National Foodborne disease Surveillance Guideline

Bhutan

Operational Surveillance Guideline

(1st Edition 2019)

Royal Centre for Disease Control
Department of Public Health
Ministry of Health
Bhutan

Preface

The high morbidity rates from diarrheal disease and an increased detection of rotavirus in children poses a challenge for the government. Rotavirus infection is a vaccine preventable disease and thus an introduction of such vaccine in the country must be monitored for its effectiveness by a sensitive surveillance system. This rotavirus gastroenteritis surveillance system is designed to understand the behaviour of rotavirus and monitor the effectiveness of the vaccine after its introduction in the immunization program.

This guide was prepared by pooling experts from different disciplines in the Ministry of Health using the principles of WHO surveillance guide for vaccine-preventable diseases in the WHO South-East Asia Region. It covers roles and responsibilities of health professionals at different levels from identification and investigation of the Foodborne diseases, case reporting and dissemination of information to relevant stakeholders. This surveillance is integrated with the existing NEWARS and FoodSIMS to improve the efficiency of the operation and realize the expected outcomes. The integration will also provide a more rational basis for decision making and implementing public health interventions that effectively respond to rotavirus related public health events.

All clinicians, laboratory staff, nurses, epidemiologist, BAFRA officials and all other health professionals including program managers working for the surveillance should be guided by this guideline.

We would like to acknowledge and appreciate the frontline health workers who have in their own way dedicated their work and lives in the field of disease detection, control and prevention.

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List of contributors:

Tshering Dorji, Dy. Chief Laboratory Officer, RCDC

Vishal Chhetri, Sr. laboratory Officer, RCDC

Tshering Pelden, Laboratory Officer, RCDC

Dorji Tshering, Sr. laboratory Technician, RCDC

Rinzin Wangdi, laboratory Assistant, RCDC

Lham Dorji, Sr. RQI, BAFRA Gelephu

Nim Dorji, Sr. RQI, BAFRA Phuentsholing

Karma Jamtsho, ICTO, BAFRA HQ Thimphu

Bikash, ICTO, MoH, Thimphu

Abbreviations and definition

ABD	Acute Bloody Diarrhea
APC	Aerobic Plate Count
AWD	Acute Watery Diarrhea
BAFRA	Bhutan Agriculture and Food Authority
CDD	Communicable Disease Division
CIF	Case Investigation Form
CLSI	Clinical Laboratory Standards Institute
CUSUMS	Complex Statistical Modelling
DHO	District Health Officer
DHRRT	District Health Rapid Response Team
EBS	Event Based Surveillance
EIDL	Enteric and Invasive Disease Laboratory
ELISA	Enzyme Linked Immunosorbant Assay
EMSD	Emergency Medical Service Division
FAO	Food and Agriculture Organization
FDS	Foodborne Disease Surveillance
FNL	Food and Nutrition Laboratory
FoodSIMS	Foodborne Disease surveillance Information management System
IBS	Indicator based surveillance
ICT	Information and Communication Technology
IHR	International Health Regulation
INFOSAN	International Food Safety Network
IPD	In-patient Department
ISO	International Standards Organization

MCB	M-cary Blair
NADSE	National Disease Surveillance Epidemiology Unit
NCAH	National Centre for Animal Health
NDSS	Notifiable Disease Surveillance System
NEWARS	National Early Warning, Alert and Response Surveillance
NFTL	National Food Testing Laboratory
OPD	Out Patient Department
PAGE	Pulse Field Gel Electrophoresis
PCR	Polymerase Chain Reaction
PHEIC	Public Health Emergency of International Concern
RCDC	Royal Centre for Disease Control
RTE	Ready to Eat
SFP	Surveillance Focal Point/Person
SMS	Short Message Service
SoP	Standard Operating Procedure
WHO	World Health Organization

Definition

a. Foodborne illness

Foodborne illnesses are defined as diseases that are generally either infectious or toxic in nature and caused by agents that enter the body through the ingestion of food. The first symptoms often occur in the gastrointestinal tract. Nausea, vomiting, abdominal cramps and diarrhoea are frequent symptoms of foodborne diseases (WHO).

b. Gastroenteritis Case Definition

Gastroenteritis is a condition that causes irritation and inflammation of the stomach and intestines. The most common symptoms are low grade fever to 100°F (37.7°C), diarrhea, crampy abdominal pain, nausea with or without vomiting.

c. Diarrhea

Diarrhea is defined as two or more loose stools per day or an unexplained increase in the number of bowel movements.

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1. Introduction

Food may be a silent vehicle for microbial, chemical and physical hazards. There is concern about transmission of multiple antimicrobial resistant bacteria via food chain. Several devastating outbreaks of foodborne diseases have been reported in Bhutan. For instance, *Campylobacte*r outbreak in Bumthang in 2012 affected about 400 students which was associate with meat consumed during sports celebration. In 2014, food poisoning was listed as one of the notifiable diseases in the country and was integrated into National Early Warning and Response Surveillance (NEWARS). More than 42 outbreaks were reported from various parts of the country through the notifiable disease and event reporting system with the introduction of NEWARS. This has established stronger systems linked to laboratory support, resulting in the efficient sharing of resources for core surveillance and support functions. However, there is no systematic foodborne surveillance system to capture detailed data on foodborne illness and lack of surveillance guideline on foodborne illness. This was found to be one of the major constraint by WHO assessment team to conduct surveillance on food safety which is an important core capacity of International Health Regulation.

2. Purpose of the guideline

This guideline provides guidance on conducting effective foodborne disease surveillance in Bhutan to strengthen the reporting as a part of indicator, and event-based reporting systems under NEWARS. This guideline is intended to be used along with NEWARS guideline and comprise of different aspects of conducting foodborne disease surveillance in the country.

3. Target audience

The surveillance guideline is intended to be used by health staff at all the surveillance sites, Bhutan Agriculture and Food Regulatory Authority (BAFRA) officials, surveillance focal person Royal Centre for Disease Control and other relevant programs under Ministry of Health. Other possible target audiences may include country focal for International Health Regulation (IHR), International Food Safety Network (INFOSAN) country focal and animal health sectors such as National Centre for Animal Health (NCAH).

4. Objectives

The objectives of this foodborne surveillance guideline are:

1. Estimate and determine the burden of food borne diseases;
2. Monitor trend of foodborne diseases;
3. Provide early warning and detect outbreaks;
4. Identify vulnerable populations;
5. Monitor the public health impact and effectiveness of applied control measures;
6. Generate reliable data for formulation of evidence-based strategy for public health policy, and plans by ministry of health and food safety authority.

5. Core capacity required for foodborne disease surveillance

The improvement of national control efforts to contain, eliminate or eradicate epidemic prone diseases is fundamental for the improvement of national health security. Similarly, control programmes are aimed at reducing public health risks associated with events of chemical, toxin and environmental origin. Laboratory services are the cornerstone to foodborne disease surveillance for national epidemic alert; including detection, investigation and response. Laboratory analysis of human, food and animal samples are critical and requires collaboration with relevant stakeholders. This must be based on reliable sample collection and transportation process, domestic diagnostic capacity and refer sample to external laboratory if required. The identification of the source of an outbreak and containment is a key IHR (2005) requirement. Hence, it is important to develop risk management capacities in order to ensure food safety throughout the food chain. If epidemiological analysis identifies food as the source of the outbreak, based on risk assessment, the adopted risk management option for preventing further spread should be put in place. Overall human capacity development should follow the principle of sustainability at all levels, in particular trained BAFRA officials and health workers who will collect samples for submission to laboratory for analysis. Categories of staff must cut across all disciplines including; laboratory staff, clinicians, microbiologists, epidemiologists, clinical toxicologists, food inspectors and environmental officers. Strengthening the knowledge and skills of all public health actors, in particular laboratory personnel, is key to the implementation of the foodborne diseases surveillance agenda.

6. Roles and responsibilities

All health professionals working in different healthcare centre are responsible for implementing NEWARS activities. Therefore, it is important that every health professional understand his/her roles and responsibilities. Health Professionals include Specialists, medical doctors, clinical officers, health assistants, nurses, and laboratory staff working in various health facilities who are the first contact person and have access to information from patients. Therefore, above listed health professionals are primary data collection point for all notifiable diseases or syndromes listed in NEWARS (indicator-based surveillance).

6.1 Responsibilities of clinicians in health facilities

1. Identify cases of foodborne illness based on surveillance clinical case definition and collect information of cases on weekly basis in OPD/IPD/Emergency using NEWARS weekly reporting form (Annex 1).
2. Handover the forms to designated NEWARS Surveillance focal points in the health facility on weekly basis.
3. Fill in the case investigation form for foodborne disease surveillance for selected case (Annex 2).
4. Refer selected patients identified to be suffering from foodborne illness to laboratory for sample collection and investigation.

6.2 Surveillance focal points in health centre

Focal point for NEWARS should serve as surveillance focal person for foodborne disease surveillance as it is integrated with NEWARS.

Responsibilities of the SFP

1. Compile surveillance data on foodborne illness collected by clinicians at the end of the day on daily basis.
2. Collate the surveillance data on foodborne illness against specified age group and gender for the specific epidemiological week.
3. Report collated data on weekly basis through NEWARS online system or Short Message Service (SMS) by midnight of **Tuesday** of the next week and file the duly filled forms in a secured place of the facility.
4. Report any foodborne illness outbreak (event) through online or SMS event reporting in NEWARS system within 24 hours for detection for immediate response.

6.3 District Health Office

District Health Officer should play important role in monitoring NEWARS reporting status of health centres under its jurisdiction.

Responsibilities of the District Health Offices

1. Follow-up and monitor when an event related to foodborne illness is reported; DHO should activate and lead district health rapid response team (DHRRT) for investigation, if required.
2. Liaise and communicate with Dzongkhag BAFRA office during outbreak of foodborne illness.
3. Liaise and communicate with RCDC, National Disease Surveillance and Epidemiology Unit (NADSE) and sort out issues during the event.

6.4 Laboratory in healthcare centres

Sample analysis by laboratory to confirm etiologic agent for foodborne illness is critical.

Responsibilities of the Laboratory personnel

1. Collect suitable specimen as per the Standard Operating Procedure (SOP).
2. Analyse samples and provide reports to requesting clinician, SFP or District Health Office.

3. Aliquot and store specimens at appropriate temperature in refrigerator or freezer and ship to RCDC in proper cold chain (M-cary blair at 2 to 8°C and Cryotube at 0 to -80°C).
4. Liaise and communicate with RCDC for any advice or assistance related to laboratory work.

6.5 Royal Centre for Disease Control

6.5.1 National Disease Surveillance and Epidemiology Unit

National Disease Surveillance and Epidemiology (NADSAE) is the national focal point for surveillance and foodborne disease outbreaks in the country.

Responsibilities of NADSAE Unit

1. Follow-up with healthcare centre to ensure timely and accurate reporting,
2. Routinely validate data reported by healthcare centre,
3. Verify foodborne events reported and perform risk assessment and provide appropriate recommendation.
4. Coordinate and collaborate with healthcare centres, DHRRT, National RRT and RCDC during investigation of an outbreak.
5. Prepare and disseminate monthly and quarterly disease surveillance report to all level of health centres and relevant stakeholders.
6. Collaborate with international agencies during emergency.
7. Conduct training for health professionals on NEWARS.
8. Conduct periodic evaluation of the surveillance, update guideline and system in collaboration with EIDL/FNL and ICT unit.

6.5.2 Enteric and Invasive Disease/Food and Nutrition Laboratory

Enteric and Invasive Disease Laboratories and Food and Nutrition laboratory, RCDC is the reference laboratory for foodborne disease surveillance and plays vital role in confirming etiology of foodborne illness and outbreak.

