Bahadurgarh 198-199, MIE., Phase -1, Industrial Area, Bahadurgarh, Haryana
21.	Choksi Laboratories Limited, Panchkula Plot No. 362, Industrial Area, Phase II, Panchkula-734112, Haryana
22.	Dove Research & Analytics, Panchkula Plot No. 298, Industrial Area, Phase-II, Panchkula-134109, Haryana
23.	Eurofins Analytical Services India Pvt. Ltd., Gurugram First Floor, Plot No 157, Udyog Vihar, Phase –I, Gurugram, Haryana
24.	Fare Labs Private Limited, Gurgaon L17/3,DLF-Phase-II M.G. Road, Gurgaon- 122002, Haryana
25.	Haryana Test House & Consultancy Services, Panipat 50-C, Sector-25, Part-II, Huda, Panipat, Haryana
26.	Idma Laboratories Ltd, Panchkula Idma Complex: 391, Industrial Area- Phase I, Panchkula – 134 113
27.	Interstellar Testing Centre Pvt. Ltd. , Panchkula 86,IndustrialArea,Phase1,Panchkula - 134109
28.	Intertek India Private Limited (Food Services), Gurgaon Plot No#68,UdyogVihar, Phase-1, Gurgoan,Haryana-122016
29.	National Collateral Management Services Limited, Commgrade- Testing Services Regional Laboratory (North), Gurgaon Plot – 883 (3rd Floor), Phase V, Udyog Vihar, Gurgaon, Haryana
30.	Ozone Pharmaceuticals Limited, Bahadurgarh 639 - 640, 1st floor, MIE, Bahadurgarh-124507, Haryana
31.	Saturn Quality Certifications Private Limited, Bahadurgarh V-17, Red Cross Road, Modern Industrial Estate (MIE), Bahadurgarh,Haryana–124507
32.	SGS India Private Limited, Manesar, Gurgaon Plot No. 21, Sector-3, IMT Manesar, Gurgaon District, Haryana-122050
33.	TUV SUD South Asia Private Limited, Gurgaon 373, Udyog Vihar, Phase II, Sector 20, Gurgaon-122 016, Haryana
	Himachal Pradesh
34.	Auriga Research Limited, Baddi D.C. Complex, Opposite Gianz Hotel, Village Bagbania, Tehsil- Nalagarh, District – Solan -174101, Himachal Pradesh
	Jammu & Kashmir
35.	Quality Control and Quality Assurance Division, CSIR- Indian Institute of Integrative Medicine, Jammu Canal Road, Jammu-Tawi180001
	Punjab
36.	Bali Test House Private Limited, Ludhiana Streetno.12,JeevanNagar,focal Point, Phase– V, Ludhiana, Punjab– 141010
37.	Industrial Testing Laboratory & Consulting House, Patiala Ghalori Gate, Patiala -147001, Punjab
38.	Punjab Biotechnology Incubator, Mohali SCO7 & 8, Phase-5, SAS Nagar, Mohali -160059, Punjab
	Rajasthan
39.	Amol Pharmaceuticals Private Limited, Jaipur Analytical Division, E -362-364, Sitapura Industrial Area, Sitapura, Jaipur- 302022,Rajasthan

40.	CEG Test House And Research Centre Private Limited, Jaipur B-11(G), Malviya Industrial Area, Jaipur -17
41.	Jagdamba Laboratories, Jaipur 181 Padmavati Colony (B), New Sanganer Road, Opp. Ryan School, Shyam Nagar, Jaipur, Rajasthan-302019
42.	National Test House (Ministry of Consumer Affairs, Food & Public Distribution, Department of Consumer Affairs) E-763, Road No. 9F-1, VKI area, Jaipur- 302013, Rajasthan
43.	Omega Test House, Jaipur J-889, Phase III, Sitapura Ind. Area, Jaipur - 302022, Rajasthan
44.	Oasis Test House Limited, Jaipur SP-2, 22 Godown Industrial Estate, Jaipur-302006, Rajasthan
	Uttarakhand
45.	Devansh Testing and Research Laboratory Private Limited, Haridwar 94, Shiv Ganga Industrial Estate, Lakeshari, Bhagwanpur-247661, Roorkee, Distt. Haridwar (U.K.)
	Uttar Pradesh
46.	Advance Research and Analytical Services, Ghaziabad 1/8, South side G.T Road, Bulandshar Industrial Area, Near Aditya Business centre, Lal Kuan, NH-24,Ghaziabad—201009, U.P
47.	AES Laboratories Private Limited, NoidaB-118, Phase-II, Noida–201305, Uttar Pradesh
48.	Atharva laboratories Pvt. Ltd., Noida B-100, Phase-II, Noida-201 305, Uttar Pradesh
49.	Eko Pro Engineers Private Limited, Ghaziabad 32/41,South side of G.T. Road, UPSIDC Industrial Area, Ghaziabad--201009, U.P.
50.	Food Analysis and Research Laboratory (FARL), Aallahabad Centre of Food Technology, Science Faculty Campus, University of Allahabad, Allahabad-211002
51.	National Test House (Northern Region), Ghaziabad Kamla Nehru Nagar, Ghaziabad – 201 002
52.	Regional Food Research & Analysis Centre (Department of Horticulture and Food Processing, UP), Lucknow Udyanbhawan Campus, 2-Sapru Marg, Lucknow – 226 001, Uttar Pradesh
53.	Regional Public Analyst Laboratory, Jhansi M.L.B. Medical College Campus, Jhansi, Uttar Pradesh
54.	Government Public Analyst Laboratory, Lucknow Sector –C, Chetan Vihar, Aliganj, Lucknow, Uttar Pradesh
B.	**WESTERN REGION**
	Dadra and Nagar Haveli, and Daman and Diu
55.	Konarch Research Foundation, Daman Plot No. 338/1, Behind Cricket Ground, Kachigam, Daman–396210
	Gujarat
56.	Accurate Laboratory, Ahmadabad E-17, Madhavpura Market, Shahibaug, Ahmedabad-380004, Gujarat
57.	Analytical & Environmental Services, 350, GIDC, Makarpura, Samir Tech Ccpmpound, Baroda -390010, Gujarat
58.	Food & Drugs Laboratory, Vadodara Near Polytechnic, Nizapuram, Vadodara-390002
59.	Gujarat Laboratory, Ahmedabad F-16,17, Madhavpura Market, Shahibaug, Ahemdabad-380004

60.	Hemshell Services – Testing Division, Vadodara, Gujarat 903/1, Makarpura G.I.D.C, Makarpura, Vadodara, Gujarat
61.	Hi-Tech Healthcare Laboratory Research centre, Ahmedabad 201, Sahaj Arcade, Opp. Lincoln Healthcare, Near Sola Gam, Science City Road, Ahemdabad – 380 060, Gujarat
62.	Pollucon Laboratories Private Limited, Surat 5/6 Pollucon House, Opp. Balaji Ind. Soc., Old Shantinath Mill Lane, Navjivan Circle, UdhanaMagdalla Road, Surat-395007, Gujarat
63.	Public Health Laboratory, Ahmedabad 1st Floor, Navrangpura Urban Health Centre, Opp. Devpath Building, B/h Lal Bunglow, C.G. Road, Ahmedabad – 380 009, Gujarat
64.	Regional Food Laboratory, Bhuj – Kachchh New Lotus Ring Road, Near Mahakali Temple, Opp: District Panchayat Staff Quarters, Bhuj – Kachchh
65.	Regional Food Laboratory, Rajkot Government of Gujarat, Near : Forensic Science Laboratory, University Road, Rajkot – 360 005, Gujarat
66.	SGS India Private Limited, Ahmedabad 201, Sumel—II, Near Gurudwara, S.G Highway, Thaltej, Ahmedabad—380054
67.	SGS India Private Limited, Gandhidham 1stFloor, Plot No.156-157, GIDC, Oslomainroad, Opp. Sector—4,Gandhidham—370201,Gujarat
68.	Vimta Labs Limited, Ahmedabad B-303 & B-304, Shilp Aaron Tower-B, Sindhu Bhavan Road, Budakdev, Ahmedabad-380059, Gujarat
69.	Lilaba Analytical Laboratories, Surat 2nd Floor, Galaxy Point Building, Above Hotel Amiras, SarthanaJakat Naka, Varachha Road, Surat - 395006, Gujarat
	Madhya Pradesh
70.	Choksi Laboratories Limited, Indore 6/3, Manorama Ganj,Indore—452001, Madhya Pradesh
71.	Cali – Labs Private Limited, Bhopal HX—21,E—7,Arera Colony, Bhopal– 462016, Madhya Pradesh
72.	Excellent Bio Research Solutions Pvt. Ltd. 1042, Napier Town, 4th Bridge, Jabalpur - 482001 Madhya Pradesh
73.	Krishna Digital Material Testing Laboratory, Bhopal 2, Bhawani Nagar, J.K. Road, Bhopal, M.P
74.	QTTL Lab Private Limited, Indore 301-302 Labbaiq Regency, 4/2 Old Palasia, Indore-452 009, Madhya Pradesh
75.	SGS India Private Limited, Indore 1-B Press Complex, A. B. Road, Indore-452008, Madhya Pradesh
76.	Shreeji Analytical & Research Laboratories Pvt. Ltd, Indore A-1, Balaji Tulisyan Industrial Estate, Gram Kumedi, Indore-453551, Madhya Pradesh
77.	Vimta Labs Ltd, Indore Unit No. 301 & 302, 3rd Floor, Maloo 01, Plot No. 26, Scheme No. 94 C, Ring Road, Indore - 452010, Madhya Pradesh
	Maharashtra
78.	Anacon Laboratory Private Limited, Nagpur FP-34,35 Butibori Food Park, Five Star Industrial Estate, Nagpur- 441122, Maharashtra
79.	Ashwamedh Engineers & Consultants, Nasik Survey No. 102, Plot No.26,WadalaPathardi Road, Indira Nagar, Nashik-422009, Maharashtra

80.	Bee Pharmo Labs Pvt. Ltd., Thane C-2, Hatkesh Udyog Nagar, Mira Bhayander Road, Mira Road (E), Dist. Thane – 401107, Maharashtra
81.	Doctor's Analytical Laboratories Private Limited, Mumbai Plot No. R 809, TTCMIDC Rabale , Off. Thane Belapur Road, Rabale, Navi Mumbai - 400701
82.	Envirocare Labs Private Limited, Mumbai Enviro House, Plot No. A-7, MIDC, Wagle Industrial Estate, Main Road, Thane-400604
83.	Envirocare Labs Pvt. Ltd., Pune 302, Transbay Balewani Gaon, Opp SKP Campus, Balewadi, Pune – 411045
84.	Equinox Labs Pvt. Ltd. Navi Mumbai Equinox Centre, R 65, TTC, Rabale, Navi Mumbai – 400 701
85.	Export Inspection Agency, Mumbai Pilot Test House, E-3, MIDC Area, Marol, Andheri(E), Mumbai-400093.
86.	Food Testing Laboratory, Food & Drugs Administration Laboratory, Mumbai Plot No 341, Opposite R.B.I, Bandra (East), Mumbai- 40005
87.	Food Hygiene and Health Laboratory, Pune A-512/513, Fourth Floor, Mega Centre, Magarpatta, Solapur Road, Hadapsar, Pune-411028
88.	Geo-Chem Laboratories Private Limited, Mumbai Pragati, Adjacent to Crompton Greaves, Kanjurmarg (E),Mumbai- 400042
89.	Maarc Labs Private Limited, Pune Plot No 1 & 2, Gate No. 27, Nanded Phata, Sinhagad Road, Pune-411041, Maharashtra
90.	MicroChemSilliker Private Limited, Mumbai Micro Chem House, A-513,TTC Industrial Area, MIDC, Mahape, Navi Mumbai-400701
91.	Microtech Laboratory, Pune Survey No.11, 5th Floor, Chaitraban complex, Office No. 5 C1, C2 & 5 D, Above Hotel Samrat, Wakdewadi, Shivajinagar, Pune–411003
92.	National Agriculture and Food Analysis and Research Institute, Pune 2nd & 3rd Floor, MCCIA Building, Tilak Road, Swargate, Pune - 411002, Maharashtra
93.	National Collateral Management Services Limited-CommGrade, Navi Mumbai Plot No. D-164, Anand House, TTC Industrial Area, MIDC, Nerul East, Navi Mumbai-400706, Maharashtra
94.	Nutralytica Research Private Limited, Nashik Plot No. 447, P.O. Unandanagar, Lakhamapur, Tal. Dindori, Dist-Nashik– 422202, Maharashtra
95.	Precise Analytics Lab, Mumbai B-22, Road .No.16, Wagle Industrial Estate MIDC, Thane (W), Mumbai, Maharashtra-400604.
96.	Pune Municipal Corporation Quality Assurance Laboratory, Pune SalunkeVihar Road, Kamella Area, Kondhwa, Pune-411048
97.	Qualichem Laboratories, Nagpur Swami Samartha Commercial Complex, 4, North Bazar Road, GokulpethMarket, Dharampeth Extn., Nagpur-440 010
98.	RCA Laboratories, (A Division of Dr. Amin Controllers Pvt Ltd) Mumbai 501/502,MilanIndustrialEstate, Abhudaya Nagar, Cotton Green, Off TJ Road, Mumbai-400033
99.	Reliable Analytical Laboratories Private Limited, Thane Relable house, 125 Indian Corporation Complex , Dapoda Road, Mankoli Naka, Bhiwandi, Thane-421302
100.	SGS India Private Limited, Thane SGS House, A-77, Road No. 16, Waghle Industrial Estate, Thane-400604
101.	State Public Health Laboratory, Pune Cantonment Water Works Compound Stavely Road, Near St. Mary's School, Pulgate Camp, Pune -411001, Maharashtra

