Food Safety Investigation Manual

Bhutan Agriculture and Food Regulatory Authority (BAFRA)
Ministry of Agriculture and Forests

Foreword

Experiences over the past years have shown that with increased volume of food trade, comes an increased risk of the spread of foodborne pathogens and contaminants within the country and beyond our National borders. This necessitates the need for Food Safety Authorities to efficiently and effectively identify and respond to food safety incidents and emergencies.

The Bhutan Agriculture & Food Regulatory Authority (BAFRA), Ministry of Agriculture & Forests through its ***Food Act of Bhutan 2005*** and its ***Rules & Regulations*** is mandated to ensure Food Safety in the Country.

In implementing a risk based Inspection System, a Food Safety Investigation is the first step in responding to food safety incidents & emergencies. Food Safety Investigation is a tool to determine the source of a food safety problem throughout the Food Chain.

The purpose of this Document is to provide direction & operational guidance for BAFRA on Food Safety Investigation and may apply to food safety events that are not necessarily emergencies but require investigation that are beyond the scope of one BAFRA Dzongkhag Office. This Document may also be useful to other Organizations that are engaged in activities in the area of food safety.

This Manual should be read in conjunction with the Food Recall Guidance Manual of BAFRA. In addition, other relevant documents and guidance materials developed by FAO & WHO such as FAO/WHO Framework for Developing National Food Safety Emergency Response Plans and FAO/WHO Guide for Application of Risk Analysis Principles and Procedures during Food Safety Emergencies are valuable resources for reference.

This Manual has been developed by BAFRA, Ministry of Agriculture & Forests, Royal Government of Bhutan with technical support from the Food & Agriculture Organization (FAO) of the United Nations.

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Introduction

In implementing a risk based inspection system that focuses resources to the highest risks in food, a food safety investigation is the first step in responding to non-compliant food or food businesses.

Purpose

The purpose of this document is to provide direction and operational guidance for Bhutan Agriculture and Food Regulatory Authority on food safety investigations and may apply to food safety events that are not necessarily emergencies but require investigation that are beyond the scope of a single Dzongkhag office.

Definitions

Alert

Food Safety Alert is a warning to consumers advising them not to consume a recalled product that poses a health risk.

Complaints

Notification about a potential non-compliant food from consumers, other food businesses, trade associations, etc.

Compliance

Compliance is a state where food businesses meet established guidelines, specifications, legislation or standards.

Enforcement

Enforcement is the range of activities undertaken by BAFRA inspectors to compel a food business to comply with legislative requirements

Food Safety

Assurance that food will not cause harm to the consumer, when prepared and/or eaten according to its intended use.

Food Safety Assessment[1]

A scientifically based process which determines the likelihood that a specific adverse effect will occur in an individual or a population following exposure to food borne hazard. The following steps are used in the development of Health Risk Assessment: 1) hazard identification; 2) hazard characterization; 3) exposure assessment; and 4) risk characterization.

[1] *A situational analysis to support risk based decision-making, it is not the Codex Risk Analysis.*

Investigations

Investigations are procedures intended to seekinformation and include:

Food safety investigations

Determine the source of a food safety problem, following an inspection / surveillance, consumer or food industry complaint, test result or other information indicating a food safety problem.

Criminal investigations[2]

Gather evidence of non-compliance in preparation for prosecution before the courts; specific requirements forobtaining evidence.

Scoping

Determining the cause of food contamination (e.g., poor sanitation, failure of process, contamination of raw material) andfood productsthat may be affected and that may pose health risk.

Traceback and trace forward

Trace back means working back through the supply chain to determine the source of a non-compliant product.

*Trace forward*means working forward through the client lists in order to identify recipients of non-compliant product to advise them of the risk.

Trigger

Initial information that prompts a food safety investigation, for example, a laboratory analysis, a consumer or trade complaint, a referral from another government department, an inspection finding, a report from a foreign government, a manufacturer-initiated product action or withdrawal, epidemiological evidence, etc.

Roles and Responsibilities

BAFRA management

The management, (Head of BAFRA, Chief Regulatory and Quarantine Officer, Chief of Analytical and Certification Division), are responsible for providing direction for food safety investigations, logistic arrangement, resource allocation and approving risk management options. The management may advise the formation of a technical committee/incident command team with relevant stakeholders depending on the nature of the food safety problem and the investigation required.

[2]*Criminal investigations are not included in this document.*

Focal officer for food safety

The focal officer for food safety is responsible for coordinating food safety investigations by providing guidance and direction to field offices, sharing information across districts through the Officer In-Charges (OICs) and advising senior management with respect to risk management options.

Dzongkhag Officers In-Charges

Officer in-charge (OIC) concerned shall take lead role in carrying out investigation and act as the link between BAFRA management and the inspectors undertaking food safety investigation. He/she shall provide direction to inspectors undertaking food safety investigation, share information to relevant stakeholders in the Dzongkhag and to the food safety officer. He/she shall also act as the media spokesperson and provide required information to the media regarding the food safety event in consultation with the BAFRA management.