Responsibilities of reference laboratories

1. Provide confirmatory diagnosis for all foodborne diseases and events.
2. Provide technical assistance to peripheral laboratories in diagnosis of diseases and events.
3. Mobilize diagnostic supplies for all the district laboratories for diagnosis.
4. Provide prompt result for samples referred by health centres, clinicians, SFP, BAFRA and other relevant stake holders.
5. Referring samples to supranational reference laboratories, if required.

6.5.3 Information Technology (IT) Unit

Foodborne Disease Surveillance Information Management System (FoodSIMS) is an online system which manages all the data related to foodborne surveillance including epidemiological, sample and laboratory information.

Responsibilities of IT personnel

1. Maintain and update web-based reporting and data management system (FoodSIMS),
2. Upgrade IT system as and when required.
3. Support health centres related to system problems.
4. Assist NADSAE in preparing monthly report and quarterly disease surveillance bulletin.
5. Supports in training of health and BAFRA personnel on FooDSIMS.

6.6 National IHR Focal Point

Food safety is one of the core capabilities of IHR. As per the IHR 2005 guideline, any disease or events of international concern should be reported to WHO through National IHR focal Point which may constitute a Public Health Emergency of International Concern (PHEIC). Chief of Emergency Medical Service Division (EMSD) is the National country focal for IHR.

Responsibilities of National IHR Focal Point

1. Assess a foodborne event report which falls under the purview of PHEIC using the "IHR (2005) Decision Instrument".
2. Notify WHO country office if the event constitutes a PHEIC in the country and help implement response measures.
3. Provide all relevant public health information to WHO if there is evidence of an unexpected or unusual public health event in the country.
4. Respond to WHO's request for verification of reports from sources other than notifications or consultations of events.

6.7 Department of public health

Communicable Disease Division (CDD) is the main stakeholder in NEWARS system under the department of Public Health.

Responsibilities of Communicable Disease Division

1. Supporting funding and training activities of health personnel at various levels.
2. Setting policies and procedures for reporting of foodborne illness surveillance and events.
3. Setting policies and procedures for responding to outbreaks or events. Mobilization of resources to maintain and improve the quality of surveillance.

6.8 Bhutan Agriculture and Food Regulatory Authority

6.8.1 BAFRA officials at the surveillance sites

1. Collect food samples as per the foodborne disease surveillance guideline.
2. Collect and collate information on food samples collected as per the variables given in Food sample information form (FoodSIMS).
3. Information on food samples should be submitted through FoodSIMS on fortnightly basis.
4. Sample storage and shipment of food samples to FNL, RCDC as required.

6.8.2 BAFRA Head Office (Quality Control and Quarantine Division-Food Safety)

1. Ensure and encourage field officials to collect required food related information on timely basis.
2. Designated staff should verify all the data received online. If any discrepancy is observed in the reported data, the surveillance officer and designate laboratory staff should call or email the field officials of that particular surveillance sites to go through the data stored in hard copy and ask them to verify once again and make necessary changes if required.
3. Coordinate and collaborate with RCDC, Department of Public Health.

6.9 National Food Testing Laboratory

1. Conduct chemical testing of food samples, whenever required.
2. Provide prompt result to respective BAFRA field office and RCDC.
3. Referring samples to supranational reference laboratories, if required.

7. Integration of foodborne disease surveillance into NEWARS

7.1 National Early warning, alert and Response surveillance (NEWARS)

National Early Warning, Alert and Response Surveillance (NEWARS) was introduced in 2014 as the integrated national disease surveillance and response system for diseases or syndromes of public health concerns.

The NEWARS consists of two components:
1. Notifiable Disease Surveillance System (NDSS)
2. Event-based Surveillance (EBS).

The NDSS captures a set of predefined diseases and syndromes which were selected by the Ministry of Health based on the following criteria:

1. Diseases or syndromes which have epidemic potential.
2. Diseases which are vaccine preventable.
3. Diseases that are aimed for elimination.
4. Disease with high morbidity and mortality.
5. Diseases that are of potential threat to international community.

The event-based surveillance is a rapid reporting of any public health event such as outbreaks, unusual death, disease and deaths in animals, contaminated food and food products, and environmental hazards including chemical and radio-nuclear. This surveillance encourages every citizen in the country to report any unusual events to the Ministry of Health through NEWARS.

Foodborne illness and outbreaks reporting is integrated with NEWARS reporting system. It collects number of patients visiting the hospitals with suspected food poisoning and diarrheal disease. This system is supplemented with epidemiological information and clinical, laboratory and food information from National Foodborne disease surveillance.

8. Components of foodborne disease surveillance

8.1 Collection of epidemiological and clinical information

Identification of patients with foodborne illness

Definition of foodborne illness

Foodborne illnesses are defined as diseases that are generally either infectious or toxic in nature and caused by agents that enter the body through the ingestion of food. The first symptoms often occur in the gastrointestinal tract. Nausea, vomiting, abdominal cramps and diarrhoea are frequent symptoms of foodborne diseases (WHO).

Foodborne disease Surveillance case definition

"Foodborne illness is any person experiences vomiting and abdominal cramps/pain or with/without dirrhea after ingestion of foods or drinks to be contaminated with bacteria, chemical substances and or toxins"

Note: *The surveillance case definition will enable clinicians and public health officials to classify and count cases consistently across reporting jurisdictions. However, surveillance case definitions should not be used by healthcare providers for making a clinical diagnosis or determining how to meet an individual patient's health needs.*

8.2 Data collection by clinicians from regional healthcare centres

In addition to the aggregated data collected through the NEWARS, additional epidemiological data should be collected by clinicians. To capture additional District hospitals should collect demographic and clinical information by interviewing the individual patients. The key information for the surveillance should be collected by using a case investigation form (CIF).

8.3 Data Collation by district hospitals

Data collation should be conducted as a part of data collation activity for NEWARS system. Apart from aggregated data collated, CIF data should also be collated from certain foodborne illness cases.

1. SFP in Dzongkhag hospitals should:

i. Collate data for a weekly report using "Weekly Reporting Form in NEWARS" to report to NADSAE, RCDC using online and SMS based NEWARS system as a part of NEWARS reporting system (See NEWARS guideline).
ii. Segregate data as per the age group and gender specified at the end of every epidemiological week before submission.
iii. Validate data before sending to NADSAE.

2. Designated Laboratory staff should:

i. Collect the CIF form from patients enrolled for specimen collection and collate on weekly basis.
ii. The patient should be sent along with the CIF to laboratory for specimen collection and laboratory investigation.
iii. The CIF should be retained by laboratory staff for online (FoodSIMS) submission of data through FoodSIMS.
iv. Document CIF form for verification purpose.

8.4 Reporting and Verification of data

8.4.1 Reporting

A. Reporting of foodborrne illness through NEWARIS

i. A clinician at the district healthcare centres should identify cases based on case definition and collect information of cases due to foodborne illness on daily basis.
ii. Daily data collection for foodborne illness including diarrheal and bloody diarrheal should be conducted using daily case recording form through NEWARS (Annex 3).
iii. The daily case recording should be handed over to surveillance focal point (SFP) of the healthcare centre.

B. Reporting of foodborne illness through FoodSIMS

i. Detailed epidemiological and clinical information should be collected from at least 10 cases in a week using CIF.
ii. The patient should be sent along with the CIF to laboratory for specimen collection and laboratory investigation.
iii. The CIF should be retained by laboratory staff for online (FoodSIMS) submission of data through FoodSIMS.

8.4.2 Verification

i. Upon the submission of data from all surveillance sites, the surveillance officer at NADSAE, RCDC should verify all the data received online.
ii. Designated laboratory officials should verify the CIF details submitted through the FoodSIMS from laboratories at surveillance sites.
iii. If any discrepancy is observed in the reported data, the laboratory officials should call or email the SFP of that particular surveillance sites to go through the data stored in hard copy and ask them to verify once again and make necessary changes if required.

9. Laboratory investigation

9.1 **Foodborne disease surveillance**

Enteric and Invasive Disease Laboratory will process human samples (stool and vomits) collected for surveillance and any foodborne illness outbreaks.

9.1.1 Human samples

Laboratories receive clinical specimens (blood, vomits, faecal sample, etc.) from patients with suspected foodborne disease. For most food borne diseases, stool is the specimen of choice, however, blood, vomits, or other tissue or body fluid occasionally are indicated. Specimens are collected as soon as possible after onset of illness and before administration of antibiotics. For details on amount and type of human samples see table 1 below.

Table 1. Common human samples for foodborne illness

Sl. No	**Sample type**	**Quantity**	**storage**	**Transport condition**
1	Blood	5-10mL	Immediate culture	Suspected growth should be transported at 2-8^{0}C
2	Stool/Vomits	5g	2-8^{0}C for upto 72 hours	Transport in mCB media at 2-8^{0}C
3	Stool/Vomits (For ELISA)	2mL	0 to -80°C	0 to -20°C

9.1.2 Sample storage and Transport

Human samples, such as stool, vomits should be collected in sterile container and stored at 2-8°C until transport. Human samples for bacteriology must be inoculated in mCB media and transported at 2-8°C and samples for immnuo-serology assay should be transferred into 2mL cryovials and stored, and transported in frozen condition (0 to -20°C).

9.1.3 Test Methods

Laboratories should follow appropriate test methods while analysing specimens/food samples, which are nationally/internationally recognized (e.g., FAO, IS, ISO, CLSI etc.). Laboratory should also use appropriate and good quality of media and chemicals for the test(s)/analysis of the samples.

9.1.4 Target Organism/Test Parameters

Suspected organisms based upon the sign/symptoms shown by the patient and the food category. The common pathogens that are isolated from different samples are listed in table 2.

Table 2: Common Pathogens seen in stool samples

SN	Disease/Syndrome	Suspected etiology	Samples	Storage	Tests
01	Acute Watery Diarrhea	Norovirus, Astrovirus Rotavirus, Adenovirus Hepatitis virus Sapovirus	Serum	2-8 °C up to 1 week or -20 °C if >1 week.	ELISA
		Entamoeba Strongyloides Microsporidium Giardia lamblia Crytopsprodium Shigella spp, Salmonella spp Campylobacter spp Yersinia spp, Vibrio spp Campylobacter spp Diarrheagenic E.coli Clostridium spp Aeromonas spp Plesiomonas spp	Rectal swabs/Stool; Use Modified Cary Blair Transport (MCB) media. Stool samples in Cryotube	2-8 °C 0 to -80°C	Microscopy Bacteriology PCR PCR ELISA
02	Acute Bloody diarrhea	Entamoeba Shigella spp,	Rectal		

		Salmonella spp Yersinia spp, Vibrio spp Campylobacter spp Diarrheagenic E.coli	swabs/Stool; Use Modified Cary Blair Transport (MCB) media. Stool samples in Cryotube	2-8 °C 0 to -80°C	Microscopy Bacteriology PCR PCR ELISA

9.1.5 Disposition of samples and isolates

Human samples and bacterial isolates at EIDL should be kept at -80°C for at least 10 years for future reference after which they should be deposited with strict adherence to the SOP.

9.1.6 Report and laboratory results

All sentinel sites should provide epidemiological and clinical information of foodborne illness through online reporting format. The laboratory results will be made available to surveillance sites through online system. Timely reporting is essential requirement of a notifiable disease surveillance system that is designated to detect outbreaks. While reporting, it is important that clinical information about the patients should be linked to laboratory results by using same unique identification number to the patient. The diagram below describes the reporting mechanism for foodborne disease surveillance data by healthcare centres.