102.	Testtex India Laboratories Private Limited, Mumbai 301-304 Premson's Industrial Estate, 3rdFloor, Caves Road, Jogeshwari (East), Mumbai – 400060
103.	TUV India Private Limited, Pune Survey No: 42, 3/1 &3/2, Sus, taluka; Mulshi, Pune-411021
104.	Vimta Labs Limited, Pune, Maharashtra Bhakthi Genesis, 5th Floor, Sr. No. 245, Wakad- Hinjewadi Road, Wakad, Pune-411057
105.	Bombay Test House Private Limited, Navi Mumbai Unit No. 1, 4th Floor, Banking Complex-2, Plot No. 9 &10,Sector -19A, Vashi, Navi Mumbai - 400703, Maharashtra
106.	Jubilant Pharma and Chemical Lab (OPC) Pvt. Ltd., Navi Mumbai Surya Gayatri, Plot No. D14/15, Sector No. 6, New Panvel (E), Navi Mumbai410206, Maharashtra
	Goa
107.	Italab, (Goa) Pvt. Ltd., Goa Italab House, Apollo Victor Hospital Road, Malbhat, Margao, Goa – 403 601
C.	**SOUTHERN REGION**
	Andhra Pradesh
108.	Food Testing Laboratory, Jawaharlal Nehru Technological University, Kakinada School of Food Technology, Jawaharlal Nehru Technological University, Kakinada, E.G. District, Andhra Pradesh, Pin 533005
109.	TUV SUD South Asia Pvt. Ltd. Vishakhapatnam A1, Industrial Estate, Kancharapalem, Vishakapatnam – 530007, Andhra Pradesh
110.	Vimta Labs Ltd, Nellore 3rd Floor, Mc Arcade, Mini Byp, Magunta Layout, Nellore – 524004, Andhra Pradesh
111.	Vimta Labs Ltd., Visakhapatnam No. 9-13-45/2-9-3, 3rd Floor, N Circle, VIP Road, Visakhapatnam – 5330003
112.	9 National Collateral Management Services Limited, Commgrade Testing Services, Regional Laboratory, Visakhapatnam Sardar Gouthulatchanna Bhavan, D. No. 3-2/2 to 4, Adarsh Nagar, Visakhapatnam-530040, Andhra Pradesh
113.	ITC Limited, Guntur, Agribusiness Division, ILTD, Spice Laboratory, Grand Trunk Road, Guntur, Andhra Pradesh-522004
	Karnataka
114.	Auriga Research Limited, Bengaluru No. 136,6th Cross, 2nd Stage, Yeshwanthpur Industrial Subhurb, Bangalore-560022, Karnataka
115.	Merieux Nutri Sciences Bangalore Private Limited, Bangalore D36, 4thMain, KSSIDC Industrial Estate, Rajaji nagar, Bengaluru-560044.
116.	Environmental Laboratory (Unit of Mineral Engineering Services), Bangalore #948, 2nd Cross, St. Thomas Town Post, Kammanahalli Main Road, Bangalore-560084, Karnataka
117.	Eurofins Analytical Services India Private Limited, Bengaluru 501/1, Doddanakundi Industrial Area 2, Hoodi, Whitefield, Banglore-560048
118.	Ganesh Consultancy & Analytical Services, Mysore No. 294/A, Hebbal Industrial Area, Mysore-570016
119.	Institute for Analysis of Pharma, Dairy, Food and Cultures (IADFAC), Bengaluru 8, Siddivinayaka Complex, Nagarabhavi 2ndStage, 2ndBlock, Near BDAComplex, 80 Feet Ring Road, Bengaluru-560072.

120.	Robust Materials Technology Pvt. Ltd., Bengaluru No. 94, 2nd Floor, Thirumala Complex, Nagarabhavi Main Road, NGEF Layout, Nagarabhavi, Bengaluru-560072
121.	Shiva Analyticals (India) PrivateLimited, Bengaluru Plot No24 D (P) & 34 D, KIADB Industrial Area Bangalore, Hoskote --562114,Karnataka
122.	Shriram Institute for Industrial Research, Bengaluru Plot No. 14/15, Sadarmangala Industrial Area, Whitefield Road, Bangalore-560048
123.	TUV SUD South Asia Private Limited, BengaluruNo. A-151, 2nd C Main Road, Peenya Industrial Estate, II Stage, Bangalore-560058
124.	TUV India Pvt. Limited (TUV- NORD Group) (Laboratory Division), Bangalore No-8 Commerce, 2nd Floor, III- Main Road, Rajajinagar, 6th Block, Opp. KSSIDC IT Park, Rajajinagar Industrial Estate, Bangalore-560044
125.	Vimta Labs Limited, Bangalore 1st & 2nd Floor, #1047, Rukmini Plaza, 20th Main, 5th Block, West of Chord Road, Rajaji Nagar, Bangalore-560010, Karnataka
126.	Vsix Analytical Labs Private Limited., Bengaluru #77 (502/503), 2nd Floor, 21st–'D' Cross, Muthurayaswamy Layout, Srigandhakaval, Sunkadakatte, Bengaluru-560091, Karnataka
	Kerala
127.	Accurate Analytic (General Purpose Laboratory), Cochin Nikarthil Road, Thoppumpady, Cochin – 682005
128.	Confederation for Ayurvedic Renaissance Keralam Ltd., Koratty KINFRA, Small Industries Park, NalukettuRoad, Koratty – 680 309, Thrissur, Kerala
129.	Export Inspection Agency, (Ministry of Commerce & Industry, Govt. of India) 27/1767A, Shipyard Quarters Road, Panampilly Nagar (South),Kochi-682036, Kerala
130.	Food Quality Laboratory & Research Centre OS-30 & 31, IIIrd Floor, GCDA Complex, Marine Drive, Ernakulam, Kochi, Kerala-682031D
131.	Food Quality Monitoring Laboratory (FQML), Kerala Council for Food Research & Development Office, Perinjottakkal P.O., Konni, Pathanamthitta Distt., Kerala- 689692
132.	Geo-Chem, Laboratories Pvt. Ltd., Aroor Aman Commercial Complex, Opp. Mercy School, Aroor-688537
133.	Interfield Laboratories, Kochi 13/1208 – A Interprint House, Karuvelipady, Kochi - 682005, Kerala
134.	Neogen Food & Animal Security (India) Pvt Ltd, Cochin Uchikkal Lane, Poonithura P.O. Cochin – 682038, Kerala
135.	SEA Lab, Aroor Seafood Park India Limited, XIII/99A, Keltron Road, Aroor, Alleppey District, Kerala-688534
136.	CEPCI Laboratory & Research Institute, Kollam Cashew Bhawan, Mundakkal, Kollam-691001
137.	Vimta Labs Limited, Cochin 5 C & D, 5th Floor, Noel Focus, Seaport- Airport Road, Chettetukara, CSEZ (PO), Kakkanad, Cochin, Kerala – 682037
138.	Govt. Analyst's Laboratory, Thiruvananthapuram Red Cross Road, Vanchiyoor P.O., Thiruvananthapuram – 695035, Kerala
139.	Regional Analytical Laboratory, Ernakulam Kakkanad, Ernakulam - 682030, Kerala
140.	Regional Analytical Laboratory, Kozhikode Malaparamba, Kozhikode, Kerala – 670009

141.	State Laboratory for Livestock, Marine & Agri Product (SLMAP), Ernakulam Maradu, Nettor P.O., Ernakulam, Kerala
	Tamil Nadu
142.	ABC Techno Labs India Private Limited, Chennai ABC Tower, No: 400, 13th Street, SIDCO Industrial Estate, North Phase, Ambattur, Chennai-600098, Tamil Nadu
143.	Aqua Designs India Private Limited Laboratory Services, Chennai Off 200 Feet Road, Kolathur, Chennai 600099, Tamil Nadu
144.	Chennai Mettex Lab Private Limited, Chennai Jothi Complex, No. 83, M.K.N. Road, Guindy, Chennai-600032
145.	Chennai Testing Laboratory Private Limited, ChennaiA-Super 19, T.V.K. Industrial Estate, Guindy, Chennai- 600 032, Tamil Nadu
146.	CVR Labs (P) Limited, Chennai Dignity Centre, 2nd Floor, New No. 2/9, Old No. 21, Abdul Razack Street, Saidapet, Chennai – 600 015, Tamil Nadu
147.	Envirocare India Private Limited, Madurai #43, 2nd Street, Harvey Nagar, Madurai-625016
148.	Export Inspection Agency, Chennai 6th Floor CMDA Tower II, No.1 Gandhi Irwin Road, Egmore, Chennai- 600008
149.	Global Lab and Consultancy Services, Tamil Nadu SF. No. 92/3A2, Geetha Nagar, AlagapuramPudur, Salem, Tamil Nadu
150.	Hubert Enviro Care Systems (P) Limited, Chennai No. 18, 92nd Street, Ashok Nagar, Chennai-600083
151.	Interstellar Testing Centre Private Limited, Chennai Plot No. 2, Site No. 12/2A, Industrial Estate, Perungudi, Sholinganallur Taluk, Chennai - 600094, Tamil Nadu
152.	MATS India Pvt. Ltd (Laboratory Services Division), Chennai No.: 1A, 1B, Perumal Koil Street, Nerkundram, Chennai-600107
153.	Monarch Biotech Pvt.Ltd, Chennai 37-A, SIDCO Industrial Estate, Thirumazhisai, Chennai - 600124.
154.	Nawal Analytical Laboratories, Hosur Plot No.100, New SIDCO Industrial Estate,Sri Nagar Hosur635109,TamilNadu
155.	Scientific Food Testing Services (P) Ltd., Chennai Plot No. 16, D. No. 8, First Street, ThangamColony, Anna Nagar West, Chennai – 600 0400
156.	SGS India Private Limited, Multi Laboratory, Chennai Opposite to State Bank of India, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Chennai-600058
157.	SMS Labs Services Private Limited, Chennai No. 39/6, Thiruvallur High Road, Puduchatram Post, Thirumazhisai Via, Poonamallee TK, Chennai – 600124
158.	TA Labs Private Limited, Chennai No: 270 A & 270 B, Burma Colony, 4th Main Road, Off OMR, Perungudi, Chennai 600 096, Tamil Nadu
159.	Bureau Veritas (India) Pvt. Ltd., Chennai F2, Thiru-Vi-ka Industrial estse, Phase III, EkkattuthangalGuindy, Chennai-600032
	Telangana
160.	Bhagavathi Ana Labs Private Limited , Hyderabad Plot No. 7-2-C/ 7&8, Industrial Estate, Sanath Nagar Hyderabad Urban-500018, Andhra Pradesh

161.	Care Labs, Hyderabad Plot No. 1, 3rd Floor, Sai Sadan Complex, Shiva Ganga Colony, LB Nagar, Hyderabad, Telengana
162.	First Source Laboratory Solutions LLP Analytical Services, Hyderabad First Floor, Plot No. A1/B, IDA Nacharam Cross Road, Hyderabad- 500076
163.	Intertek India Private Limited (Food Services), Hyderabad Plot no. D-53, IDA, Phase-1, Jeedimetla, Hyderabad-500055, Telangana
164.	Megsan Labs Private Limited, Hyderabad #3-31/33, Plot No.:33/Part Sy. Nos. 123,124,125 &142, Kompally, Hyderabad-500 014
165.	State Food Laboratory, Hyderabad Nacharam, Manikchand Road., Opp. Raheja Estate, Hyderabad, Telangana- 500076
166.	Testing Services-Comm Grade, National Collateral Management Services Limited, Hyderabad Team Tower,4th - 6th Floor, Plot No-A-1/2/A, Industrial Park, IDA-Uppal,Hyderabad-500039
167.	Vimta Labs Limited, Hyderabad Plot No.5, Alexandria Knowledge Park, Genome Valley, Shameerpet, Hyderabad -500078, Andhra Pradesh
168.	Vision Labs, Hyderabad H.No. 16-11-23/37/A, 2nd Floor, Opp. R.T.A Office, Musarambagh, Malakpet, Hyderabad – 500036, Telengana, India
169.	Trilogy Analytical Laboratory Private Limited, Hyderabad Plot No. 7 C.F. Area, Phase-II, Cherlapally, Opp. Surana Chowrasta, Hyderabad, Telangana-500051
D.	**EASTERN REGION**
	Jharkhand
170.	Sun Tech, Jharkhand 40-p, Tupudana Industrial Area, Tupudana, Hatia, Ranchi, Jharkhand – 834003
	Odisha
171.	Kalyani Laboratories Private Limited, Bhubaneswar Plot No- 841-A, Rasulgarh, Bhubaneswar – 751010, Odisha
	Tripura
172.	Food Testing Laboratory, Agartala Food Park, Bodhjungnagar, Agartala, Tripura -799008
	West Bengal
173.	Edward Food Research and Analysis Centre Limited, Kolkata Subhas Nagar, Barasat, P.O: Nilgunj Bazar, Kolkata -700121
174.	Export Inspection Agency Laboratory, Kolkata(Ministry of Commerce & Industries, Govt of India) 101, Southend Conclave, 1582, Rajdanga Main Road, Kolkata-700107, West Bengal
175.	Mitra S.K. Private Limited, Kolkata Udayan Industrial Estate, Building No. P-48, 3 Pagladanga road, Kolkata-700015
176.	Oil Laboratory, Department of Chemical Technology, Kolkata University of Calcutta, 92, A.P.C. Road, Kolkata-700009
177.	SGS India Private Limited, Kolkata CS Plot 512(P), Hanspukuria, D.H. Road, Joka, Kolkata-700104
178.	Vimta Labs Ltd, Kolkata Dn-51, Merlin Infinite, 11th Floor, Salt Lake, Sector –V, Kolkata-700091, West Bengal
179.	Pesticide Residue Laboratory, Tea Research Association, Kolkata 113, Park Street, 9th Floor, Kolkata700016, West Bengal