BAFRA Inspector

Inspectors are responsible for investigating consumer complaints, and other food safety investigations. They are responsible for gathering information from complainants and inspecting food businesses. They will work with district OICs and other inspectors on food safety investigations.

Food Industry/Food Establishments

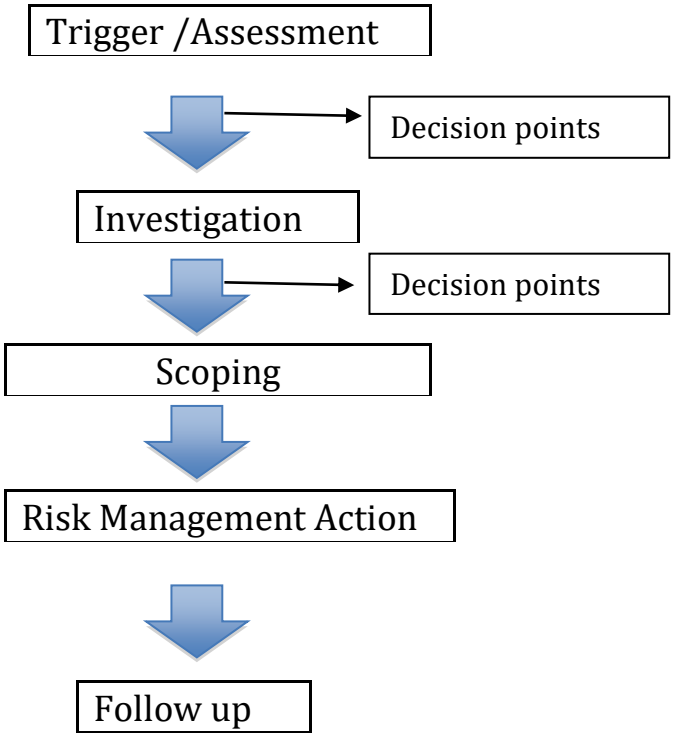
Food businesses (e.g., manufacturers, importers, vendors, retailers) are responsible, in cooperation with inspectors, to investigate food safety issues, identify the problem, recall, remove affected/implicated product from the market, and prevent re-occurrence.

Key principles

The key principles for food safety Investigation include;

- Timely –investigationsshould be carried out immediately.
- Thorough–to identify the cause of the problem and affected product, using a systematic approach for tracing products within the food chain.
- Documented – information should be accurate, detailed and documented
- Collaboration with relevant stakeholders
- Consistent –follow appropriate policies, guidelines and standard

FoodSafety Investigation – Process flow



Trigger/Assessment

Food safety investigations can result from:

- Consumer complaints
- Complaints from other food businesses, often called Trade complaints
- Information from doctors or other health practitioners of food borne illness outbreaks or epidemiological information
- Information from other government departments, either nationally or internationally of potential food safety problems
- Unsatisfactory lab results/laboratory report indicating non-confirmatory with standards/requirements
- Unsatisfactory inspections/Inspection reports indicating non-compliance
- Rejections on import
- Notification by a food business of a problem (e.g., company initiated recall)

On receiving information about a potential food safety issue or non-compliant food, record as much information as possible (See Annex 1: Forms), particularly contact information for further followup.

Information should include:

1. Date of complaint

2. Complainant name
3. Contact information (address, phone/SMS, email)
4. Type of complaint (e.g., quality, adulteration, illness)
5. Description of complaint (e.g., symptoms)
6. If illness, where it occurred (e.g., home, restaurant)
7. Implicated/suspected food
8. Suspected Food Business details

Once documented, the inspector should consultOIC to assessif other similar complaints have been received (e.g., trend analysis) and the potential scope of the issue (e.g., number of illnesses, or number of food businesses).

The OIC will assign aninspector to follow up with the complainant, and to gather further information as possible about the implicated food. Note: if the inspector receives the complaint they may choose to gather the information at that time.

In the case that the complaint is a multi-person food borne illnesses, advise the food safety focal officer immediately. Consider the need for establishing an inter-ministerial committee as per the Standard Operating Procedures for Food Safety Outbreaks, and in accordance with the principles established in the Bhutan One Health Strategy document[3].

Priorities

Complaints related to a potential serious injury, illness, hospitalization, or death requires immediate action,

Other complaints should be assessed to determine appropriate follow up (e.g., timeframe, depth), and may be undertaken during the next scheduled food business inspection.

Follow up/interviews

In following up on complaints, the inspector may need to interview the complainant and/or others knowledgeable about the incident (e.g., other family members, health professionals, law enforcement officials.). Ask questions to assist in identifying the problem, as the complainant may not volunteer theinformation(See Annexure 2).