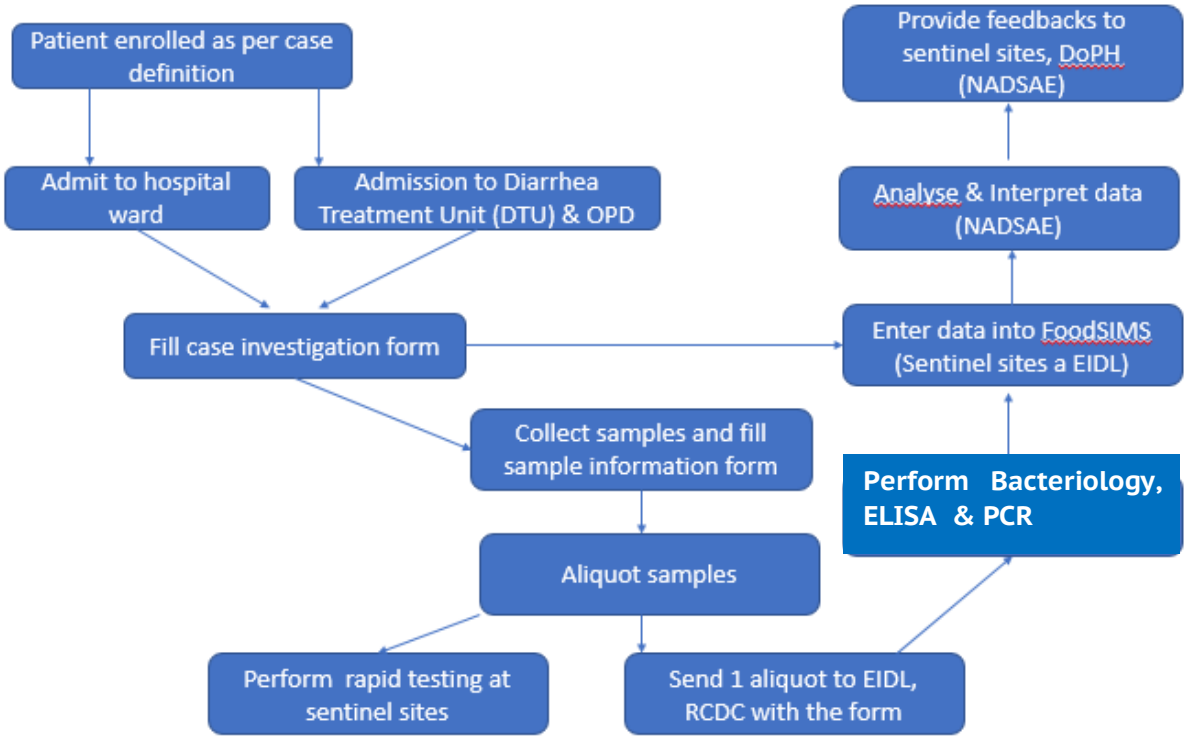


Fig 1. Reporting of foodborne disease surveillance data.

9.2 Food Surveillance

9.2.1 Food information collection

Food related information should be collected on fortnight basis by the BAFRA officials. The information should be collected as per the Food information collection form (FoodSIMS). The information of food production facility should be collected as per the details given in annex 4.

Food and Nutrition Laboratory (RCDC) will carry out analysis of food samples for surveillance and any samples of foodborne disease outbreaks.

9.2.2 Sample

Specimens must be collected in prescribed containers, labelled appropriately and delivered to the laboratory, as quickly as possible, under approved conditions. Ready to eat food items and left-over food from food outlets should be collected as per the sampling plan. At least 250g of food samples should be collected aseptically and packed in sterile packaging material. Perishable foods which are not frozen at the time of collection should be rapidly chilled to 4º C and kept at this temperature until examined. These samples should not be frozen (<2^{0}C) as certain bacteria such as *Clostridia* die off rapidly when frozen.

The laboratory should be consulted about proper sample collection procedures and be alerted when samples are submitted for testing. All effort should be made for samples to be received at the laboratory within the shortest possible time.

The sample collection process must ensure that samples are properly labelled, collected, stored and transported at appropriate condition.

Food samples should be collected using random sampling technique from food outlets for surveillance.

Table 3: Common types of food samples

Sl. No	**Sample type**	**Quantity**	**storage**	**Transport condition**
1	Ready to eat food*	250g	2-8^{0}C for upto 72 hours	2-8^{0}C
2	Liquid food	250mL	2-8^{0}C upto 72 hours	2-8^{0}C
3	Meat or poultry	250g	2-8^{0}C upto 24hrs	2-8^{0}C
4	Frozen foods	100g	<2^{0}C	Frozen
5	Sea foods	250g	2-8^{0}C	2-8^{0}C
6	Fruits and vegetable	250g	2-8^{0}C	2-8^{0}C

*Ready to eat foods: Ready-to-eat food is food that is ordinarily consumed in the same state as that in which it is sold or distributed and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.

9.2.3 Sample storage and Transport

Food sample should be despatched to RCDC following the sample dispatch protocol by BAFRA officials. BAFRA officials should transport the samples to RCDC through Bhutan Post. Sample shipment schedule to Bhutan post in annex 5.

9.2.4 Test Methods

Laboratories should follow appropriate test methods while analysing specimens/food samples, which are nationally/internationally recognized (e.g., FAO, IS, ISO, FASSAI, CLSI etc.). Laboratory should also use appropriate and good quality of media and chemicals for the test(s)/analysis of the samples.

9.2.5 Target Organism/Test Parameters

Aerobic plate count (APC) or aerobic colony count (ACC)", also known as the total viable count or standard plate count, represent the total number of bacteria able to grow in an aerobic environment in moderate temperature. It is an indicator of quality, not safety, and cannot directly contribute towards a safety assessment of food. In addition, APCs can provide useful information about the general quality and remaining shelf life of the food in question, and thus highlight potential problems of storage and handling since production; however they are not deemed a priority in a risk based analysis.

Hygiene indicator organisms refers to the selected surrogate markers. The main objective of using bacteria as indicators is to reflect the hygienic quality of food. *E. coli* is a commonly used faecal indicator organism. Its presence in food generally indicates direct or indirect faecal contamination. Substantial number of *E. coli* in food suggests a general lack of cleanliness in handling and improper storage.

Specific Foodborne Pathogens is examination for foodborne pathogens (bacteria that may cause food poisoning) in ready-to-eat food contributes to food safety. The symptoms of food poisoning vary from nausea and vomiting (e.g. caused by *Staphylococcus aureus* enterotoxin), through diarrhoea and dehydration (e.g. caused by *Salmonella* spp. and *Campylobacter* spp.) to severe conditions such as septicaemia, meningitis, paralysis and death (e.g. caused by invasive *Listeria monocytogenes* and in the rare cases of botulism caused by *Clostridium botulinum* toxin). The infective doses of different foodborne pathogens vary from less than ten to more than 10^8 organisms.

Yeasts and molds are able to contaminate foods and are responsible for quick spoilage of the infested food stuff. Due to their ability to survive low water activity and produce toxic or allergenic substances molds are especially predestinated to be a potential health risk. As these organisms might be rapidly spread by dusts and aerosols, surfaces in the production environment will be consistently contaminated. Therefore, they are usually studied for general hygiene monitoring. The term mold is commonly used for the visible part of the fungi present on the surface of contaminated food. Under the surface the fungi forms mycelium which cannot be recognized with the naked eye. Specific molds as well as yeast are used for industrial purposes (e.g. cheese production).

The common pathogens that are found in different foods are listed in table 4.

Table 4. Bacterial pathogen/food association

Pathogen	Associated food	Remarks
Aeromonas	Pigs, broilers, eggs, milk, vegetables, fresh water	Aeromonas sp. have furthermore been recovered from fresh water sources, and some isolates are resistant to chlorination which makes it a further risk factor.
Bacillus cereus	Cooked foods such as: -Rice dishes -Potato and pasta dishes -Meat, vegetables and fish curries	Spores are widely present in the environment and may be present on the raw materials. The spores survive and are activated by cooking. When foods are cooled too slowly or displayed out of temperature control for extended periods, warm conditions allow for vegetative cells to grow to high levels and produce toxins
Campylobacter spp	Main food vehicles: -undercooked/improperly handled poultry -raw meat -unpasteurised milk -contaminated water -raw vegetables	Campylobacter spp. can colonise the intestinal tract of food-producing animals, such as chickens, cattle, sheep and pigs. Inadequate processing (e.g. undercooked poultry, unpasteurised milk) and cross contamination of RTE foods or food contact surfaces with raw meat and poultry can result in sufficient numbers being present in food to cause illness.
Clostridium spp	Cooked foods such as: - meats, particularly rolled and large joints -meat containing products such as stews, gravies, curries, sausage and pies -vegetable dishes (curries, soups etc.)	Spores are widespread in the environment and are a part of normal intestinal flora of animals. The spores survive and are activated by cooking. Slow cooling/reheating, particularly of large volumes of food, provides warm, anaerobic conditions that allow for vegetative cells to grow to high levels that cause illness when ingested
Diarrheagenic *E.coli*	Foods include: -inadequately cooked ground beef (hamburger patties) -uncooked fermented comminuted meat (e.g. salami) -raw or inadequately pasteurised dairy products (milk and cheese) -fresh produce such as leafy greens and sprouted seeds	Ruminants, in particular cattle and sheep, are the major animal reservoir of STEC. Infected animals shed the bacteria in their faeces, resulting in contamination of the environment. Primary products (such as meat, milk and fresh produce) can be either contaminated directly by faecal material or indirectly via contaminated water or soil. STEC infection is associated with contaminated foods that are eaten without further processing or have been inadequately processed.
Listeria monocytogenes	RTE foods that can support the growth of *L. monocytogenes* and have an extended refrigerated shelf life. Foods that have been	*L. monocytogenes* is widespread in the environment and able to persist in food processing environments. RTE foods can become contaminated post processing

	associated with outbreaks include soft cheeses, delicatessen meats, cooked chicken, smoked seafood, salads and melon	through contamination from food contact surfaces. *L. monocytogenes* is able to grow at refrigeration temperatures and can reach high levels in food that supports its growth
Plesiomonas	Sea foods, contaminated water	Usually present in untreated water
Salmonella spp	A wide range of foods have been implicated in outbreaks of foodborne salmonellosis: -animal products such as eggs (particularly raw or lightly cooked egg dishes), poultry, raw meat, milk and dairy products, - fresh produce (such as leafy greens, seed sprouts, melons) - low moisture foods such as spices, peanut butter, chocolate flour and bakery products	*Salmonella* is widely dispersed in environment. A primary reservoir is the intestinal tracts of vertebrates, including livestock, wildlife, domestic pets, and humans. Contaminated raw foods that are eaten without further processing (such as cooking), cross contamination during food handling and poor hygiene and temperature control practices are factors contributing to foodborne salmonellosis.
Staphylococcus aureus and other coagulase positive staphylococci	A variety of foods, particularly those high in protein and requiring extensive handling during preparation. These can include: -meat and meat products -poultry and egg products -milk and dairy products -cream or custard filled bakery products - sandwich fillings -rice	Food handlers are the main source of food contamination via direct contact (staphylococci can normally be present in people's nasal passages, throat and skin). Contamination of food can occur via hands or respiratory secretions. Time and temperature abuse of contaminated food can result in growth of *S. aureus* and production of enterotoxin in the food.
Vibrio spp	Foods predominantly associated with foodborne illness caused by *Vibrio* spp are fish, shellfish and crustaceans.	*Vibrio* occurs in coastal and estuarine waters and is a natural contaminant of seafood. Initial levels will depend on environmental factors at harvest. Illness is associated with eating raw or lightly cooked seafood, or cooked seafood that has been cross contaminated. Inadequate refrigeration of seafood contaminated with *Vibrio* spp allows growth to levels that cause illness.

9.2.6 Disposition of samples and isolates

Food samples should be kept at 2-8°C for two weeks and bacterial isolates at FNL should be kept at -80°C for at least 10 years for future reference after which they should be deposited with strict adherence to the SOP.

9.2.7 Report and laboratory results

Based on the standard plate counts, levels of indicator organisms and the number or presence of pathogens the quality of food is assigned as either satisfactory, marginal, unsatisfactory and potentially hazardous. The reference for levels for determining the microbiological quality of ready-to-eat is attached in annex 4. The laboratory results for the food surveillance will be made available to surveillance sites through online system.