Annexure 6: Weekly Reporting format – IDSP

Form P

Name of Reporting Institution:		**I.D. No.:**	
State:	**District:**	**Block/Town/City:**	
Officer-in-Charge	**Name:**	**Signature:**	
IDSP Reporting Week:-	**Start Date:-**	**End Date:-**	**Date of Reporting:-**
	__/__/____	__/__/____	__/__/____

S.no	Diseases/Syndromes	No. of cases
1	Acute Diarrhoeal Disease (including acute gastroenteritis)	
2	Bacillary Dysentery	
3	Viral Hepatitis	
4	Enteric Fever	
5	Malaria	
6	Dengue / DHF / DSS	
7	Chikungunya	
8	Acute Encephalitis Syndrome	
9	Meningitis	
10	Measles	
11	Diphtheria	
12	Pertussis	
13	Chicken Pox	
14	Fever of Unknown Origin (PUO)	
15	Acute Respiratory Infection (ARI) / Influenza Like Illness (ILI)	
16	Pneumonia	
17	Leptospirosis	
18	Acute Flaccid Paralysis < 15 Years of Age	
19	Dog bite	
20	Snake bite	
21	Any other State Specific Disease (Specify)	
22	Unusual Syndromes NOT Captured Above (Specify clinical diagnosis)	
23	Total New OPD attendance (Not to be filled up when data collected for indoor cases)	
24	Action taken in brief if unusual increase noticed in cases/deaths for any of the above diseases	

Form L

Name of the Laboratory:		**Institution:**	
State:	**District:**	**Block/Town/City:**	
Officer-in-Charge:	**Name:**	**Signature:**	
IDSP Reporting Week:-	**Start Date:-**	**End Date:-**	**Date of Reporting:-**
	___/___/_____	___/___/_____	___/___/_____

Diseases	No. Samples Tested	No. found Positive	
Dengue / DHF / DSS			
Chikungunya			
JE			
Meningococcal Meningitis			
Typhoid Fever			
Diphtheria			
Cholera			
Shigella Dysentery			
Viral Hepatitis A			
Viral Hepatitis E			
Leptospirosis			
Malaria		**PV:**	PF:
Other (Specify)			
Other (Specify)			

Annexure 7: Example form of Investigation for foodborne outbreak occurred in an event/ Ceremony

Information on person reporting disease outbreak	
Name of official:	
Address:	
Telephone number(s):	
Other information (organization, affiliation, request for anonymity):	
Information on disease outbreak	
Description of event:	
Suspected exposure (e.g. event, meal, restaurant visit, food):	
Number of cases suspected:	Geographical area of concern: Landmark:
Number of persons at risk:	Date of first suspected case:
Date when suspected exposure first occurred:	Date of most recent case:
Is the suspected exposure still occurring?	Yes / No
How was the event first discovered?	
Date:	Signature

Primary Information Sheet (Patients information)

Case ID:		Date:
Details of Infected individual		
Patient Name:		
DOB:	Sex:	Occupation:
Address: Telephone number:		
Clinical details		
Date & time of onset of symptoms:		Date & time when symptoms stopped:
Predominant symptoms *(severity, duration)*:		
Doctor consulted? *(if yes, provide name and details)*		
Hospital attended? *(if yes, provide name and details)*		
Laboratory specimen taken? *(if yes, provide details)*		
Diagnosis available?		

Suspect food items? *(if yes, provide source of food, preparation mode, when consumed)*
Suspect meal, event, place? (if yes, describe; provide, name, date, address, telephone number of manufacturer)

Persons attending suspect meal/event	**ill/well**	**Address & telephone number**
1 2 3 4		

Other relevant information

Summary list of Patients w.r.t to the outbreak

ID	Name	Age	Sex	Date & time of onset of illness	Major signs and symptoms	Laboratory tests	
						Specimen	Result

Sample Questionnaire

Enquiry into suspected food poisoning

This questionnaire should be filled for all symptomatic individuals originating in a particular incidence of food borne disease outbreak.

Interviewer's name _____ Interviewer's code_____

Date and time of interview _____ at _____ Place _____

Section 1 – Personal details

1. Name _____
2. Sex M ☐ F ☐
3. Age (years) _____
4. Address _____

   _____
5. Phone no. _____
6. Occupation *(describe what person actually does)* _____
7. Workplace contact _____

Section 2 - Clinical details

8. In last 3 days, have you had an illness with diarrhea (three loose motions in 24 hours) or any gastrointestinal upset? Yes -1- No -2-
9. When did your symptoms start? _____ at _____

   (date) *(time)*
10. Is anyone else in family or close contact having similar symptoms (please provide details)

    _____

    _____

    _____

    _____

11. Did you have any of the following symptoms? (if symptoms still are still persisting please consult medical practitioner)

	Yes	No	Not sure	Duration
Diarrhea	1	2	9	___
Blood in stool	1	2	9	___
Nausea (feeling sick)	1	2	9	___
Vomiting (being sick)	1	2	9	___
Feeling feverish	1	2	9	___
General aches and pains	1	2	9	___
Other symptoms (describe)	_____			

_____

12. Did you contact your Doctor because of this illness? Yes -1- No -2-

13. Name and address of Doctor _____

_____

14. Did your Doctor prescribe any medication? Yes -1- No -2-

15. Details of prescription byDoctor? _____

_____

16. Were you admitted to hospital because of this illness? Yes -1- No -2-

If yes please answer

a. When were you admitted to hospital? _____ at _____
(date) *(time)*

b. What hospital were you admitted to? _ _____

c. What was the name of your doctor? _____

d. How long were you in hospital for? _____

e. Has any other person in your knowledge has been ill with the same or similar symptoms consumed food from same source? Yes -1- No -2-

f. Please specify *(ONLY for persons who consumed the same source and for whom questionnaire will be completed)* _____
_____
_____
_____

Section 3 – Food history

17. In last 3 days, have you attended any parties, special functions, receptions, or have you been eating in other places than usual? Yes -1- No -2-

Please describe activity, place, date, type of food, etc. _____

(Please get answer for all items; overlaps between food items allowed)

	Yes	No	Don't Know	
Chicken	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Mutton	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Beef	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Paneer	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Cheese	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Other dairy products **Specify** _____ _____	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐

Salad	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Fruits	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Cauliflower	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Cabbage	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Stuffing	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Carrots	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Green Salad	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐ Don’t know ☐
Other Salads	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ “A bite” ☐

				Don't know ☐
Roast Potatoes	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Fried Potatoes	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Mayonnaise	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐
Any other (specify) _____ _____ _____	☐	☐	☐	If yes, specify portion Portion ☐ Half portion ☐ "A bite" ☐ Don't know ☐

18. Would you like to make any additional comments?

_____

_____

_____

_____

_____

_____

_____

_____

This completes the interview. Thank you very much for your cooperation.

Annexure 8: Sample Investigation report forms from various agencies

Example of an outbreak report form to be used by agencies Liaoning for surveillance of food borne disease outbreaks

Report of incident		
1. State:	2. Year:	3. Report no.:

4. Place of incident:

City/Town: _____ Province/District: _____

5. Causative agent/type:

Code: ☐☐☐☐☐☐ _____

Phage type: ☐☐☐ **Confirmed:**☐ **Presumed:**☐

6. Number of persons: **at risk ill hospitalized died**

by age groups:

from 0 to 4 years	_____	_____	_____
from 4 to 15 years	_____	_____	_____
from 15 to 60 years	_____	_____	_____
over 60 years	_____	_____	_____

7. Symptoms:

☐**Nausea** ☐**Vomiting** ☐**Diarrhea** ☐**Abdominal pain**

☐**Fever** ☐**Neurological** ☐**Cardiovascular** ☐**Other (_____)**

8. Date of onset of illness:

first person: _ _ / _ _ / _ ___ (day month year) **last person:** _ _ / _ _ / _ _ __ (day month year)

9. Incubation time and duration of illness: **(in hours):** ☐☐**?**

Incubation time: shortest_____ **longest**_____ **median**_____

Duration of illness: shortest_____ **longest**_____ **median**_____

10. Food/vehicle involved:

Code: ☐☐☐☐☐☐ _____

Confirmation: Laboratory☐ **Epidemiological**☐

Commercial name of product:_____ **Producer:**_____

11. Methods of marketing, processing, serving:

Marketed:☐ **Home cooked:** ☐ **Treatment before final preparation and serving: code**☐☐

12. Place where food was possibly contaminated:

Place: code☐ **Country: code☐**

13. Place and date where food was acquired and eaten:

Date: _ _ / _ _ / _ ___ **Place: _____**
day month year

During transit: ☐Means of transit: Railway ☐Flight ☐Bus ☐Taxi ☐

from: _____ to: _____

14. Factors contributing to incident:

(a) Code☐☐ **(b) Code ☐☐**

Other

_____

_____

Note: **In case more than one factor contributed, list all that are applicable but code only the two major factors.**

15. Results of lab. tests:

Testing laboratory: _____

Specimens/samples	**No. tested**	**Positive**	**Details/comments**
Ill people*	_____	_____	_____
Well people*			_____
Food-handler	_____	_____	_____
Suspect food			_____
Other foods			_____
Environment			_____

*** Clinical samples.**

Foodborne disease outbreak report form for submission to the National Emergency Contact Point, India

Electronic Foodborne Outbreak Reporting System*	INVESTIGATION OF A FOODBORNE OUTBREAK This form is used to report foodborne disease outbreak investigations to NECP, India. It can be also used for reporting specific pathogen outbreak investigations involving any mode of transmission. A foodborne outbreak is defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food in India. This form has 6 parts. Part 1 asks for the minimum or basic information needed and must be completed for the investigation to be counted in the NECP annual summary. Part 2 asks for additional information for any foodborne outbreak, while Parts 3–6 ask for information concerning specific vehicles or etiologies. Please complete as much of all parts as possible.	NECP Use Only _____
*if not, available offline submission will be required		State Use Only _____

Part 1: Basic information

1. Report type

☐ **Please check if this is a finalreport**

☐ **Please check if data does not support a FOODBORNE outbreak**

2. Number of cases

Lab-confirmedcases_(A) Including _____secondarycases

Probablecases__(B) Including _____secondary cases

Estimated totalill _____

(if greater than sum A + B)

3. Dates

Please enter as many dates as possible

Date first case became ill

_____/_____/_____

Month Day Year

Date last case became ill

_____/_____/_____

Month Day Year

Date first known exposure

_____/_____/_____

Month Day Year

Date last known exposure

_____/_____/_____

Month Day Year

4. Reporting state

_____

If multiple states involved

☐ **Exposure occurred in multiple states**

☐ **Exposure occurred in single state,but cases resided in multiple states**

List of states_____

_____

_____

_____

5. Approximate percentage of cases in each age group **<1 year % 20–49 yrs% 1–4 yrs% ≥50 yrs% 5–19 yrs% Unknown%**	6. Sex **(Estimated percentage of the total cases)** **Male** **_____%** **Female _____%**	7. Investigation methods **(check all that apply)** ☐ **Interviews ofonlycases** ☐ **Environment / food sample cultures** ☐ **Foodpreparationreview** ☐ **Food product traceback** ☐ **Investigation atfactoryor** ☐ **Case–controlstudy productionplant Cohortstudy** ☐ **Investigation at original source (farm, marine estuaries. etc)**

8. Implicated food(s) (please provide known information)

Name of food e.g. lasagna	**Main ingredient**(s) e.g. pasta, sauce, eggs, beef	**Contaminated ingredient**(s) e.g. eggs	**Reason(s) suspected** (see codes just below) e. g. 4	**Method of preparation** (see attached codes) e.g. M1
1)				
2)				
3)				

☐ Food vehicle undetermined

Reason suspected (list above all that apply)

1. Statistical evidence from epidemiological investigation
2. Laboratory evidence (e.g. identification of agent in food)
3. Compelling supportive information
4. Other data (e.g. same phage type found on farm that supplied eggs)
5. Specific evidence lacking but prior experience makes it likely source

9. Etiology (Name the bacteria, virus, parasite, or toxin. If available, include the serotype and other characteristics such as phage type, virulence factors, and metabolic profile. Confirmation criteria available at http//www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol. 49/SS-1/App. B)

Etiology		Serotype	Other Characteristics (e.g. Phage type)	Detected in (see codes just below)
	☐ Confirmed			
	☐ Confirmed			
	☐ Confirmed			

☐ Etiology undetermined

Detected in (list above all that apply)

1. Patient specimen (s) 2. Food specimen(s) 3. Environment specimen(s) 4. Food worker specimen(s)

10. Contributing factors (check all that apply: see attached codes and explanations)

Contamination factor

☐C1 ☐C2 ☐C3 ☐C4 ☐C5 ☐C6 ☐C7 ☐C8 ☐C9 ☐C10 ☐C11 ☐C12 ☐C13 ☐C14 ☐C15 (*describe in Comments)* ☐ N/A