9.3 Environment sample

Environmental samples are collected from food processing units to determine the environment quality. The commonly collected environmental samples are given in table 5.

Table 5. Common environmental samples

Sl. No	**Sample type**	**Quantity**	**storage**	**Transport condition**
1	Environment swab	2 swabs	2-8^{0}C for up to 72 hours.	2-8^{0}C in normal saline
2	Swab from utensils	2 swabs	2-8^{0}C	2-8^{0}C in normal saline
3	Settled plate (air quality)	Minimum 3 plates from one area	Immediate incubation or 2-8^{0}C for upto 72 hours.	Transport at 2-8^{0}C

10. Data Collation, Analysis and Dissemination

Foodborne illness surveillance data should be collected and maintained using online surveillance system (FoodSIMS). Syndromic data collected through NEWARSIS should be managed and maintained by NADSAE. The surveillance data should be regularly reviewed, verified and validated.

The verified and validated data must be analysed for following outcome/variables:

10.1 Notification rates

A crude notification rates are calculated by dividing the number of notifications of a foodborne disease (both suspected and confirmed) by the number of people in the population of interest. Demographic data are required to calculate this rate. Notification rates are useful for comparing notification of diseases in different populations as shown in the table 6.

Table 6: Example for comparison of notification rates in three subgroups

Population	Crude notification rate per 100,000 populations
Dzongkhag A	45.6
Dzongkhag B	30.0
Dzongkhag C	41.3

Standardized notification rates use a reference population to account for underlying age and sex differences between difference areas. For example, age-standardized notification rates can be used to compare disease burden in different provinces within a country using the national population as reference population.

10.2 Monitoring trends

A histogram or line graph can be used to display the number of cases occurring over a given period of time. These are useful for examining long term trends and for detecting clusters. For example, figure 2 shows the occurrence of diarrheal disease in district A for five years. The cases appears to increase from epidemiological week 3 of 2018. Foodborne diseases are often seasonal, possibly because different foods are available at different times and also because of environmental conditions change with the season, supporting or inhibiting the growth of pathogens.

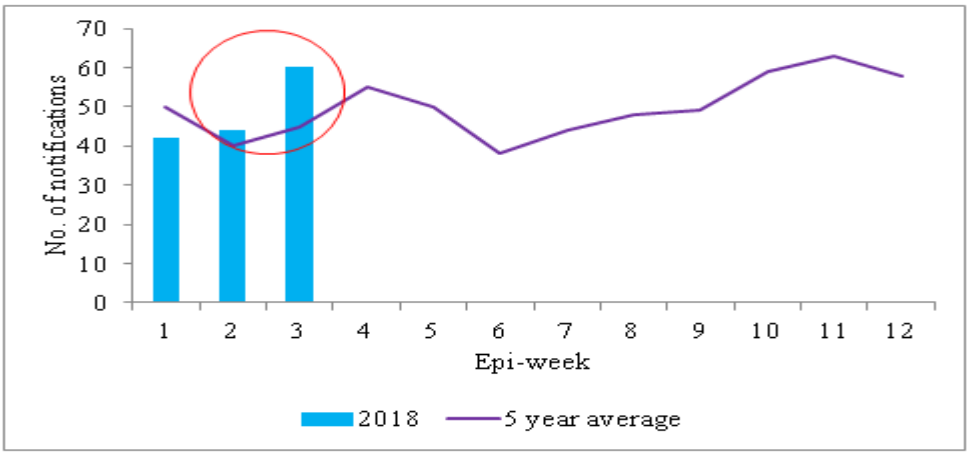


Figure 2: Weekly 5 year average data and number of case cases exceeds alert threshold.

10.3 Thresholds for cluster detection from the surveillance data

Clusters are most defined in relation to time and place. For a surveillance system to be able to monitor trends and detect clusters of illness, the data need to be analyzed regularly. Alert thresholds should be applied to foodborne illness surveillance data to provide guidance for triggering further action. Alert threshold provide an alert when the number of cases of specific disease or syndrome exceeds a pre-established threshold. Cluster detection methods range from simple calculations of historical averages (Figure 3) to complex statistical modelling such as cumulative sums (CUSUMs), scan statistics and model-based approaches.

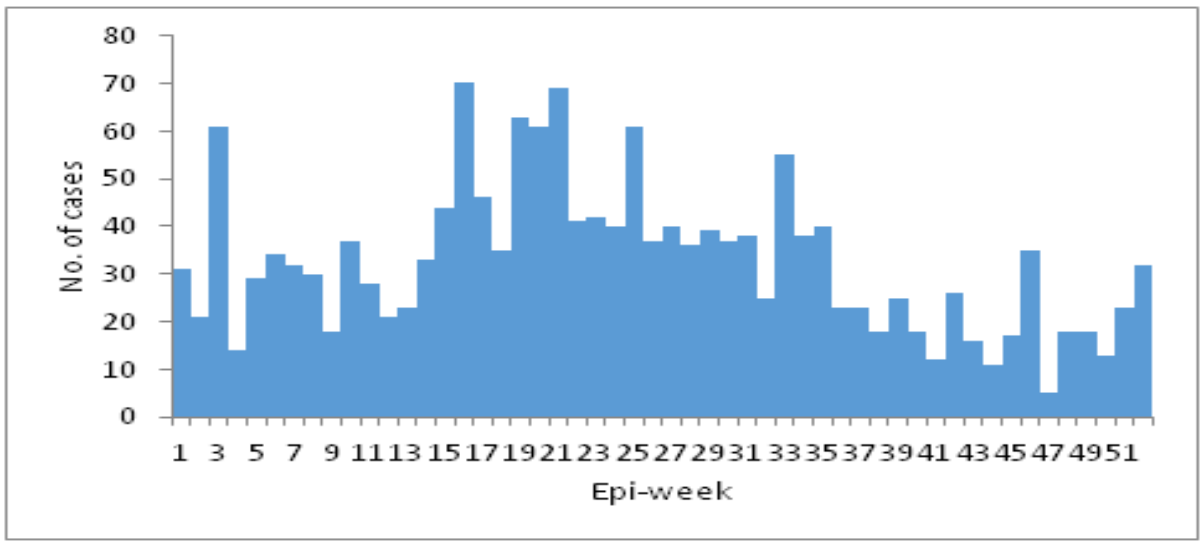


Figure 3: Weekly 5 year average data and number of case cases exceeds alert threshold.

10.4 Describing the surveillance data by person

Bar charts showing notifications of cases by age group can be especially useful in identifying vulnerable groups and enabling comparisons between age groups. Mean, median and mode also be analysed for the data. Example figure below (figure 4) shows bar chart for diarrheal infection with highest number of cases (notifications) observed in 1-4 years age group.

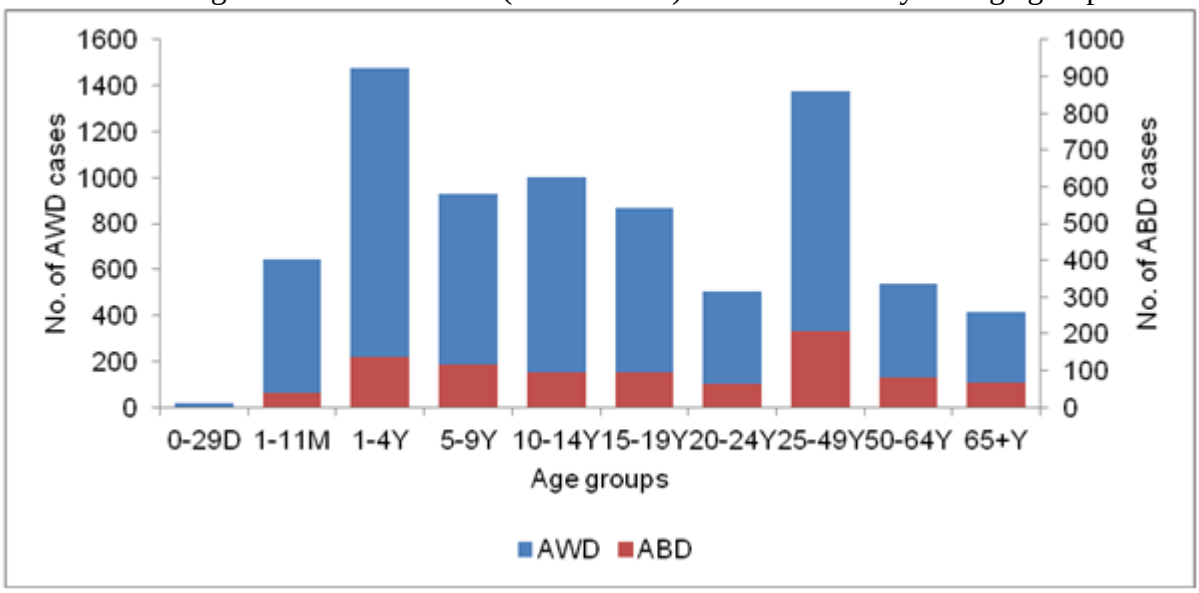


Figure 4: Bar graph showing age wise AWD/ABD cases

10.5 Describing the surveillance data by place

Map showing the number of cases may help to identify areas that have a greater burden of specific foodborne diseases. Figure 5 shows an example for incidence of both acute watery diarrhea (AWD) and acute bloody diarrhea (ABD) in 20 districts in Bhutan in 2017.

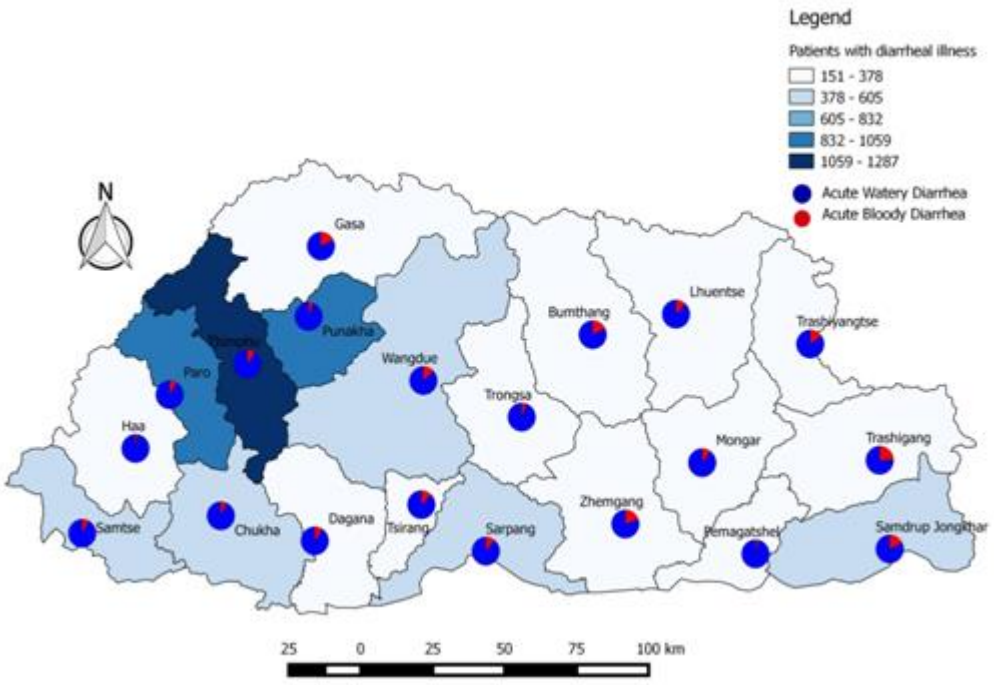


Figure 5: Incidence of AWD/ABD incidences in Bhutan

11.Feedback

Surveillance bulletin should be produced to send feedback about the surveillance data to the clinicians, laboratories and other stake holders contributing to the surveillance system. The outputs from the data analysis and the use of thresholds to identify clusters should be published. Besides providing feedback, the bulletin also provides evidence for developing policy and future interventions. For example, if the notification rates for diarrhoea increases every year at a time of national celebration, it may be possible for BAFRA officials to carry out more inspections of food premises before the next celebration in order to reduce the number of cases of diarrhea in that community.