Proliferation/amplification factor (bacterial outbreaks only)

☐P1 ☐P2 ☐P3 ☐P4 ☐P5 ☐P6 ☐P7 ☐P8 ☐P9 ☐P10 ☐P11 ☐P12 (*describe in Comments)* ☐N/A

Survival factor (microbial outbreaks only)

☐S1 ☐S2 ☐S3 ☐S4 ☐S5 (*describe in Comments)* ☐N/A

Was food-worker implicated as the source of contamination? ☐ Yes ☐ No

If yes, please check only one of following:

☐ laboratory *and* epidemiologic evidence

☐ epidemiologic evidence (w/o lab confirmation)

☐ lab evidence (w/o epidemiologic evidence)

prior experience makes this the likely source (*please explain in Comments*)

Part 2: Additional Information

11. Symptoms, signs and outcomes

Feature	**Cases** with outcome/feature	**Total cases** for whom you have information available
Healthcare provider visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Fever		
Abdominal Cramps		
HUS or TTP		
Asymptomatic		
*		
*		
*		
*		

12. Incubation period (Circle appropriate units)

Shortest _____(hrs/days)

Longest _____(hrs/days)

Median _____(hrs/days)

☐ Unknown

13. Duration of Illness (among those who recovered) (circle appropriate units)

Shortest _____ (hrs/days)

Longest _____ (hrs/days)

Median _____ (hrs/days)

☐Unknown

* Use the following terms, if appropriate, to describe other common characteristics of cases

Anaphylaxis	Headache	Sorethroat
Arthralgia	Hypotension	Tachycardia
Bradycardia	Itching	Temperaturereversal

	Bullouslesions	Jaundice	Thrombocytopenia
	Coma	Lethargy	Urticaria
	Diplopia	Paranesthesia	Wheezing
	Flushing	Septicemia	Descendingparalysis
			Flushing

14. If cohort investigation conducted

$$\textbf{\textit{Attack rate}} * (\%) = \frac{\boldsymbol{E}}{\boldsymbol{N}} \boldsymbol{x100}$$

* The attack rte is applied to persons in a cohort who were exposed to the implicated, where E is number of persons who were exposed and fell ill and N is the total number of people exposed to implicated vehicle. Calculation not required for unknown vehicles

15. Location where food was prepared **(Check all that apply)**		**16.** Location of exposure or where food was eaten **(check all that apply**	
☐**Restaurant or deli**	☐Nursing home	☐Restaurant or deli	☐**Nursing home**
☐**Day care center**	☐Prison, jail	☐Day care center	☐**Prison, jail**
☐**School**	☐Private home	☐School	☐**Private home**
☐**Office Setting**	☐Workplace, not cafeteria	☐Office Setting	☐**Workplace, not cafeteria**
☐**Workplace cafeteria**	☐Church, temple, etc.	☐Workplace cafeteria	☐**Church, temple, etc.**
☐**Banquet facility**	☐Camp	☐Banquet facility	☐**Camp**
☐**Caterer**	☐Hospital	☐Caterer	☐**Hospital**
☐**Grocery store**	☐Packed food	☐Grocery store	☐**Packed food**
☐**Fair, Festival, other temporary/ mobile services**		☐**Fair, Festival, other temporary/ mobile services**	
☐**Commercial product, served without further preparation**		☐**Commercial product, served without further preparation**	
☐**Unknown or undermined**		☐**Unknown or undermined**	
☐**Other (describe) _____**		☐**Other (describe) _____**	

17. Trace back

☐**please check if trace back conducted.**

Source to which trace back led _____

Source **(eg. Chicken farm, food processing plant)**	**Location of source**		Comments
	State	**District**	

18. Recall

☐**Please check if any food product recalled.**

Recall comments _____

_____

_____

19. Available reports **(please attach)**

☐**Unpublished agency report**

☐**Epi-Aid report**

☐**Publication (please reference if not attached)**

_____

_____

20. Agency reporting this outbreak

_____

Contact person

Name _____

Title _____

Phone _____

E-mail _____

21. Remarks

Briefly describe important aspects of the outbreak not covered above (e.g. restaurant closure, immunoglobin administration, economic impact etc.)

_____

_____

_____

_____

_____

_____

_

Part 3: School questions (mid-day meal)

1. Did the outbreak involve a single or multiple school?

☐**Single**

Multiple (*if yes*, number of schools_____)

2. School characteristics **(for all involved students in all involved schools)**

a) Total approximate enrolment (number of students)
☐**Unknown or undetermined**

b) Grade level(s) (please check all grades affected)
☐**Preschool**
☐**Middle school**
☐**High school (grades10+2)**
Please check all grades affected: ☐ K ☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ 9th ☐ 10th ☐ 11th ☐ 12th
☐**College/university/technical school**
☐**Unknown or undetermined**

c) Primary funding of involved school(s)
☐**Public** ☐**Private** ☐**Unknown or undetermined**

3. Describe the preparation of implicated item

☐**Heat and serve (item mostly prepared or cookedoff-site, reheatedon-site)**
☐**Serveda-la-carte**
☐**Serve only (preheated or served cold)**
☐**Cooked on-site using primary ingredients**
☐**Provided by a food service management company**
☐**Provided by a fast-food vendor**
☐**Provided by a pre-plate company**
☐**Part of a club/fundraising event**
☐**Made in the classroom**
☐**Brought by a student/teacher/parent**
☐**Other**
☐**Unknown or undetermined**

4. How many times has the state, district or local health department inspected this school cafeteria or kitchen in the 12 months before the outbreak? *
☐**Once**
☐**Twice**
☐**More than two times**
☐**Not inspected**
☐**Unknown or undetermined**

5. Does the school have a HACCP plan in place for the school mid-day meal program? *
☐**Yes**
☐**No**
☐**Unknown or undetermined**

***If there are multiple schools involved, please answer according to the most affected school.**

6. Was implicated food item provided to the school through the National School Lunch/Breakfast Program?

☐**Yes**
☐**No**
☐**Unknown or undetermined**

If Yes, was the implicated food item donated/purchased by

☐**Govt. approved distributor through the Commodity Distribution Program**
☐**Purchased commercially by the state/school authority**
☐**Other**_____
☐**Unknown or undetermined**

Part 4: Non-veg (Chicken/mutton/beef)

1. What % of ill persons (for whom information is available ate) ground _____(non-veg type) raw or undercooked? _____%
2. Was ground _____ (non-veg type) case ready? **(Non-veg item coming in form of processed and packaged for sale by manufacturer and not altered or repackaged by the retailer)**
   ☐**Yes**
   ☐**No**
   ☐**Unknown or undetermined**
3. Was the particular _____ (non-veg commodity) was ground or reground by the retailer?
   ☐**Yes**
   ☐**No**
   ☐**Unknown or undetermined**

If yes, was anything added while grinding (e.g. shop trim or add product to alter the fat content)?

Part 5: Mode of transmission

1. Mode of transmission **(for greater than 50% ofcases)**

Select one

☐**Food**

☐**Person to person**

☐**Swimming or recreational water**

☐**Drinking water**

☐**Contact with animals or their environment**

☐**Unknown or undetermined**

2. Pathogenic organisms of concern **(list only those for which tests have been found positive by lab)**

_____

_____

_____

_____

_____

Part 6: Additional egg questions

1. Were eggs **(check all thatapply)**

☐**in-shell,un-pasteurized?**
☐**in-shell, pasteurized?**
☐**liquid or dry egg product?**
☐**stored with inadequate refrigeration during or after sale?**
☐**consumed raw?**
☐**consumed undercooked?**
☐**pooled?**

2. If eggs traced back to farm, was *Salmonella* enteritidis found on the farm?

☐**Yes**
☐**No**
☐**Unknown or undetermined**

Comment _____

Contamination factors[2]

C1 – Toxic substance part of tissue (e.g. ciguatera)

C2 – Poisonous substance intentionally added (e.g. cyanide or phenolphthalein added to cause illness)

C3 – Poisonous or physical substance accidentally/incidentally added (e.g. sanitizer or cleaning compound)

C4 – Addition of excessive quantities of ingredients that are toxic under these situations (e.g. niacin poisoning in bread)

C5 – Toxic container or pipelines (e.g. galvanized containers with acid food, copper pipe with carbonated beverages)

C6 – Raw product/ingredient contaminated by pathogens from animal or environment (e.g.*Salmonella* enteriditis in egg, norovirus in shellfish, *E. coli* in sprouts)

C7 – Ingestion of contaminated raw products (e.g. raw shellfish, produce, eggs) C8 – Obtaining foods from polluted sources (e.g. shellfish)

C9 – Cross-contamination from raw ingredient of animal origin (e.g. raw poultry on the cutting board) C10 – Bare-handed contact by handler/worker/preparer (e.g. with ready-to-eat food)

C11 – Glove-handed contact by handler/worker/preparer (e.g. with ready-to-eat food)

C12 – Handling by an infected person or carrier of pathogen (e.g.*Staphylococcus*, *Salmonella*, norovirus

C13 – Inadequate cleaning of processing/preparation equipment/utensils leads to contamination of vehicle (e.g. cutting boards)

C14 – Storage in contaminated environment leads to contamination of vehicle (e.g. store room, refrigerator) C15 – Other source of contamination (*please describe in Comments*)

Proliferation/amplificationfactors2

P1 – Allowing foods to remain at room or warm outdoor temperature for several hours (e.g. during preparation or holding for service)

P2 – Slow cooling (e.g. deep containers or large roasts)

P3 – Inadequate cold-holding temperatures (e.g. refrigerator inadequate/not working, iced holding inadequate) P4 – Preparing foods a half day or more before serving (e.g. banquet preparation a day in advance)

P5 – Prolonged cold storage for several weeks (e.g. permits slow growth of psychrophilic pathogens)

P6 – Insufficient time and/or temperature during hot holding (e.g. malfunctioning equipment, too large a mass of food)

P7 – Insufficient acidification (e.g. home canned foods)

P8 – Insufficiently low water activity (e.g. smoked/salted fish) P9 – Inadequate thawing of frozen products (e.g. room thawing)

P10 – Anaerobic packaging/modified atmosphere (e.g. vacuum packed fish, salad in gas flushed bag) P11 – Inadequate fermentation (e.g. processed meat, cheese)

P12 – Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*)

Survival factors: [2]

S1 – Insufficient time and/or temperature during initial cooking/heat processing (e.g. roasted meats/poultry, canned foods, pasteurization)

S2 – Insufficient time and/or temperature during reheating (e.g. sauces, roasts) S3 – Inadequate acidification (e.g. mayonnaise, tomatoes canned)

S4 – Insufficient thawing, followed by insufficient cooking (e.g. frozen turkey)

S5 – Other process failures that permit the agent to survive (*please describe in Comments*)

Method of preparation:[3]

M1 – Foods eaten raw or lightly cooked (e.g. hard shell clams, sunny side up eggs) M2 – Solid masses of potentially hazardous foods (e.g. casseroles, lasagna, stuffing) M3 – Multiple foods (e.g. smorgasbord,buffet)

M4 – Cook/serve foods (e.g. steak, fish fillet)

M5 – Natural toxicant (e.g. poisonous mushrooms, paralytic shellfish poisoning) M6 – Roasted meat/poultry (e.g. roast beef, roast turkey)

M7 – Salads prepared with one or more cooked ingredients (e.g. macaroni, potato, tuna) M8 – Liquid or semi-solid mixtures of potentially hazardous foods (e.g. gravy, chili, sauce) M9 – Chemical contamination (e.g. heavy metal, pesticide)

M10 – Baked goods (e.g. pies, eclairs)

M11 – Commercially processed foods (e.g. canned fruits and vegetables, ice cream) M12 – Sandwiches (e.g. hot dog, hamburger, Monte Cristo)

M13 – Beverages (e.g. carbonated and non-carbonated, milk) M14 – Salads with raw ingredients (e.g. green salad, fruit salad)

M15 – Other, does not fit into above categories *(please describe in Comments)*

M16 – Unknown, vehicle was not identified

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[2] BryanFL,GuzewichJJ,ToddECD.Surveillanceoffoodbornedisease.III.Summaryandpresentationofdataonvehiclesand contributory factors: their value and limitations. *Journal of Food Protection*, 1997,60(6):701–714.

[3] WeingoldSE,GuzewichJJ,FudalaJK.UseoffoodbornediseasedataforHACCPriskassessment.*JournalofFood Protection,* 1994, 57(9):820–830.

Annexure 9: Example of Investigation report format

Outline of an outbreak investigation report

Cover page

- **Title of report**

  Indicate whether this is a preliminary or a final report. Keep the title short and memorable but include information on the type of problem under investigation, the location and date.

- **Date of report**
- **Names and affiliations of the main authors and investigators**

Abstract

The abstract should be written after the report has been completed. It should stand alone and contain the most relevant data and conclusions. All data mentioned in the abstract must also appear in the main section of the report. Sentences from the Discussion section can be used verbatim in the abstract.

Report

- **Introduction**

  Statement of the problem and its public health importance. Details and time frame regarding initial source of information. Reasons for investigating event.

  Type of investigations conducted, and agencies involved.

- **Background**

  Generally available information to help the reader interpret epidemiology and data presented in the report (e.g. population size, socioeconomic status of community, ethnicity, etc.).

  If outbreak occurred in a food premises, description of premises (e.g. size of restaurant, usual practices and operations, etc.).

  Description of the problem.

  Sequence of events leading to the study or investigation. Brief statement of the working hypothesis.

- **Objectives**

  Specify targets to be achieved by the investigations.

  Keep objectives concise and follow a logical, sequential pattern. The objectives may include hypotheses, if any, to be tested.

- **Methods**

  Epidemiology

  - description of studypopulation
  - type of studyconducted
  - case definition
  - procedures for case-ascertainment and selection of controls (ifany)
  - methods of data collection, including questionnaire design, administration and contents
  - methods of dataanalysis.

  Medical laboratory testing

  - methods of specimen collection and processing
  - name of laboratory carrying out tests
  - laboratory techniques employed and methods of data analysis.

  Food and food testing

  - description of inspection process
  - methods of food and environmental sampling
  - name of laboratory carrying out tests
  - laboratory techniques employed and methods of data analysis.

- **Results**

  Present all pertinent results from clinical, laboratory, epidemiological and environmental findings.

  Present results in same order as described in the methods section. Do not interpret or discuss the data in this section.

  Epidemiology

  - number of cases, overall attack rate
  - clinical details of illness (symptoms, duration, hospitalization, outcome, etc.)
  - descriptive epidemiology by time (epidemic curve), place and person (age, sex, race, specific characteristics) expressed as rates
  - risk factor exposures

- further data analysis and data presentation depending on specific studies undertaken (e.g. cohort or case–control study).

Laboratory (microbiology, chemical, toxicological)

- number of specimens collected
- findings by type of laboratory analysis.

Food investigation and food testing

- findings of food inspections
- results of laboratory tests performed on food and environmental samples.

- **Discussion**

  The discussion is the most important part of the report and should cover

  - summary of the major findings
  - likely accuracy of the results
  - conclusions with justification for those conclusion and rejection of alternative explanations
  - relationship of these results to other studies and the literature
  - implications of the findings
  - an assessment of control measures
  - needs for future research

- **Recommendations**

  Initial recommendations and those for future prevention and control should be listed numerically.

- **References**

  Select appropriate references, including reviews in major scientific journals. Follow a standard style of referencing (e.g., Vancouver style), numbering the references in the order in which they appear in the text.

- **Appendices**

  - Questionnaires and/or other survey forms
  - Appropriate field reports
  - Any other relevant documents, including press releases.

Annexure 10: Statistics

Calculating Rates

Rates are the most common way of measuring disease frequency in a population and are calculated as:

$$\frac{number\ of\ new\ cases\ of\ disease\ in\ population\ at\ risk}{number\ of\ persons\ in\ population\ at\ risk}$$

The numerator is new cases of disease (or deaths or other health events) during a specified period; the denominator is the population at risk. Rates imply changes over time and the period of time for which the rate has been calculated (e.g. month, year) must be specified. Rates can be expressed per hundreds, per thousand or per millions as convenient.

Rates that are calculated with the total population in an area are known as *crude rates*. Crude rates from different populations cannot be easily compared especially where there are striking differences in, for example, age and sex between populations. Rates may also be calculated using data from specific segments of the population; these are called *specific rates* (e.g. age- or sex-specific – rates for certain age groups and for men or women, respectively).

An a*ttack rate* is defined as the proportion of those who became ill after a specified exposure. For example, in an outbreak of gastroenteritis with 50 cases among a population at risk of 2500, the attack rate of disease is

50/2500 = 0.02 or

= 2/100 or

= 20/1000

Specific attack rates are calculated to identify persons in the population who are at a higher risk of becoming ill than others. Examples of commonly used specific attack rates are attack rates by age group, residence, sex or occupation. To identify the potential vehicle in a foodborne disease outbreak, the food-specific attack rate is often calculated, which is the attack rate for consumption of a specified food, calculated as

$$\frac{number\ of\ cases\ of\ disease\ among\ people\ who\ ate\ food\ "X"}{number\ of\ persons\ who\ ate\ food\ "X"}$$

To calculate a measure of association between food "X" and illness, a second attack rate must be calculated for those who did not eat food "X". The two attack rates can then be compared with each other as a relative risk (division) or as a risk difference (subtraction).

Example

After a dinner attended by 100 people, 12 individuals become ill. All 100 people are interviewed about their food consumption at the dinner. The interviews show that 8 of the 12 people who are ill and 25 of the 88 who are healthy ate fish.

	Ill	Well	Total	Attack rate (%)
Ate fish	8	25	33	24.2
Did not eat fish	4	63	67	6.0
Total	12	88	100	

The relative risk for eating fish is 24.2/6.0 or 4. The risk difference is 24.2% – 6% = 18.2%

Median

- The median is the midpoint of a series of ordered values. It divides a set of values into two equal parts. To identify the median from individual data:
- Arrange the observations in increasing or decreasing order

Find the middle rank using the following formula: middle rank = (n + 1)/2.

  - If the number of values is odd, the middle rank falls on one observation.
  - If the number of values is even, the middle rank falls between two observations.
- Identify the value of the median
  - If the middle rank falls on a specific observation, the median is equal to the value of the middle rank.
  - If the middle rank falls between two observations, the median is equal to the average of the values of those observations.

Example 1

To calculate the median for the following observations: 1, 20, 5, 3 and 9;

- Arrange the observations (n = 5) by order of magnitude: 1, 3, 5, 9, 20.
- Identify the middle rank: (5 + 1)/2 = 3.
- The median is the third observation of the ordered series, namely 5.

Example 2

To calculate the median for the following observations: 1, 20, 5, 3, 9, 21:

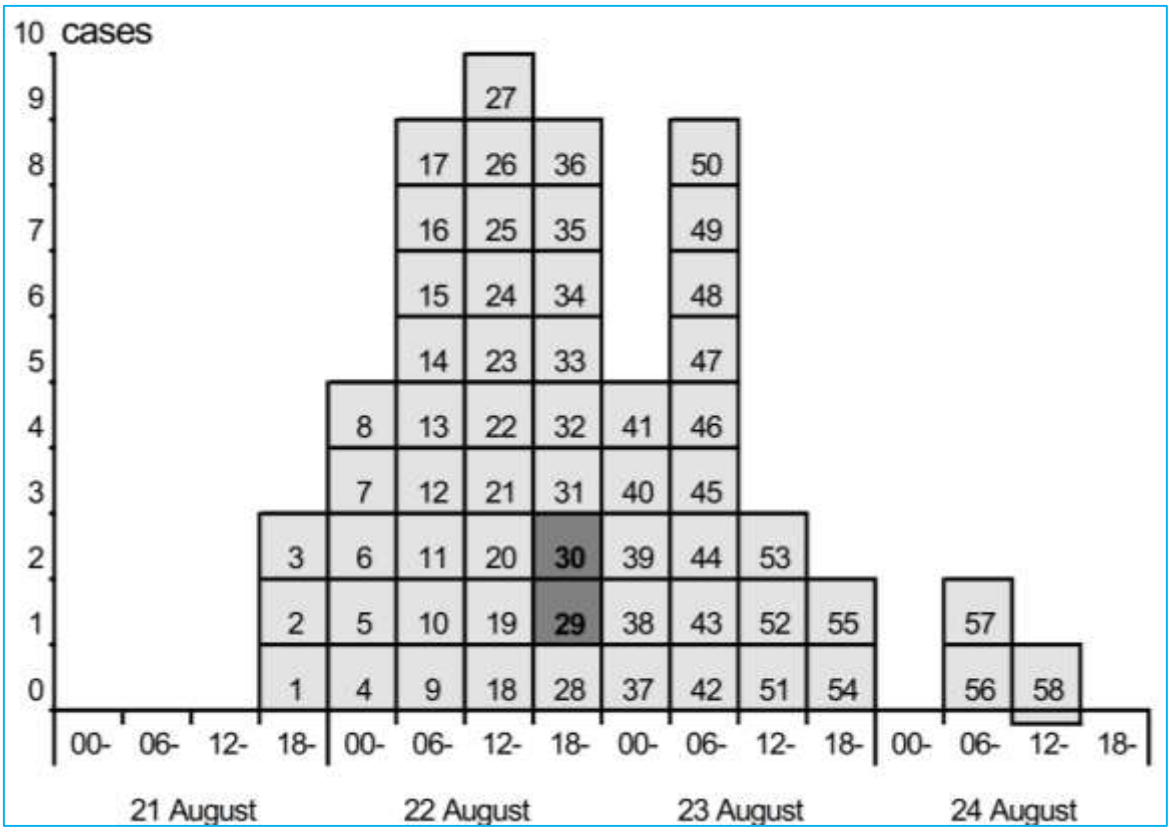
- Arrange the observations (n = 6) by order of magnitude: 1, 3, 5, 9, 20, 21.
- Identify the middle rank: (6 + 1)/2 = 3.5.
- The median is the average of the value of the third and fourth observations, namely 5 and 9.
- Thus the median = (5+9)/2 = 7.

To identify the median from a frequency distribution (e.g. epidemic curve)

- Count the number of observations.
- Identify the middle rank as above.
- If the middle rank falls within a row, the median interval equals the value of the row. If the middle rank falls between two rows, the median interval is the average of the values of the two rows.

Example 3

The epidemic curve shows 58 cases. The middle rank is (58+1)/2 = 29.5. Case numbers 29 and 30 both occur between 18:00 and 24:00 hours on 22 August, which is the median interval.



Statistical significance testing

In the 2x2 table below the attack rate for eating vanilla ice cream is 79.6%, while the attack rate for those who did not eat vanilla ice cream is 14.3%. A test of statistical significance determines the probability that the difference between the two attack rates occurred by chance alone. In other words, the test asks, "How likely is it that the 54 exposed and the 21 non-exposed persons would divide into 46 who are ill and 29 who are well purely by chance?" If this probability is very low (arbitrarily, "very low" is defined as 5% or less and expressed as a p-value of <0.05) we assume that the differences are real and related in one way or another to eating vanilla ice cream.

	Ill	Well	Total	Attack rate (%)
Ate vanilla ice cream	43	11	54	79.6
Did not eat vanilla ice cream	3	18	21	14.3
Total	46	29	75	61.3

To calculate statistical significance, the chi-square (χ^2) test can be used. The principles are illustrated in the following 2x2 tables

	Ill	Well	Total	*Observed*
Exposed	$O_1 = a$	$O_2 = b$	$n1$	
Non exposed	$O_3 = c$	$O_4 = d$	$n2$	
Total	***n*3**	***n*4**	***N***	

We can calculate the expected numbers of ill and well that would occur if exposure were not related to becoming ill and the division into ill and well were by chance alone

	Ill	Well	Total	*Expected*
Exposed	$E_1 = \frac{n_1 n_3}{N}$	$E_2 = \frac{n_1 n_4}{N}$	$n1$	
Non exposed	$E_3 = \frac{n_2 n_3}{N}$	$E_4 = \frac{n_2 n_4}{N}$	$n2$	
Total	***n*3**	***n*4**	***N***	

The chi-square tests compare the observed numbers with the expected numbers for each of the four cells using the following formula

$$\frac{(observed - expected)^2}{observed} = \frac{(O_i - E_i)^2}{O_i}$$

$$\chi^2 = \sum \frac{(O_i - E_i)^2}{O_i} (1)$$

An easier way to calculate the χ^2 for a 2x2 table which leads to the same result can be obtained with the following formula

$$\chi^2 = \frac{N(ad - bc)^2}{n_1 n_2 n_3 n_4} (2)$$

If the expected number (E_i) inside any of the cells is less than 5, the χ^2 needs to be corrected using the following formula

$$\chi^2_{Corrected} = \frac{N[(ad - bc) - N/2]^2}{n_1 n_2 n_3 n_4} (3)$$

The results for χ^2 are compared with theoretical values for the chi-square. As a rough guide, if the calculated χ^2 value is

≥ 10.83, the difference between the two groups is highly significant ($p \leq 0.001$)

≥ 6.64, the difference between the two groups is strongly significant ($p \leq 0.01$)

≥ 3.84, the difference between the two groups is significant ($p \leq 0.05$).

If the calculated χ^2value is <3.84, the difference between the two groups is considered to be not statistically significant ($p > 0.05$).

Calculated example, using formula (2)

	Ill	Well	Total
Ate vanilla ice cream	43	11	54
Did not eat vanilla ice cream	3	18	21
Total	46	29	75

$$\chi^2 = \frac{75(43x18 - 11x3)^2}{54x21x46x29} = 27.2$$

Since the χ^2 value of 27.2 > 10.83, the p-value is <0.001. This means that the probability of finding the distribution presented in this 2x2 table by chance alone is small – less than 1/1000. The exact p-value as calculated by a computer is 0.0000002. In other words, it can be assumed that vanilla ice cream is strongly associated with the risk of becoming ill.