Regular feedbacks to all the surveillance sites and stake holders is crucial to keep them motivated and improve the surveillance. The feedback is also essential to reinforce the field staff effort to actively participate in the surveillance. Informal feedback by phone and email should also be used regularly and especially during foodborne illness outbreaks. Additional feedback through supervisory visits should be shared to field staff and monitor implementation of follow-up actions.

11.1 Monitoring and Evaluation

Monitoring and evaluation is important component of any surveillance. Indicators for monitoring and evaluation of foodborne disease surveillance includes:

11.1.1 Administrative Indicators

a. Time between onset of an outbreak and reporting
b. Time between reporting and the beginning of the investigation
c. Availability of data (are they accessible when needed?)
d. System coverage, by population group and geographical area (units reporting/total units)
e. Quality and timeliness of reports
f. Percentage of outbreaks in which sufficient number of samples were obtained
g. Timeliness and regularity of the shipment of samples for laboratory analysis
h. Timeliness and regularity of laboratory tests
i. Timeliness and regularity of reporting of laboratory results
j. Ratio of notified to investigated outbreaks
k. Timeliness and regularity in the delivery of reports and recommendations to the next higher level of authority

11.1.2 Epidemiological Indicators

a. Trends in morbidity and mortality from FBDs
b. Incidence and prevalence of FBDs
c. Identification of the population groups that are most exposed and vulnerable
d. Identification and percentage distribution of sites and incriminated foods, causative agents, and the most frequent determining factors
e. Determination of the geographical and temporal distribution of FBDs
f. Identification of the actual and estimated number of individuals exposed, sick, hospitalised, and deceased

g. Percentage of risk establishments (having identified the most important critical points where outbreaks occurred)

11.1.3 Activity Indicators

a. Percentage of establishments that implemented the recommended control measures
b. Percentage of establishments inspected compared to establishments where outbreaks were reported in outbreak areas
c. Percentage of trained food handlers at establishments where outbreaks were reported
d. Percentage of outbreaks investigated compared to the total number of notified outbreaks

Targets for the above indicators must be set in-order to enable M&E officers to evaluate the above indicators.

10. Foodborne illness outbreak investigation

The systematic collection of data on foodborne events and outbreak is important, in order to understand which pathogens are causing most foodborne disease outbreaks and to identify high-risk foods for which interventions can be considered. Foodborne disease outbreaks are reported as event through NEWARS. The minimum information required in the initial reporting are shown in the annexure 5 (event reporting from NEWARS).

Once the foodborne event or potential outbreak has been detected through various surveillance system, the risk assessment team need to assess the credibility of the report and determine if it presents a potential risk to public health that requires further action. The assessment includes gathering information, assessing risk and assigning a level of risk to further spread of foodborne events such as outbreaks. It documents the available evidence related to the impact of the event on public health and provides the basis for action to manage and reduce the negative consequences of acute public health risks. All staff and experts who participate in rapid risk assessments should be trained in how to conduct a rapid risk assessment. The formulation and prioritization of questions to be answered during the rapid risk assessment of public health event are of critical importance. Detailed methods on investigating foodborne outbreak is mentioned in food safety investigation manual (2017).

Annex 1 Weekly reporting form

Disease ID	Disease/ Syndrome	Type	0-29 days		1-11 months		1-4 years		5-9 years		10-14 years		15-19 years		20-24 years		25-49 years		50-64 years		65 years +	
2	Acute bloody Diarrhea	Case																				
		Death																				
3	Acute Watery Diarrhea	Case																				
		Death																				
7	Acute Jaundice Syndrome	Case																				
		Death																				
8	Acute Respiratory Infection	Case																				
		Death																				
10	Dengue Fever	Case																				
		Death																				
11	Mumps	Case																				
		Death																				
13	Fever with Rash	Case																				
		Death																				
14	Food Poisoning	Case																				
		Death																				
21	Typhoid/Paratyphoid Fever	Case																				
		Death																				
23	Severe Acute Respiratory Infection	Case																				
		Death																				
24	Rickettsioses	Case																				
		Death																				

Annex 2 Case investigation form

Case investigation form

Lab ID: Health Center:			
Hospital visit: Date: Time:			
DEMOGRAPHY			
Name:		Age: Year Months	
Gender: ☐Male ☐Female		Occupation:	
Residential address: Place:_____Geog:_____District:_____			
Contact Number:			
CLINICAL INFORMATION			
Onset of symptoms: Date: at Time:			
Did you have any of the following signs and symptoms?			
Signs and symptoms	**Yes**	**No**	**Duration (days), if "Yes"**
Diarrhea			
Vomiting			
Nausea			
Dehydration			
Blood in stool			
Fever			
Abdominal cramps			
Others, specify:			
Were you admitted in the hospital: ☐No ☐Yes, specify (☐DTU ☐Ward)			
Duration of admission (in hours):			
Have you taken any medication/s:☐Yes ☐No		If yes, specify:_____	
Treatment administered: ☐Plan A ☐Plan B ☐Plan C ☐Others, specify:			
FOOD HISTORY			
Suspected foods or drinks consumed within the last 7 days: ☐Yes ☐No			
If yes, name of foods/drinks:			
Travel history: ☐Yes ☐No			
If yes, name of place: Date:			
LABORATORY INFORMATION			
Specimen collected: ☐Yes ☐No Date of collection:			
Type of specimen: ☐Stool ☐Vomitus ☐Others, specify:			
Color: ☐Brown ☐Reddish ☐Clay ☐Blackish ☐Others, specify:			
Consistency: ☐Hard ☐Soft ☐Loose ☐Watery		Mucus: ☐Present ☐Absent	
RBCs (enumerate): _____/HPF		WBCs (enumerate):_____/HPF	
Ova/cyst, if any:			
Culture and antimicrobial susceptibility testing result (if performed):			
Date of shipment: Name of the reporting official:			

Annex 4 Microbiology limits

Test (Indicator Organism)	Limits
Coliform count/Total plate count	$<10^5$ CFU/g
E. coli count	$<10^2$ CFU/g
Enterobacteriaceae	$<10^2$ CFU/g
Listeria (other than *Listeria monocytogenes*)	$<10^2$ CFU/g
Clostridium spp	<10 CFU/g
Yeast/Mold	$<10^2$ CFU/g
Pathogenic organism	
Bacillus cereus	$<10^2$ CFU/g
Clostridium perfrigenes	Not detected in 25g of Food
Coagulase positive *Staphylococcus aureus*	$<10^2$ CFU/g
Listeria monocytogenes	Not detected in 25g of Food
Vibrio spp	Not detected in 25g of Food
Salmonella spp	Not detected in 25g of Food
Shigella spp	Not detected in 25g of Food
Campylobacter	Not detected in 25g of Food
Aeromonas	200 CFU/100g
Plesiomonas	200 CFU/100g
Pathogenic E coli	Not detected in 25g of Food

Annex 5 Event reporting form

EVENT REPORTING FORM

Reporting site: ----------

Date of Reporting: ----------

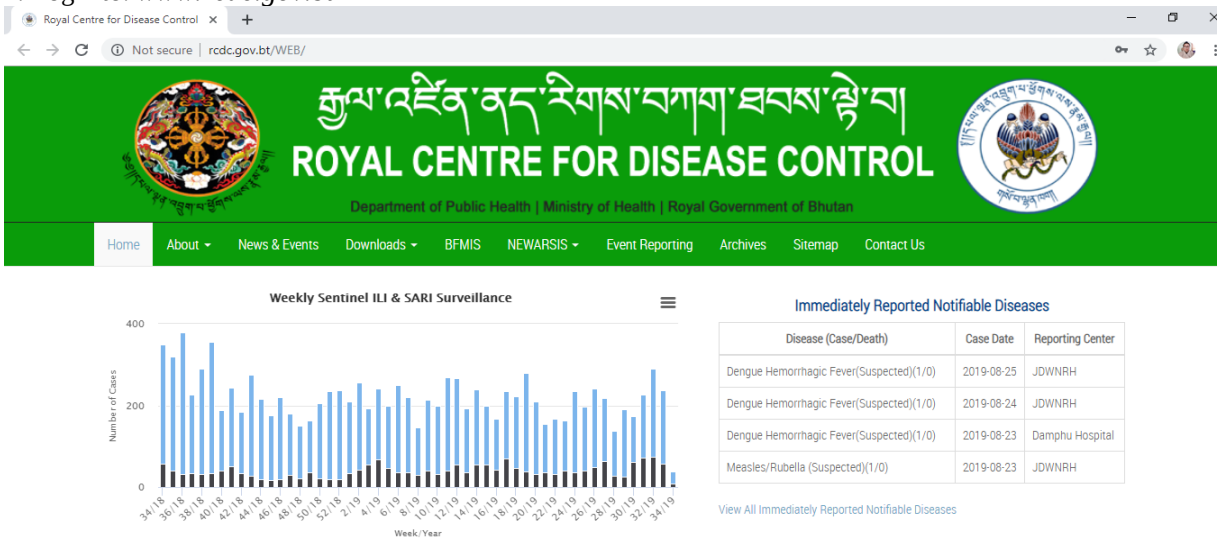
What do you want to report?(Name of event/suspected outbreak)
When did this happen?(Date/Time of Event):
When did this happen?(location of event):
Number of people affected:
Number of people died:
Mention common signs and symptoms(Clinical Information):
Do you have any other information?

Reported by ----------

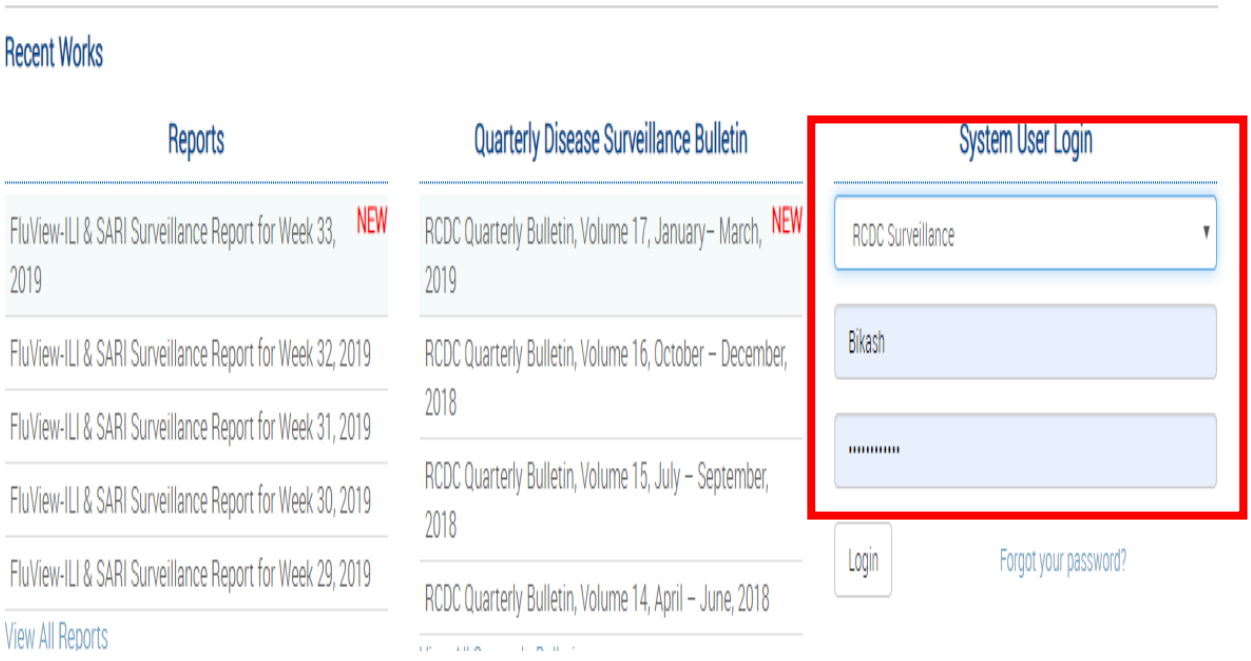
Mobile No ----------Dated----------

Annex 6 FoodSIMS sample submission (Operational guideline)