Annexure 11: Situations likely to contribute to foodborne disease outbreaks

Key A. *Situations that likely contributed to outbreaks of foodborne diseases when meat products were implicated as vehicles.*

Legend

- ■ Principal contributory factor
- ▲ Contributory factor
- ● Potential contributory factor
- — Source of contamination, but likely to be destroyed during subsequent processing
- T Toxin survives heat process
- C Cooling water source of contamination
- C Contamination
- S Survival
- G Growth

Process	Etiologic agent of concern or microbe that produces it	Raw product/ingredient/ pre-processing: Colonized infected animal (C)	Animal feces/manure (C)	Animal access to human sewage (C)	Soil contamination (C)	Contamination by worker (C)	Inadequate cooling (G)	Food contaminated (C)	Water contaminated (C)	Processing or preparation (contamination, survival, proliferation) in food processing plant, food service establishment or home: Excessive amount of additive (C)	Insufficient concentration of additive (S)	Improper pH adjustment (S/G)	Improper a_w adjustment (salt conc.) (G)	Cross contamination (C)	Contamination by food worker (C)	Improper cleaning of equipment (C)	Environmental contamination (C)	Organism toxin survives process (S)	Heat process failure (S)	Manipulation spread during process (G)	Improper hot-holding (G)	Room-temperature holding (G)	Improper cooling (G)	Inadequate refrigeration (G)	Contamination during cooling (C)	Improper or defective packaging (C/G)	Selective packaging environment (G)	Inadequate reheating (S)	Post-processing/preparing abuse at home or social events or during transport: Contamination during reconstitution (C)	Cross contamination (C)	Contamination by person (C)	Improper cleaning of equipment (C)	Improper cooling (G)	Inadequate refrigeration (G)	Improper hot-holding (S/G)	Room-temperature holding (G)	Inadequate reheating (S)
Raw, heated lightly	*Salmonella*	■	■				▲	■	●					■	●	●				■		●	●	●					▲		●				●	
	Escherichia coli O157 ...	■	■				●	●	●					■	●	●				■		●	●	●					▲		●				●	
	Campylobacter jejuni	■	■											▲		●				●		●							■		●				●	
	Bacillus anthracis	■			▲											●			■																	
	Toxoplasma gondii	■												▲																						
	Trichinella spiralis	■												▲		●					▲															
	Tapeworm	■		■																																
Retorted	*Clostridium botulinum*		—		—						■									■			●		C		■	▲								
	Salmonella	—	—				—	—	—						●								▲													
	Staphylococcus aureus	—				—									■								●													
Cooked, pasteurized,	*Salmonella*	—	—				—	—	—					■	●	▲				■	▲	■	■	■	■	●		●	■		■	●	▲		■	■	■
hot smoked and other	*Campylobacter jejuni*	—	—											●		●				■		■						■				●		●	●	
heat processes	*Yersinia enterocolitica*	—	—				—		—					●		●				■	●	■	▲					■			●		■	●	●	
	Clostridium botulinum		▲		■						●								▲			■	▲					■	▲			▲	■		■	▲
	Clostridium perfringens	■	■		■	●								●	●	●	●	■			●	■	■	■	■	●		●	■		●	●	●	■	■	■
	Staphylococcus aureus	—												●	■	●			●			■	■	■	■			●	T			●	■	■	■	
	Bacillus cereus				■											●	●	■				■	■	■	■	●			T▲				●	■	■		T▲
	Escherichia coli	—	—				—	—	—					■	●	▲				■	■	■	■	■	■				■		▲	●	▲	■	■	■	■
	Listeria monocytogenes	—	—		—		—	—	—					▲		■				■	●		▲	▲	■			■	●		●		●	■	■	●	●
	Hepatitis A virus					—									■					■																
	Trichinella spiralis	—												▲		●				■	▲															
	Norovirus		●						●	■																										
Dried	*Salmonella*	■	■				▲	■	●				▲	▲	●	▲	●	▲	▲	●						●		●	●	●	●	●	●			
	Staphylococcus aureus	■				■							▲		■	●		▲	▲	●						●		T	●		●	●				T

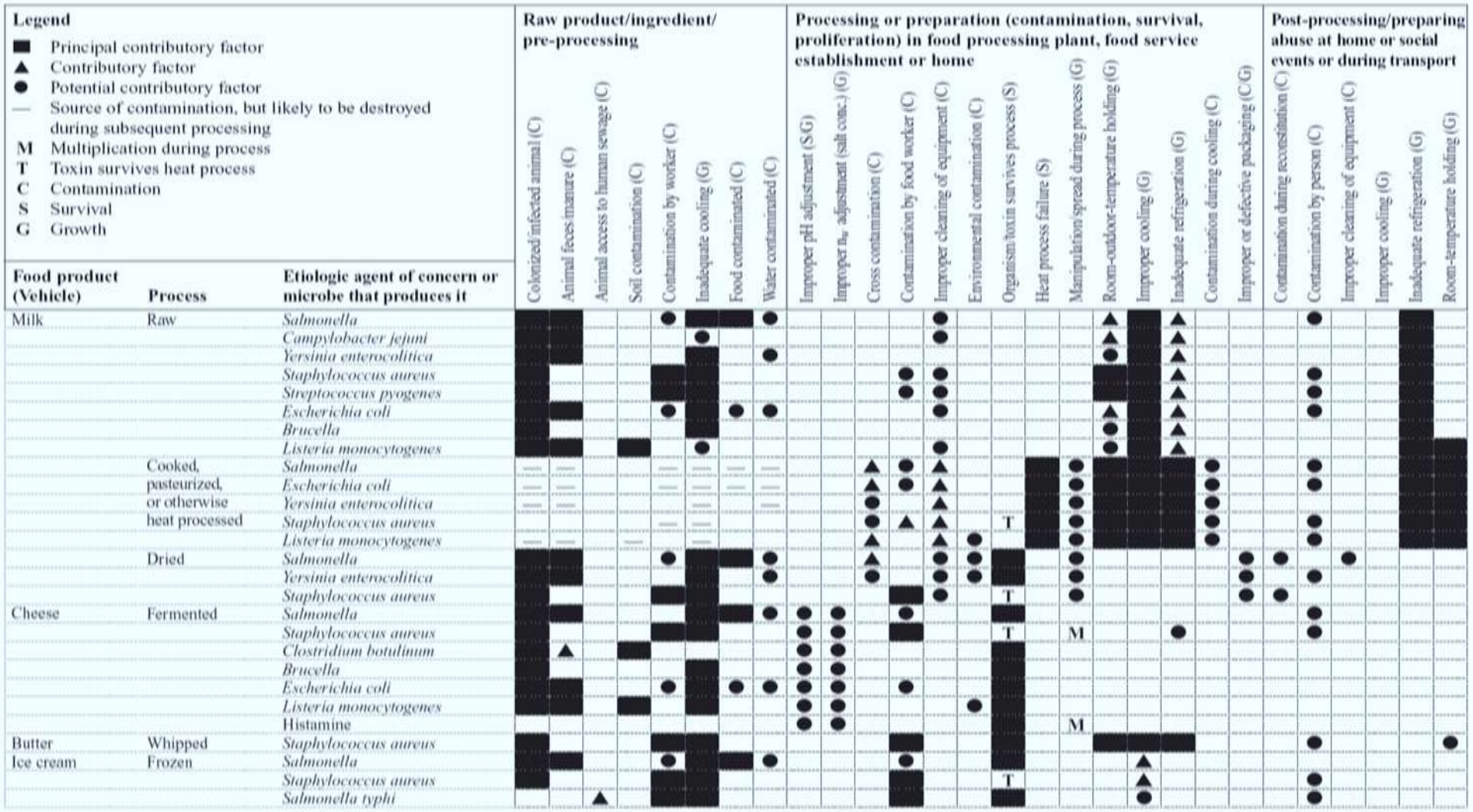
Key B. *Situations that likely contributed to outbreaks of foodborne diseases when poultry, poultry products, or eggs were implicated as vehicles.*

Legend

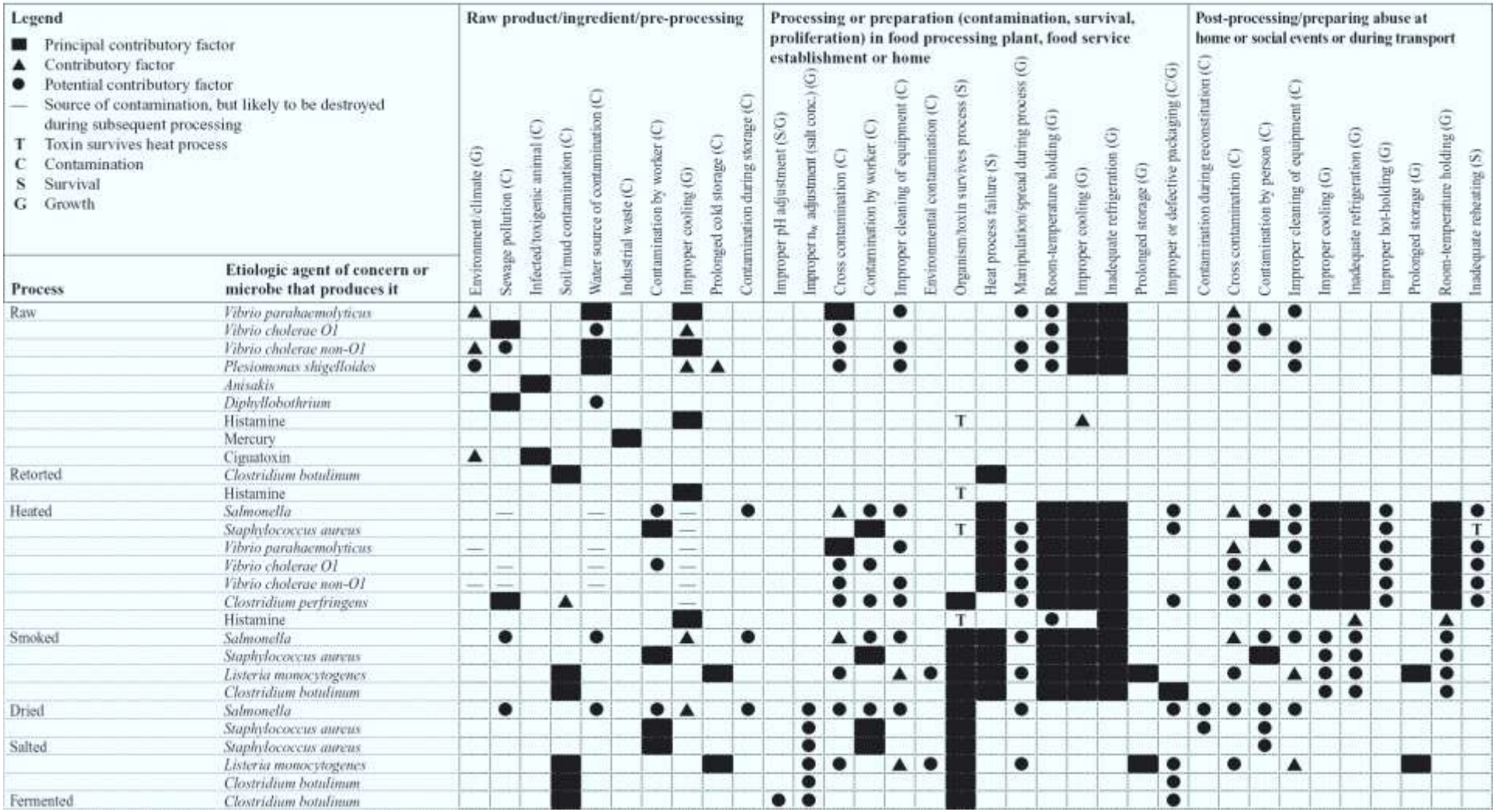
- ■ Principal contributory factor
- ▲ Contributory factor
- ● Potential contributory factor
- — Source of contamination, but likely to be destroyed during subsequent processing
- T Toxin survives heat process
- C Contamination
- S Survival
- G Growth

Food product (Vehicle)	Process	Etiologic agent of concern or microbe that produces it	Raw product/ingredient/ pre-processing: Colonized infected animal (C)	Animal feces/manure (C)	Soil contamination (C)	Contamination by worker (C)	Inadequate cooling (G)	Food contaminated (C)	Water contaminated (C)	Processing or preparation (contamination, survival, proliferation) in food processing plant, food services establishment or home: Excessive amount of additive (C)	Insufficient concentration of additive (S)	Improper pH adjustment (S/G)	Improper a_w adjustment (salt conc.) (G)	Cross contamination (C)	Contamination by food worker (C)	Improper cleaning of equipment (C)	Environmental contamination (C)	Organism/toxin survive process (S)	Heat process failure (S)	Manipulation spread during process (G)	Improper hot-holding (G)	Room temperature holding (G)	Improper cooling (G)	Inadequate refrigeration (G)	Contamination during cooling (C)	Improper or defective packaging (C/G)	Selective packaging environment (G)	Inadequate reheating (S)	Post-processing/preparing abuse at home or social events or during transport: Contamination during reconstitution (C)	Cross contamination (C)	Contamination by person (C)	Improper cleaning of equipment (C)	Improper cooling (G)	Inadequate refrigeration (G)	Improper hot-holding (S/G)	Room temperature holding (G)	Inadequate reheating (S)
Poultry	Raw, heated lightly	*Campylobacter jejuni*	■	■										▲		●				●		●														
	Retorted	*Clostridium botulinum*	—		—														■									■	●								●
	Heated	*Salmonella*	—	—			▲	■	●					■	●	▲			■		■	■	■	■	■	●		●	■		■		▲	■	■	■	■	■
		Campylobacter jejuni	—	—										●		●			■		●		●					●	●		■		●				●	●
		Listeria monocytogenes	—	—	—		●	●	●					▲		■	●		■		▲		●	●	■	●		■	●		●		●		■	●	●	●
		Staphylococcus aureus	—			—									■	●			T	■	●	●	■	■	■				T		●	■	●		■	■	■	T
		Clostridium perfringens	■	■		●								●	●	●			■		●	■	■	■	■	●		●	■		●	●	●		■	■	■	■
		Salmonella	■	■			▲	■	●					■	■	▲			■		▲						●				●		●	●				
	Dried	*Staphylococcus aureus*				■							●			●	●		T		●						●		T	●		●	●				
	Cured	*Staphylococcus aureus*				■				●	●	●	●			●			T	●	▲		▲	▲	●				T			■	●		■	■	■	T
Eggs	Raw/heated lightly	*Salmonella*	■	■		●	●	■						■	●	▲															●		●		●		●	
	Heated	*Salmonella*	—	—		—	—	—						■	●	●				■	●	●	■	■	■			●			■	●	●					—
		Staphylococcus aureus	—			—									■				T	■		●	■	■	■				T			■	▲		■	■	■	T
		Streptococcus pyogenes	—			—									■					■		●	■	■	■				●									■
	Dried	*Salmonella*	■	■			▲	■	●				●	■	●	●	●		■		▲										●	●	●					T
	Frozen	*Salmonella*	■	■			▲	■	●					■	●	●			■		●		●	▲							●	●	●					■