1. Log into: *www.rcdc.gov.bt*

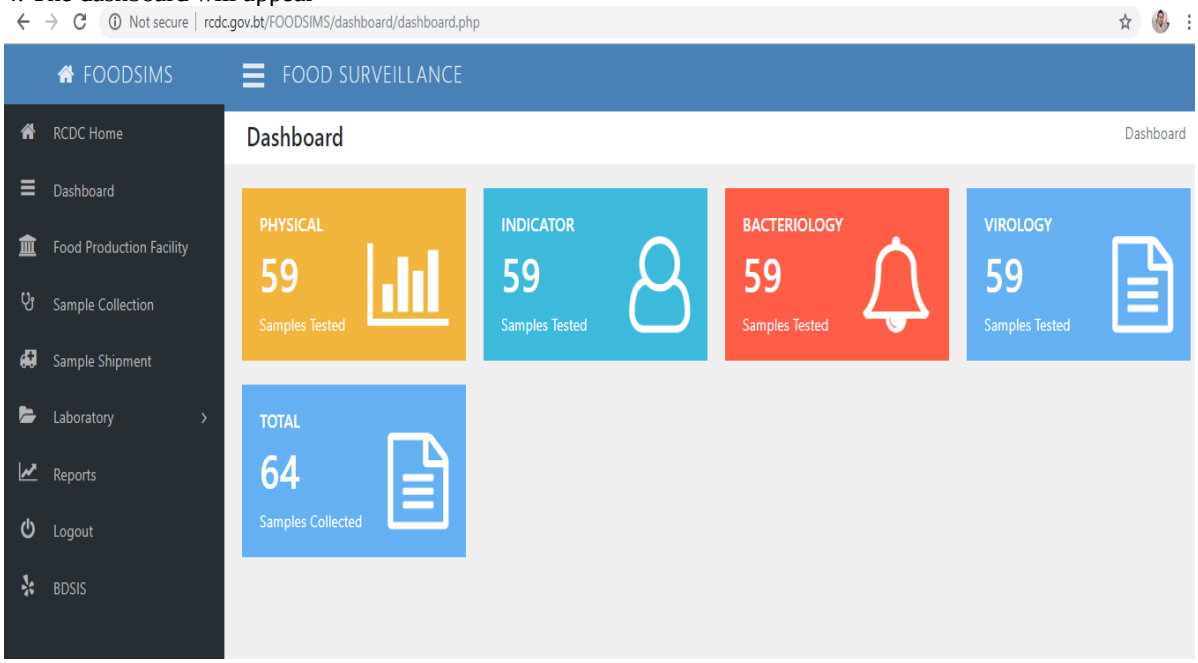


2. System Login with your respective given user name and password



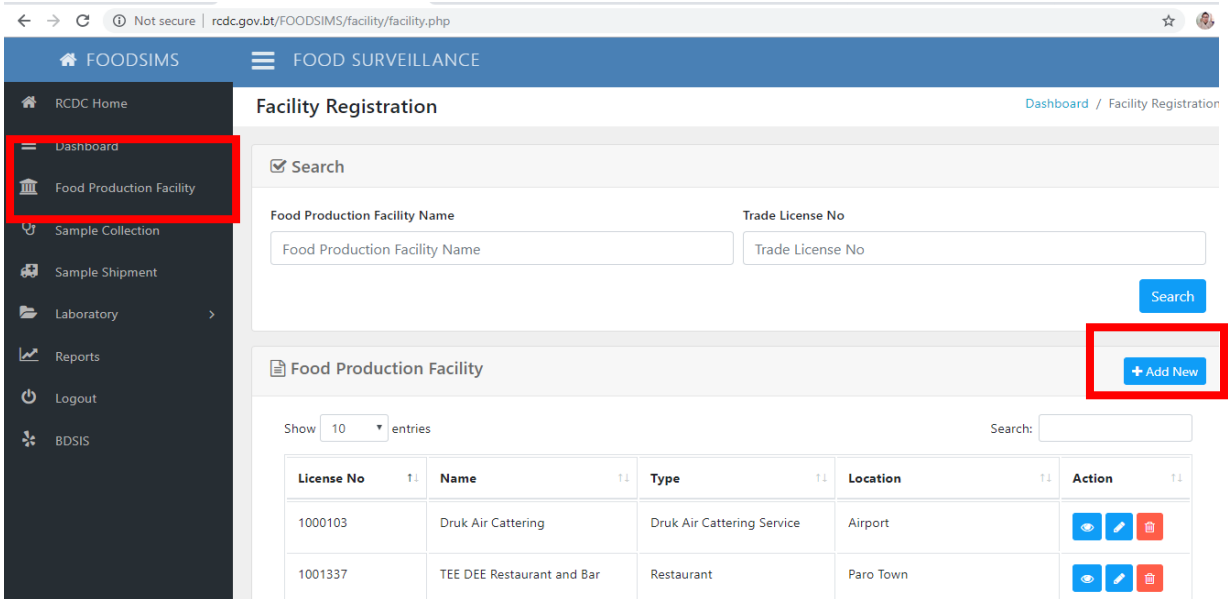
3. Click on Food -borne Disease Surveillance information Management System (FoodSIMS)

4. The dashboard will appear



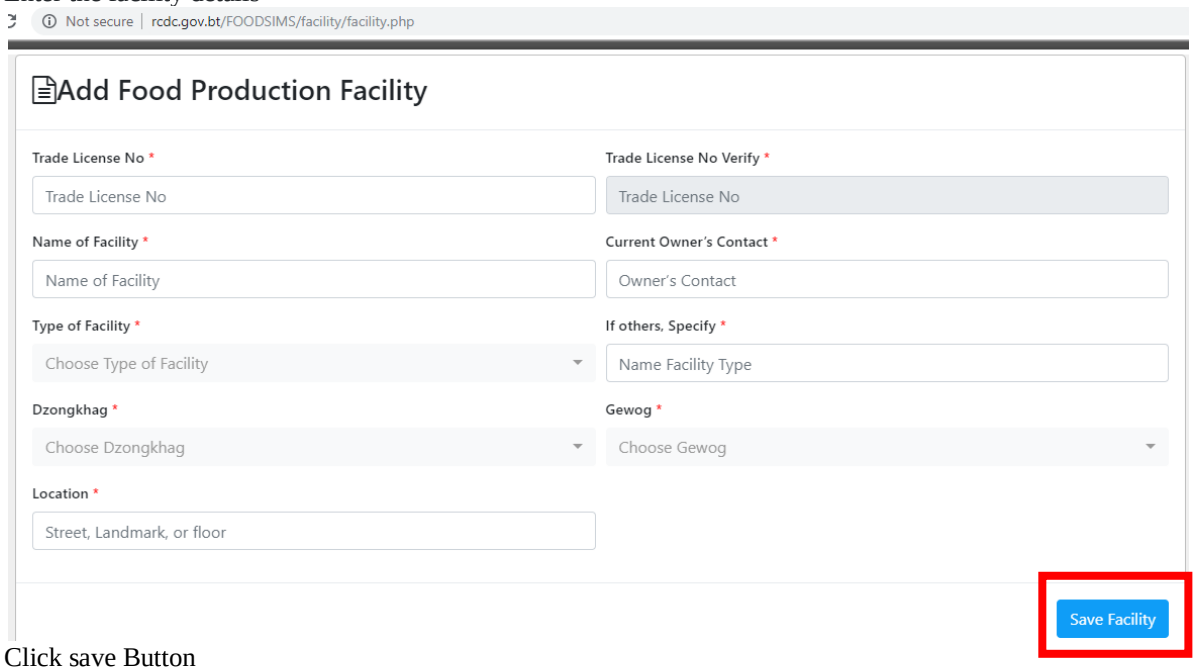
Data Entry

5. Select Food Production Facility



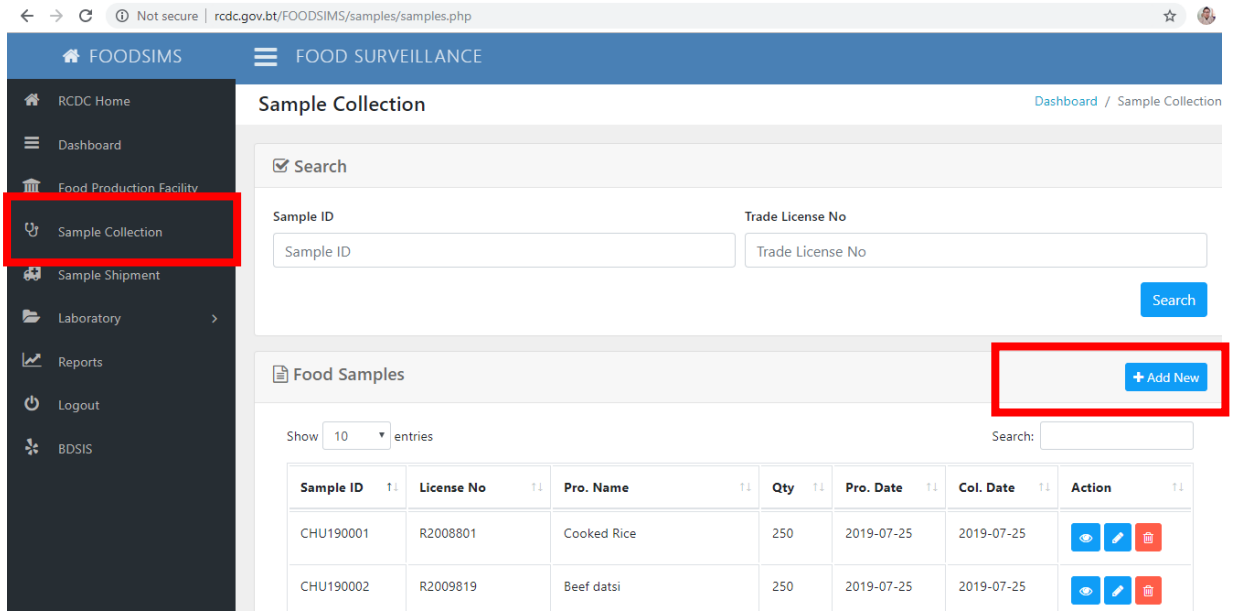
Click Add New button to add Food Production Facility