Key C. *Situations that likely contributed to outbreaks of foodborne diseases when milk or milk products were implicated as vehicles.*



Key D. *Situations that likely contributed to outbreaks of foodborne diseases when fish were implicated as vehicles.*



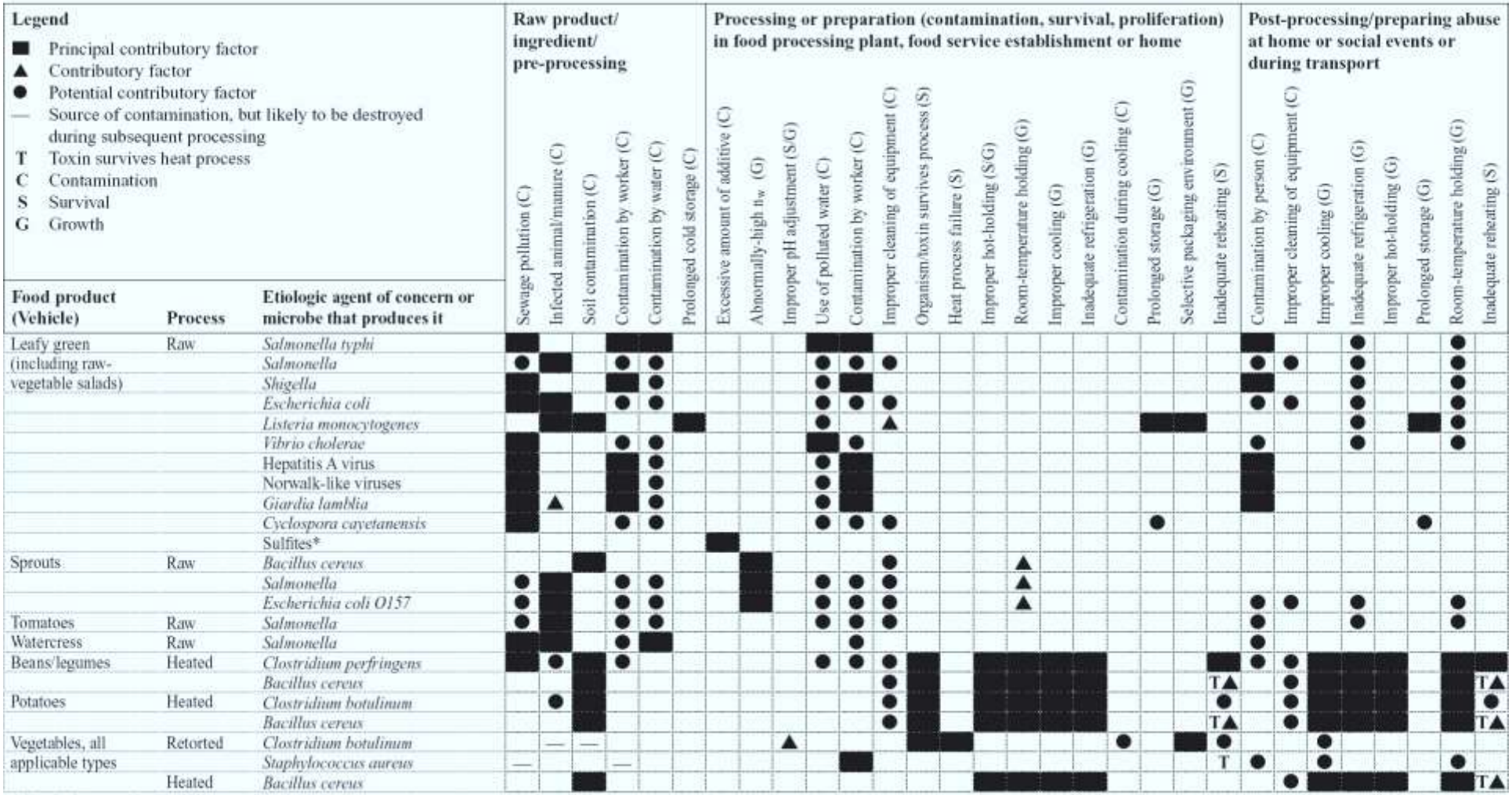
Key E. *Situations that likely contributed to outbreaks of foodborne diseases when shellfish, crustaceans or marine mammals were implicated as vehicles.*

Legend

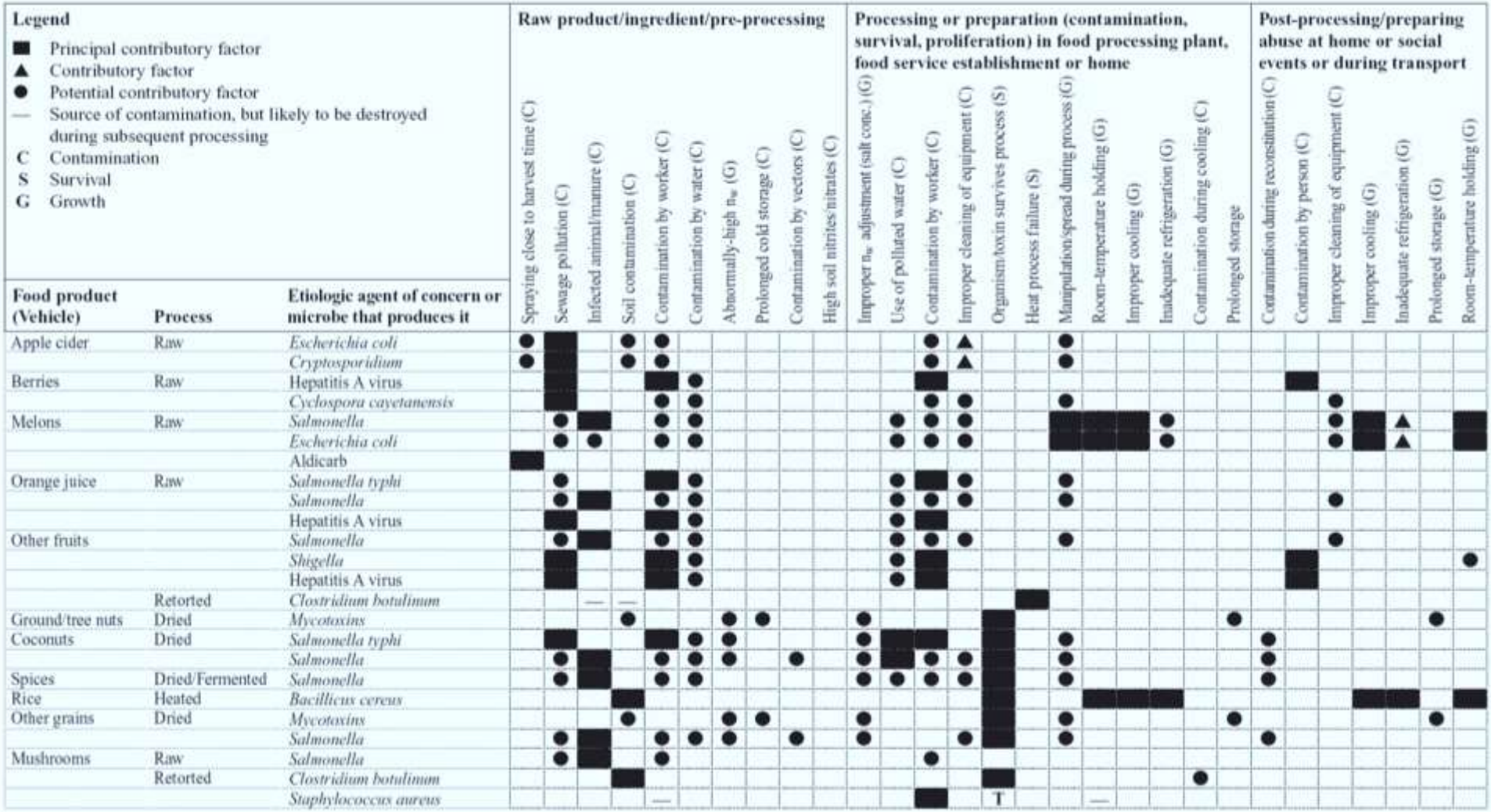
- ■ Principal contributory factor
- ▲ Contributory factor
- ● Potential contributory factor
- — Source of contamination, but likely to be destroyed during subsequent processing
- **T** Toxin survives heat process
- **C** Contamination
- **S** Survival
- **G** Growth

Food product (Vehicle)	Process	Etiologic agent of concern or microbe that produces it	Raw product/ingredient/ pre-processing: Environment/climate (G)	Sewage pollution (C)	Infected/toxigenic animal (C)	Soil/mud contamination (C)	Water source of contamination (C)	Industrial waste (C)	Contamination by worker (C)	Improper cooling (G)	Contamination during storage (C)	Processing or preparation (contamination, survival, proliferation) in food processing plant, food service establishment or home: Improper pH adjustment (S/G)	Improper a_w adjustment (salt conc.) (G)	Cross contamination (C)	Contamination by worker (C)	Improper cleaning of equipment (C)	Organism/toxin survives process (S)	Heat process failure (S)	Improper hot-holding (S/G)	Room-outdoor-temperature holding (G)	Improper cooling (G)	Inadequate refrigeration (G)	Inadequate reheating (S)	Post-processing/preparing abuse at home or social events or during transport: Contamination during reconstitution (C)	Cross contamination (C)	Contamination by person (C)	Improper cleaning of equipment (C)	Improper cooling (G)	Inadequate refrigeration (G)	Improper hot-holding (G)	Room-outdoor-temperature holding (G)	Inadequate reheating (S)
Shellfish	Raw	*Salmonella typhi*		■					■	▲						■				●		▲						●		■	
		Salmonella		●					●	■	●				●		●			●	●	■					●	●	●	■		
		Vibrio cholerae O1		■					■	■					●	●				●	●	▲					●		▲			
		Vibrio cholerae non-O1	▲				■			■					▲		●			●	●	■				▲				■		
		Vibrio parahaemolyticus	▲				■			■					▲		●			●	■	■				▲				■		
		Vibrio vulnificus	▲				■			●										●		●							●		●	
		Hepatitis A virus		■					▲							▲																
		Norwalk-like virus		■					▲							▲																
		Paralytic shellfish poison (Saxitoxin)	■		■																											
		Amnesic shellfish poison (Domoic acid)	■		■																											
		Mercury						■																								
	Heated	*Salmonella*		●					●		●				●	●			■	●	■	■	■	●			●		●	■	●	■
		Staphylococcus aureus							●	●						■	●	T	■	●	■	■	■	T			■	●	●	■	●	T
		Vibrio paraphaemolyticus	▲				■								■		●		■	●	■	■	■	●		▲		●	■	■	●	
Crustaceans	Heated	*Vibrio paraphaemolyticus*	▲				■			■					■		●		■	●	■	■	■	●		▲		●	■	■	●	
	Dried	*Vibrio paraphaemolyticus*	▲				■			■				●	●		●	■								▲		●	■	■	●	
		Staphylococcus aureus							●	●				●		■	●	■							●		●				
Marine mammals	Raw	*Salmonella*		●					●	●	●				●	●	●				●	●	■					●	■	■		
	Fermented	*Clostridium botulinum*				■				●		▲					■														

Key F. *Situations that likely contributed to outbreaks of foodborne diseases when vegetables were implicated as vehicles.*



Key G. *Situations that likely contributed to outbreaks of foodborne diseases when fruits, nuts, spices, grains or mushrooms were implicated as vehicles.*



Legend

- ■ Principal contributory factor
- ▲ Contributory factor
- ● Potential contributory factor
- — Source of contamination, but likely to be destroyed during subsequent processing
- **C** Contamination
- **S** Survival
- **G** Growth

Food product (Vehicle)	Process	Etiologic agent of concern or microbe that produces it
Apple cider	Raw	*Escherichia coli*
		Cryptosporidium
Berries	Raw	Hepatitis A virus
		Cyclospora cayetanensis
Melons	Raw	*Salmonella*
		Escherichia coli
		Aldicarb
Orange juice	Raw	*Salmonella typhi*
		Salmonella
		Hepatitis A virus
Other fruits		*Salmonella*
		Shigella
		Hepatitis A virus
	Retorted	*Clostridium botulinum*
Ground/tree nuts	Dried	*Mycotoxins*
Coconuts	Dried	*Salmonella typhi*
		Salmonella
Spices	Dried/Fermented	*Salmonella*
Rice	Heated	*Bacillicus cereus*
Other grains	Dried	*Mycotoxins*
		Salmonella
Mushrooms	Raw	*Salmonella*
	Retorted	*Clostridium botulinum*
		Staphylococcus aureus

Raw product/ingredient/pre-processing

- Spraying close to harvest time (C)
- Sewage pollution (C)
- Infected animal/manure (C)
- Soil contamination (C)
- Contamination by worker (C)
- Contamination by water (C)
- Abnormally-high a_w (G)
- Prolonged cold storage (C)
- Contamination by vectors (C)
- High soil nitrites/nitrates (C)

Processing or preparation (contamination, survival, proliferation) in food processing plant, food service establishment or home

- Improper a_w adjustment (salt conc.) (G)
- Use of polluted water (C)
- Contamination by worker (C)
- Improper cleaning of equipment (C)
- Organism/toxin survives process (S)
- Heat process failure (S)
- Manipulation/spread during process (G)
- Room-temperature holding (G)
- Improper cooling (G)
- Inadequate refrigeration (G)
- Contamination during cooling (C)
- Prolonged storage

Post-processing/preparing abuse at home or social events or during transport

- Contamination during reconstitution (C)
- Contamination by person (C)
- Improper cleaning of equipment (C)
- Improper cooling (G)
- Inadequate refrigeration (G)
- Prolonged storage (G)
- Room-temperature holding (G)

Annexure 12: Procedures and equipment for specimen collection

Clinical specimens

General

Enclose specimens in a secure container and label the container with a waterproof pen. Place this container in a waterproof bag with tissue, towels or other blotting material to absorb any leakage. Put all specimen containers in an insulated box packed with ice or frozen refrigerant packs and deliver them to the laboratory as soon as possible. If sending specimens by post or courier, ensure that they are delivered during business hours on a weekday.

Address the package clearly, including the name and telephone number of the receiving laboratory. Write instructions as appropriate, for example, “Medical specimens. Call addressee on arrival. Hold refrigerated.”

Faeces

Collect stool specimens as soon as possible since delay may impede identification of the causative agent.

Ideally, swabs of fresh stool or rectal swabs should be collected for bacteriological examination, large volumes of diarrhoeal stool (at least 30g) for viral examination, and fresh bulk stool (with preservative) for parasite examination.

Bacteria

Collect at least two rectal swabs or swabs of fresh stools (less than one hour old) from each case

- If possible, refrigerate Cary-Blair transport medium in advance, so that the swabs can be placed into a cool medium.
- Insert swab into Cary-Blair medium to moisten it.
- Insert swab 3-5 cm into rectum and rotate gently.
- Remove swab and examine it to ensure that the cotton tip is stained with faeces.
- Insert swab immediately into tube of transport medium.
- Push the swab to the bottom of the tube.
- Repeat procedure with the second swab and place in same tube as the first.
- Break off top parts of sticks, tighten screw-cap firmly**.**

If specimens arrive at the laboratory within the 48 hours after collection, they can be refrigerated at 4 °C. Pathogens can still be recovered from refrigerated samples up to 7 days after collection, although the yield decreases after the first 2 days. During transport, refrigeration for up to 36 hours can be achieved by shipping in a well-insulated box with frozen refrigerant packs or wet ice.

If it is impossible for specimens to reach a laboratory within 2 days, they can be frozen at

–20 °C (home-type freezer) although freezing at –70 °C (ultra-low freezer) is preferable. Frozen specimens should be shipped with dry ice, observing the following precautions

- Protect specimens from direct contact with dry ice, as intense cold can crack the glass tubes.
- Protect specimens from carbon dioxide by sealing screw-caps with tape tubes in plastic bags or by sealing
- Ensure that container is at least one-third full of dry ice.

Viruses

Obtain a large quantity (as much as possible but at least 10 ml) of diarrhoeal stool that has not been mixed with urine in a clean, dry, leak-proof container. To permit diagnosis of certain viral agents, specimens must be collected during the first 48 hours of illness. Immediately refrigerate the specimen at 4 °C (do not freeze) and send as soon as possible to the laboratory.

Parasites

Obtain fresh bulk-stool that has not been mixed with urine and place in a clean container. Then add preservative solution (10% formalin or 10% polyvinyl alcohol) at a ratio of 1 parts to 3 parts preservative. If there is a delay in obtaining the preservatives, refrigerate untreated stool specimens at 4 °C (do not freeze) for up to 48 hours. Once preserved, the specimens can be stored and transported at room temperature or refrigerated.

Vomitus

If the person is still vomiting at the time of the investigation, collect vomitus. Let the patient vomit directly into a specimen container that has been thoroughly cleaned and boiled in water. Take the specimen directly to the laboratory. If this is not possible, refrigerate (but do not freeze) the specimen.

Serum

In the investigation of foodborne disease outbreaks, serological examination is sometimes useful to detect the development of antibodies as a result of infection.

Blood should be obtained only by a person legally qualified to undertake the procedure; check appropriate laws. If possible, obtain blood specimens from the same patients from whom stool samples were obtained.

Submit two serum specimens – one acute-phase and one convalescent-phase – for each patient thought to have illness caused by viruses or bacteria. Obtain the acute-phase serum specimen as close to the time of onset of illness as possible (at most, within a week after onset of illness). The convalescent-phase serum specimen should be obtained 3 weeks – or, if a viral agent is suspected, 6 weeks – after the onset of illness.

Collect blood specimens from adults (15 ml) and from children (3 ml) in tubes that do not contain anticoagulants. For antibody studies the specimens need not be refrigerated during the day of the collection (unless the weather is extremely hot) but should be kept out of direct sunlight. Centrifuge the blood and send only the serum for analysis. If no centrifuge is available, store the blood specimens in a refrigerator until a clot has formed; then remove the serum and pipette it into an empty sterile tube. Refrigerate the tubes of spun or unspun serum and ship them refrigerated.

Urine

Clean the area around the urethral orifice with a pad that has been pre-moistened with a 4% tincture of iodine or other appropriate antiseptic. Begin to urinate into the toilet and collect 30ml of midstream urine. The specimen should be refrigerated but not frozen.

Other clinical specimens (food-handlers)

Skin lesions (boils, lesions, abscesses, secretions)

- Clean skin with normal saline or weak disinfectant to prevent contamination of the specimen with saprophytic organisms.
- Apply pressure to the lesion using sterile gauzes and collect specimen on sterile swab, trying to obtain as much secretion as possible.
- If the lesion is closed, disinfect skin and extract specimen using sterile syringe.
- Transport immediately to laboratory at ambient temperature. If this is not possible, the specimen can be left for up to 24 hours, at which time the swab should be placed in a container of ice.

Oropharynx and nostrils

- Collect specimen with a sterile swab and immediately place in transport medium (Stuart's).

- Transport immediately to laboratory at ambient temperature. If this is not possible, the specimen can be left for up to 24 hours, at which time the swab should be placed in a container of ice.

Food and environmental specimens

Equipment

- **Sterile sample containers**
  - Disposable plastic bags
  - Wide-mouth jars (100-1000 ml) with screw-caps Bottles for water samples
  - Foil or heavy wrapping paper Metal cans with tightly fitting lids
- **Sterile and wrapped instruments for sample collection**
  - Spoons, scoops, tongue depressors Butcher's knife
  - Forceps, tongs, spatula Drill bits
  - Metal tubes (1.25-2.5 cm in diameter, 30-60 cm in length) Pipettes, scissors
  - Moore swabs (compact pads of gauze made of 120 x 15 cm strips, tied in the centre with a long, sturdy twin or wire for samples taken from sewers, drains, pipes, etc.)
  - Sponges
- **Sterilizing agents**
  - 95% ethanol
  - Propane torch
- **Refrigerants**
  - Refrigerant in plastic bags
  - Heavy-duty plastic bags or bottles that can be filled with water and frozen Heavy-duty plastic bags for ice
- **Food temperature measurement**
  - Bayonet-type thermometers (–20 °C to 110 °C), between 13 and 20 cm length Bulb thermometer (–20 °C to 110 °C)
- **General**
  - Marking pen (waterproof) Adhesive tap

- Cotton
- Peptone or buffered distilled water (5 ml in screw-capped tubes) Electric drill (if frozen foods to be sampled)
- Distilled water
- Insulated chest or polystyrene box

General

- Collect samples aseptically. Put them into sterile jars or plastic bags to avoid any cross-contamination.
- If samples are to be examined for organophosphate pesticides or heavy metals, plastic containers should not be used. Chemicals from the plastic may leach into the food and interfere with the analysis.
- Obtain samples of approximately 200 grams or 200 ml.
- Take packaged foods to the laboratory in their original containers. Empty containers can be used to identify micro-leaks, or rinsing from these containers can be used to detect pathogens.
- Check original packages or containers for code numbers that can be used to identify the place and time of processing. Include any unopened packages or cans belonging to the same batch.
- Keep all packages not sent for laboratory examination until the end of the investigation.
- Refrigerate samples of perishable foods at 4 °C until they can be examined. Do not freeze food samples as certain pathogens (e.g. Gram-negative bacteria, vegetative forms of Clostridium perfringens) die off rapidly when frozen – but foods that were frozen when collected should be kept frozen until examined.
- Enrichment broth and dry materials require no refrigeration.
- Solid foods or mixture of two foods
- Cut or separate out a portion of food, using a sterile knife or other utensil if necessary. Collect sample aseptically and put into a sterile plastic bag or wide-mouth jar. Collect samples from top centre, and elsewhere, as necessary, refrigerate.

Liquid food or beverages

Stir or shake. Collect samples using one of the following methods

- Using a sterile utensil, transfer approximately 200 ml into a sterile container; refrigerate.
- Place a long sterile tube into liquid, cover the opening with finger. Transfer liquid to the sterile container; refrigerate.
- Dip a Moore swab in the liquid or into the pipe so that liquid circulates around it. Leave in place for several hours, if possible. Transfer swab to a jar containing enrichment broth. Refrigeration is not usually necessary.
- If the liquid is not too thick, pour 1 to 2 litres through a membrane filter. Transfer the filter pad aseptically to a jar containing enrichment broth. Refrigeration is not usually necessary.

Frozen foods

Keep frozen, using dry ice as necessary. Transport or ship the specimen in an insulated container. Use one of the following methods

- Send or take small frozen samples to the laboratory, without thawing or opening.
- Break frozen material into pieces using a sterilized hammer and chisel and collect pieces using a sterilized utensil.
- Using a large-diameter sterilized drill, drill from one side at the top of the container
- diagonally through the centre down to the bottom of the opposite side. Repeat on the other side until sufficient material has been collected.

Raw meat or poultry

Use one of the following methods

- Using a sterile utensil or sterile glove, place poultry carcass or large piece of meat in a large sterile plastic bag. Add 100–300 ml enrichment broth. Remove sample and seal the bag.
- Wipe a sterile sponge over a large section of the carcass or piece of meat. Place swab in a jar containing enrichment broth.
- Moisten a swab in buffered distilled water or 0.1% peptone water. Wipe the swab over a large section of the carcass or piece of meat. Place swab in enrichment broth.

- Using a sterile glove wipe the carcass or the piece of meat with sterile gauze pads and place the pads in a jar containing enrichment broth.
- Aseptically cut a piece of meat or skin from different parts of the carcass or large piece of meat, or remove part of the carcass. Place at least 200 g of sample in a sterile plastic bag or glass jar; refrigerate.

Dried foods

- Insert a sterile hollow tube near one edge at the top of the container diagonally through the centre down to the bottom of the opposite side.
- Keep the top part of the sample and transfer to sterile container.
- Repeat the procedure on the other side of the container until a sufficiently large sample has been collected.
- Alternatively, use sterile spoon, spatula, tongue depressor or similar utensil to collect sample. Transfer to sterile jar.
- Keep in water- and airtight container.

Scrapings from food equipment, pipes, filters etc.

- Cut or collect enough material with a sterile tongue depressor, spatula, spoon or similar utensil and place in sterile bags or wide-mouth jars.
- Refrigerate as required (depending on material, see above).

Environmental swabs

- Moisten swab with 0.1% peptone water or buffered distilled water and wipe over contact surfaces of equipment or environmental surfaces. Place in enrichment broth.
- **Air:** Touch plate or liquid with the device for sampling air, or let airborne particles settle on broth or agar plates obtained from microbiology laboratory. Seal with insulation tape. Refrigerate liquid samples.
- **Water:** Collect water from suspected areas, including from bottles in refrigerators, ice cubes, basins, etc. When taking water from a tap, let the water run for 10 seconds before collecting the sample. To sample water that has not been standing in proximal pipes, let water run for 5 minutes. Place sterile jar under running water and let it fill to 2.5 cm from the top. Collect 1-5 litres. Alternatively, membrane filters can be used. Moore swabs may be used to collect water samples from streams or plumbing; they should be left in place for up to 48 hours and then transferred to sterile jars containing enrichment broth.

Specimen collection for suspected chemical toxicants 5

- Avoid contamination at all costs.
- Refrigerate or freeze specimens as rapidly as possible.
- Used only screened collection material if possible. This material has been tested for extraneous contaminants and is specially washed and packaged. If unscreened material is used, randomly select at least three of each of the containers being used (collection cup, vacutainer, etc), seal them in a clean bag and submit them with the other samples to the laboratory. This may allow evaluation of possible extraneous contaminants from the collection material at hand.
- Urine is the preferred specimen if the suspected toxicant is an inorganic chemical (e.g. lead, arsenic, mercury). Urine should also be collected if the toxicant is unknown. Freeze promptly.

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