Enter the facility details



Click save Button

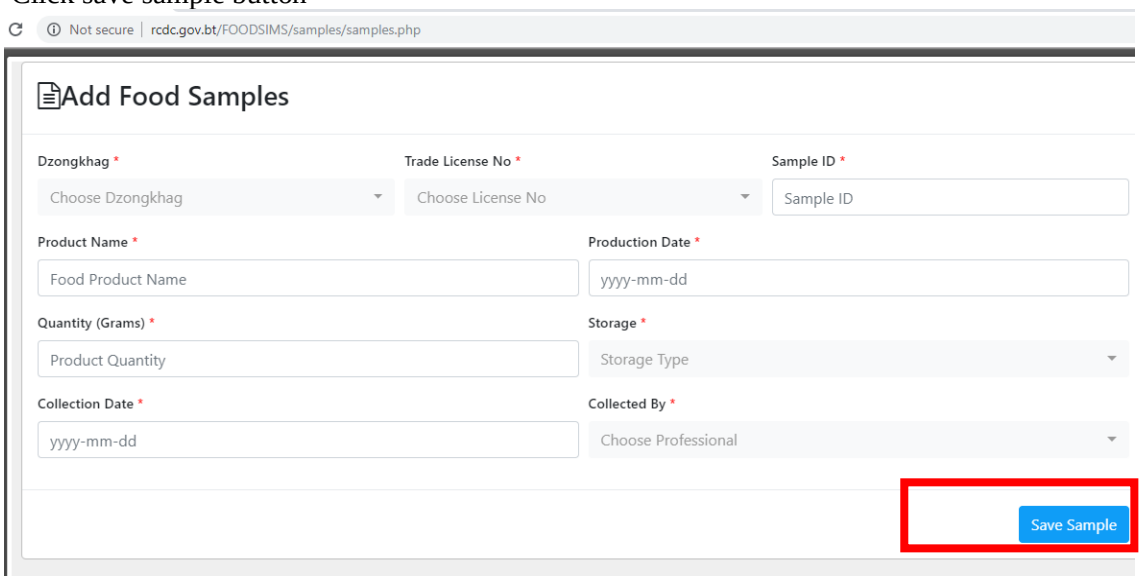
6. Sample Collection



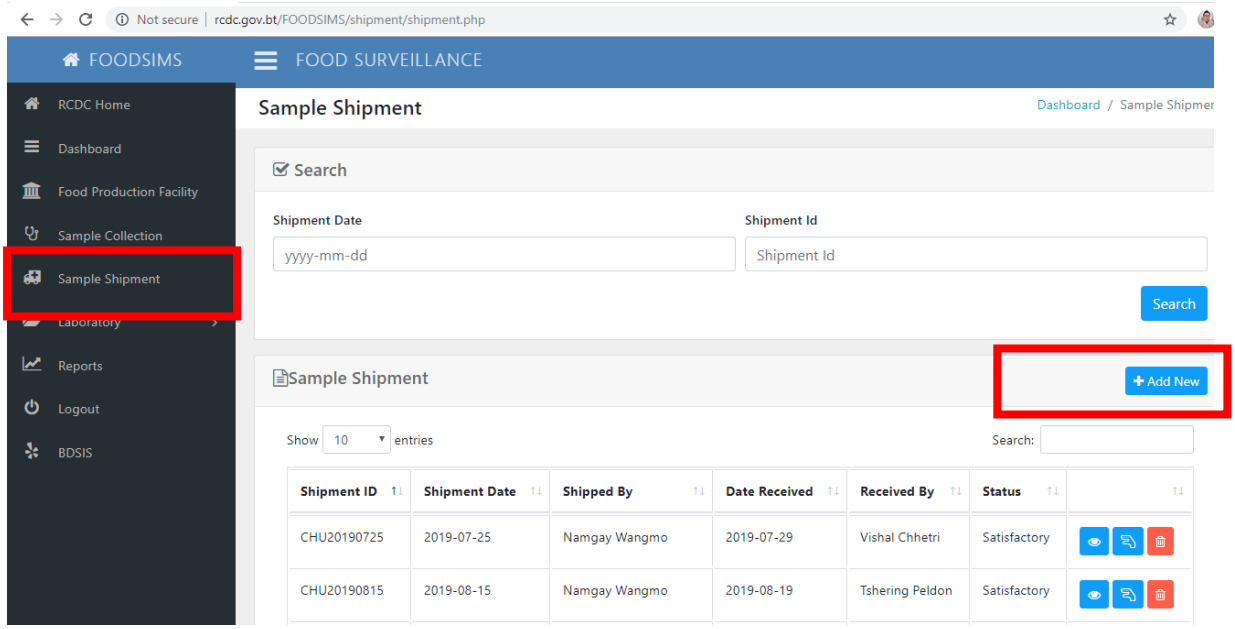
Click add New to add sample details

Add sample details

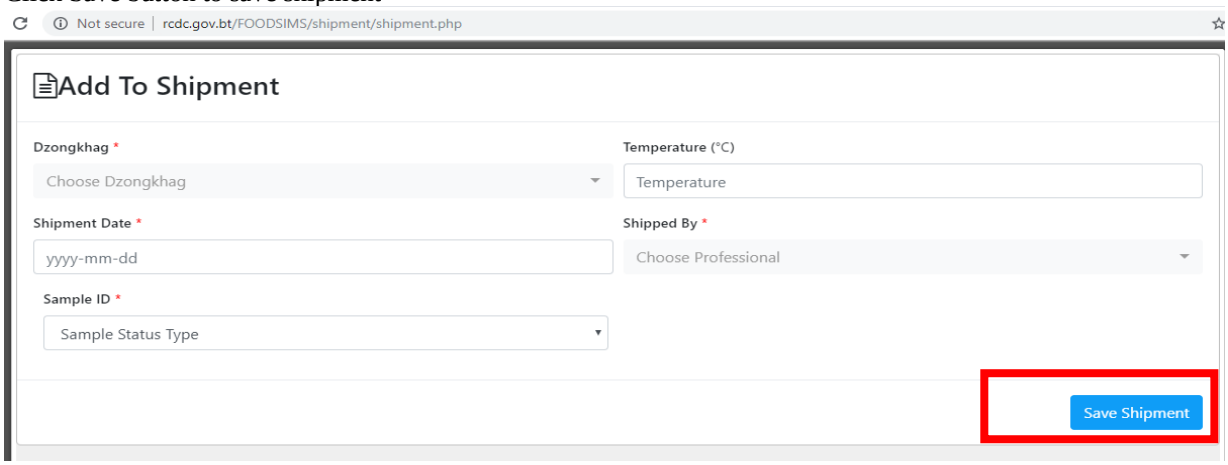
Click save sample button



7. Sample Shipment

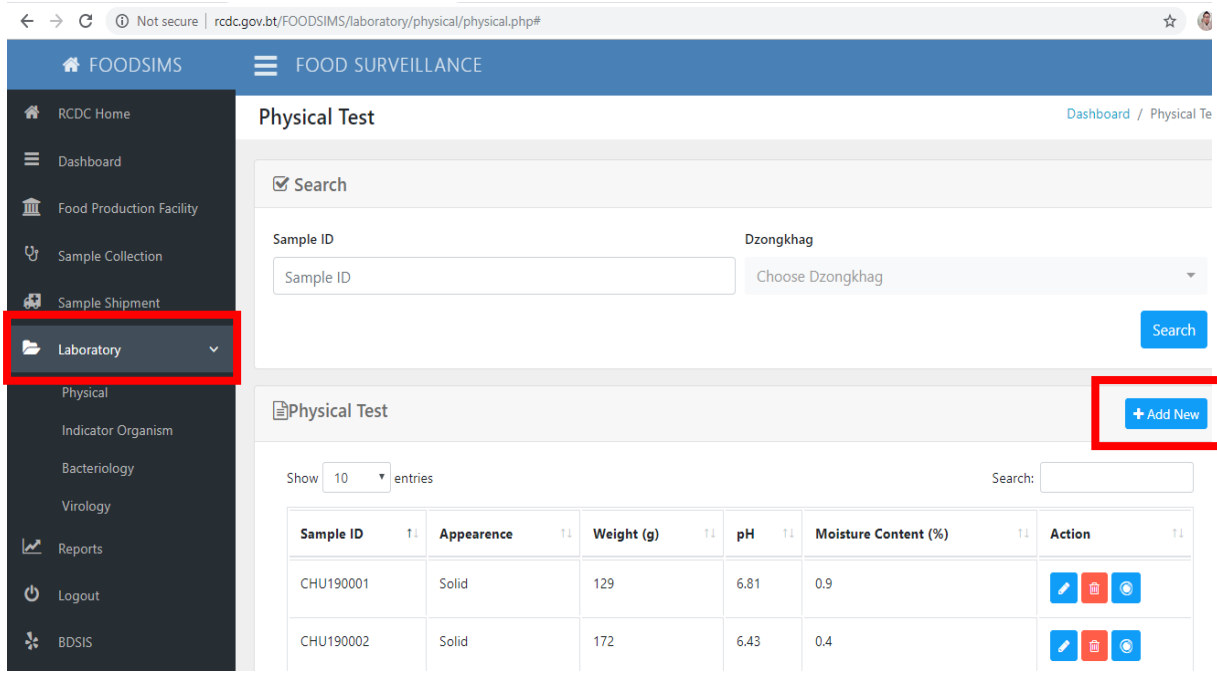


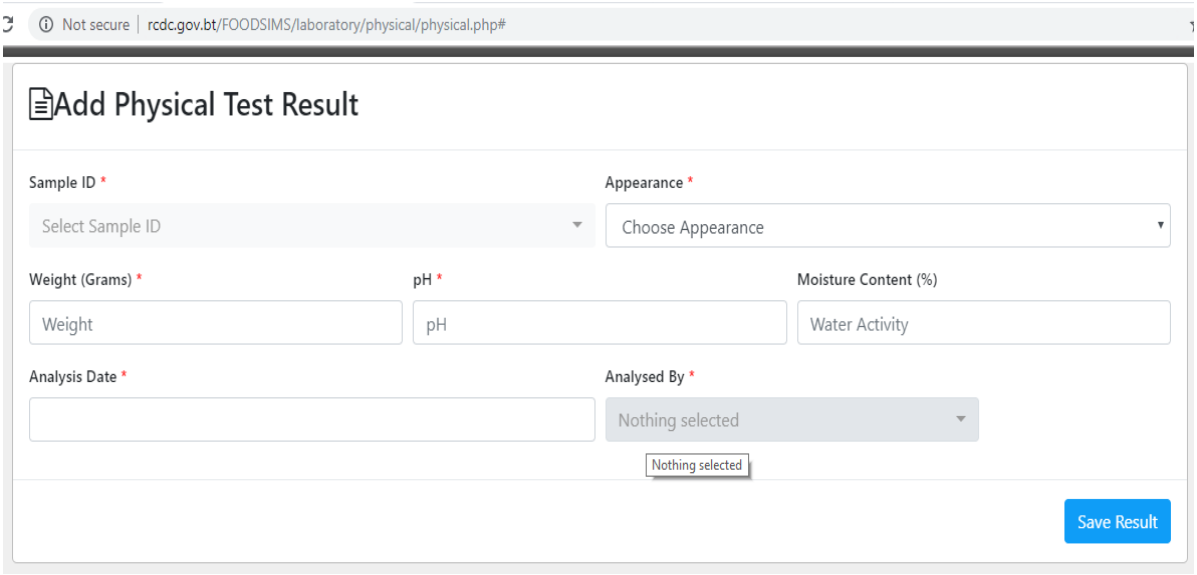
Click Add New to add new sample details
Click Save button to save shipment

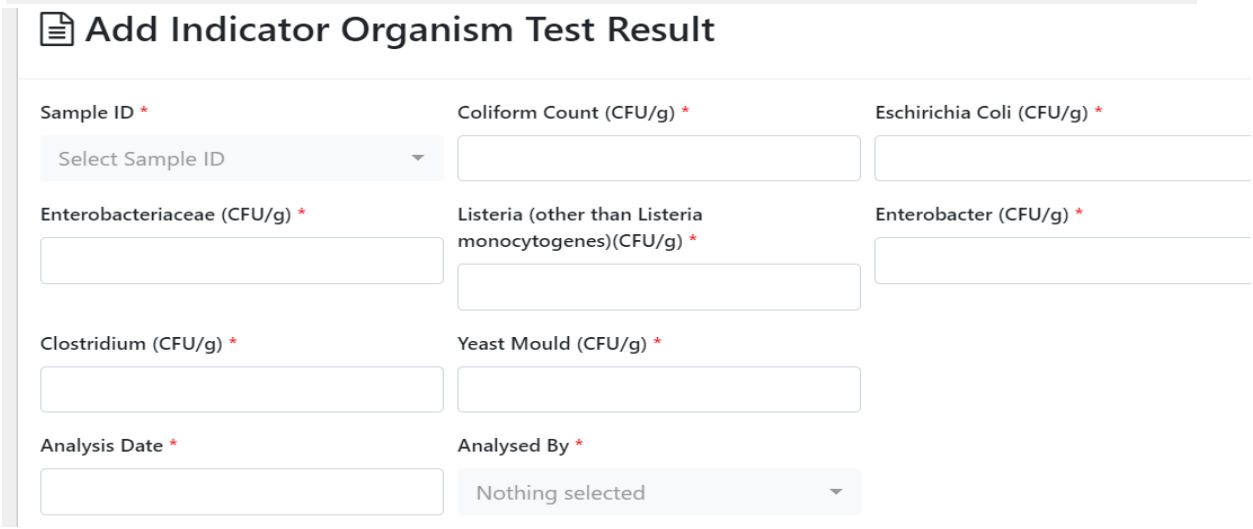


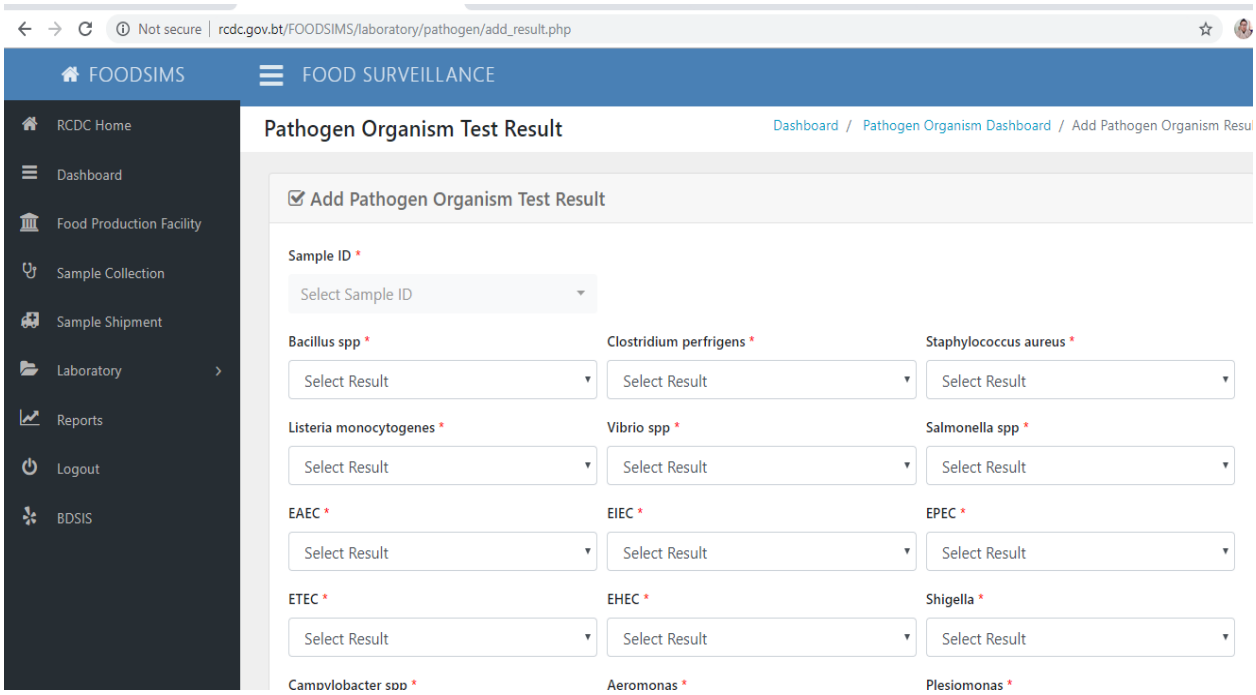
Sample Receive: The FNL, RCDC Staff upon receiving the samples will verify each samples.

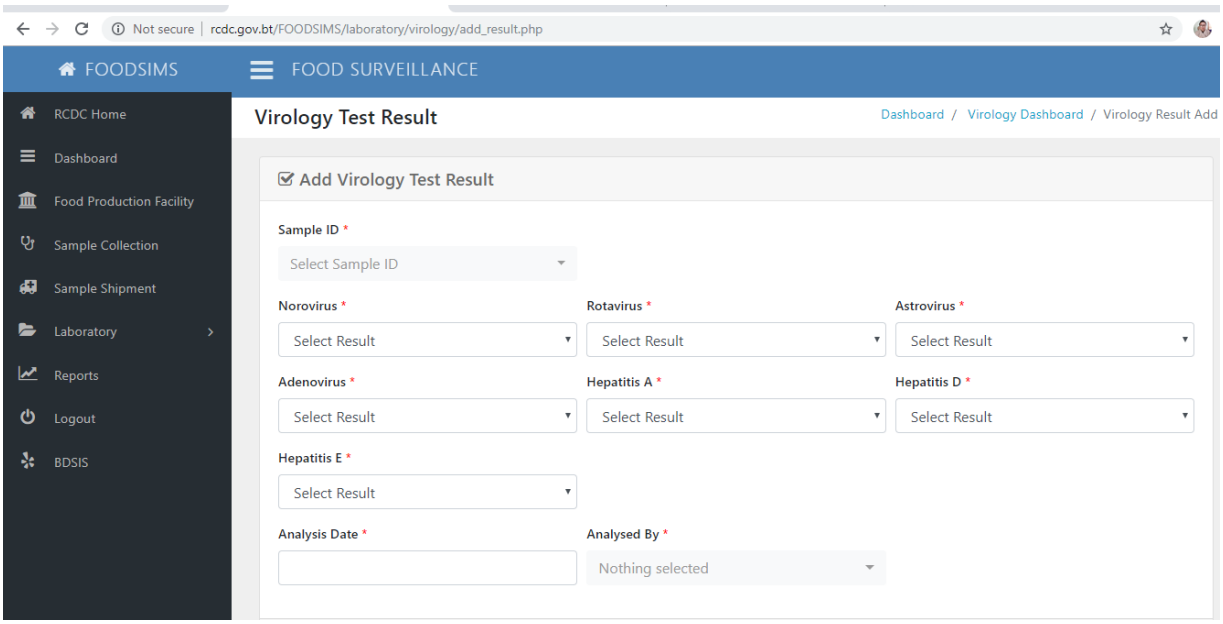
8. Laboratory Results
Click Laboratory Link to enter Physical Test/Indicator/Pathogenic/Virology test results


Not secure | rcdc.gov.bt/FOODSIMS/laboratory/physical/physical.php#
FOODSIMS
FOOD SURVEILLANCE
RCDC Home
Dashboard
Food Production Facility
Sample Collection
Sample Shipment
Laboratory
Physical
Indicator Organism
Bacteriology
Virology
Reports
Logout
BDSIS
Physical Test
Dashboard / Physical Te
Search
Sample ID
Sample ID
Dzongkhag
Choose Dzongkhag
Search
Physical Test
+ Add New
Show 10 entries
Search:
Sample ID
Appearence
Weight (g)
pH
Moisture Content (%)
Action
CHU190001
Solid
129
6.81
0.9
CHU190002
Solid
172
6.43
0.4


Not secure | rcdc.gov.bt/FOODSIMS/laboratory/physical/physical.php#
Add Physical Test Result
Sample ID *
Select Sample ID
Appearance *
Choose Appearance
Weight (Grams) *
Weight
pH *
pH
Moisture Content (%)
Water Activity
Analysis Date *
Analysed By *
Nothing selected
Nothing selected
Save Result


Add Indicator Organism Test Result
Sample ID *
Select Sample ID
Coliform Count (CFU/g) *
Eschirichia Coli (CFU/g) *
Enterobacteriaceae (CFU/g) *
Listeria (other than Listeria monocytogenes)(CFU/g) *
Enterobacter (CFU/g) *
Clostridium (CFU/g) *
Yeast Mould (CFU/g) *
Analysis Date *
Analysed By *
Nothing selected





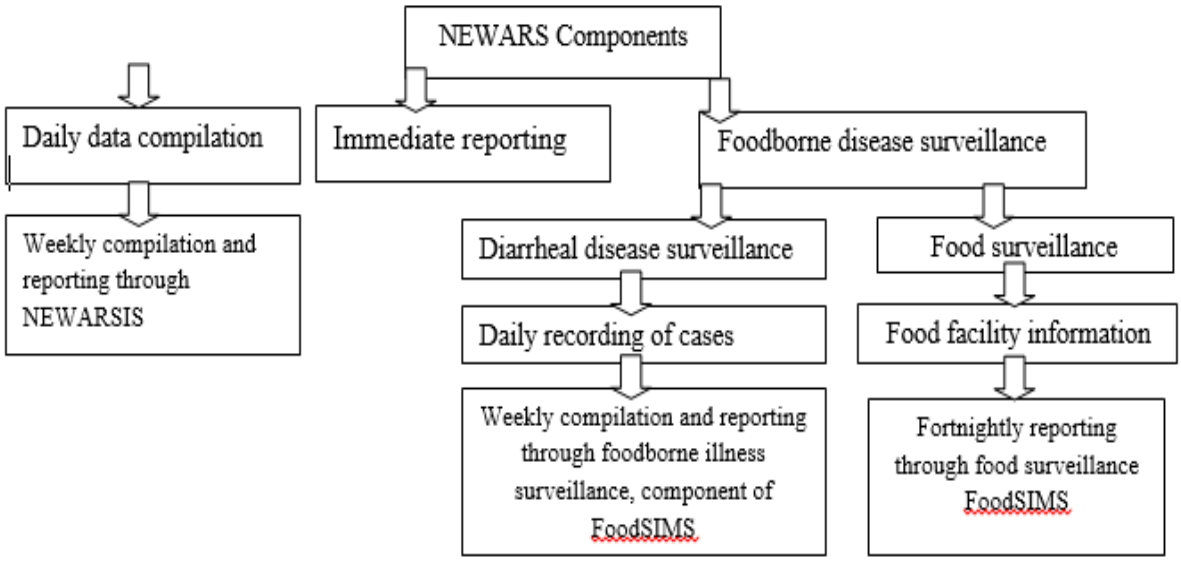
Click save button in each physical/indicator/pathogenic/virology report form to save

Verify of each results

Sample ID	Result Date	Analysed By	Verified On	Verified By	Action
CHU190001	2019-07-31	Vishal Chhetri	2019-08-01	Tshering Peldon	
CHU190002	2019-07-31	Vishal Chhetri	2019-08-01	Tshering Peldon	
CHU190003	2019-07-31	Vishal Chhetri	2019-08-01	Tshering Peldon	
CHU190004	2019-07-31	Vishal Chhetri	2019-08-01	Tshering Peldon	
CHU190005	2019-07-31	Vishal Chhetri	2019-08-01	Tshering Peldon	

8. Click on Report button to view or select to print report

Annex 7 NEWARS reporting format



Annex 8 Sample rejection form

FAECAL SAMPLE REJECTION NOTIFICATION FORM

Section 1 Demographics

1. Patient Name (Full): _____
2. District: _____
3. Address: _____
4. Sex: (1) Male (2) Female
5. Date: ___/____/_____
6. Hospital: _____ Ward/Unit: _____

Section 2: Laboratory Procedure (please tick)

1. Test Order:

Culture _____

2. Specimen:

Blood _____
Faeces _____
Urine _____
Sputum _____
Fluid _____
CSF (Cerebrospinal fluid) _____
Eye _____
Ear _____
Throat _____
Pus _____
Wound _____
Tips _____

3. Date sample taken: ___/____/_____
4. Date received sample: ___/___/_____

Sample accepted Sample rejected

Rejection Criteria: Insufficient sample sent
Sample Spill
Sample too old to be processed (for culture)
Non sterile container (for cultures)
Sample not labeled
Sample/form improperly labeled

Corrective actions: Send new sample Collect new sample