Document all information provided on complaint form. Information should include:

1. Accurate and complete description of the product:
    a. Brandname, product name, flavour or variety, how packaged,

[3]*Consideration should also be given to the principals and approaches established in the FAO/WHO Framework for developing national food safety emergency response plans.*

storage conditions required (i.e., refrigerated or shelf stable),imported or domestic, other information
   b. Name and address of vendor, and date purchased
   c. Condition of the product when purchased or consumed, (tampering complaints, mould in foods, possible mishandling, product abuse in the home, etc.); and storage of the products (if filth is the subject of the complaint)
   d. Sample availability (other opened or unopened packages available) (See Annexure 2)

2. Events prior to the illness/injury complaint:
   a. 72-hour food history (for food related illness); as complainants often associate illness with the most recent food consumed
   b. Persons interviewed, dates interviewed, relation to the complainant
   c. Medical history of the complainant, particularly regarding allergies

Note: for illness investigations, the reference table (Annexure 6) developed by the United States Food and Drug Administration provides information on diseases, agents, signs or symptoms, and possible foods involved.

Decision point

Once sufficient information is available, an initial assessment can be made to either:

1. Close the file with no further investigation, if the information cannot be substantiated or is invalid, or if the problem was the result of consumer handling.
2. Undertake further investigation, if the information is validated.

Investigation

During this phase, the inspector will gather as much information as possible through interviews, inspections, and assessment of food business practices. Following the food, including ingredients for further processing, will ensure complete and accurate investigation of the issue and may require collaboration from other districts or other government organisations.

The key is to follow the food through the food chain, which can mean trace back or trace forward or both.

For consumer complaints, a trace back means following the food from:

Consumer→vendor → distribution → responsible food business→Supplier (in collaboration with relevant agencies)

For investigations following sample or inspection results, a trace forward means following the food from:

Supplier →Food business → distribution → vendor → consumer

Vendor

The inspector should meet with the vendor of the suspect product to gather and document the following information:

1. Vendor details (name, address), contact numbers
2. Product details including date purchased, from whom
3. Product transportation to the vendor, storage conditions, handling
4. Date of sale and if possible, to whom
5. Other complaints, if so, action taken
6. Sample availability (Numbers of packages available); samples taken (dates; quantity, analysis requested)
    a. Results when available
7. Link to inspection report

The inspector should inspect the vendor's premise and document the conditions. Note all of the non-compliances and identify areas that may have caused problems identified by the complainant.

Decision point

Once sufficient information is available, an assessment can be made to either:

1. Determine if the vendor conditions caused the food safety issue, if so; follow up with the vendor to ensure product is removed from sale, recall product if needed and identify appropriate corrective action.
2. Undertake further investigation at the distribution, manufacturer or retailer, if the retail investigation demonstrates the problems occurred elsewhere.

Food business

The inspector should meet with the food business responsible for the suspect product to gather the following information:

1. Food business details (name, address, registration) contact numbers
2. Product details (date of manufacture, storage requirements, processing controls, batch/lot number)
3. Product history (other complaints, if so, action taken, issues)
4. Product transportation / storage / handling
5. Distribution and sale history (to whom, when, what quantities)
6. Sample availability (Numbers of packages available); samples taken

(dates; quantity, analysis requested)
    a. Results when available
7. Link to inspection report
    a. Corrective actions required

Once notified of a food safety investigation, the food business should initiate a full assessment of their processes and procedures (e.g., sanitation, sources of ingredients, process controls, manufacturing, storage and transport). The inspector should review the results of the assessment. The inspector should also inspect the food business premises, and document the conditionsas set out in the Food Safety Licensing of Food Businesses: Licensing Process. Note non-compliance; identify areas that may have caused problems identified by the complainant. Review distribution records and examine warehouse stock.

During the inspection, verify all potential contamination sources (See Annex 4) to identify the cause of the food safety issue.

Once non-compliance is identified, corrective measures should be implemented, and the inspector should verify that the corrective measures are in place and functioning.

Decision point

Once sufficient information is available, an assessment can be made to either:

1. Determine the food business conditions caused the food safety issue, if so, follow up with the food business to scope the problem and identify the root cause.
2. Undertake a health risks assessment (See Annexure 4) to determine appropriate risk management actions (e.g., Product recall).
3. Undertake further investigations (trace forward) to ensure that all affected products that may have been distributed or used by other food businesses have been appropriately addressed.

Scoping

Scoping identifies all food and food products including foods that come from all scales of food establishments and vendors, which may pose a health risk.

Assessment to determine the causes of food contamination and food safety should be conducted taking into consideration the following points:

1. What is the food or food product that is affected? Where is the affected food or food product found? Which food establishment or vendor? What time frame and batch?

- How and from where was the non-compliant food/food product sourced or produced?
- Were trained food handlers involved during the processing of the food/food product?
- What is the probable cause of food contamination or food safety issue? Food handlers? Raw materials? Transportation/storage? Preparation/manufacturing/ practice methods?
- Was the same non-compliant product sold or distributed by another food establishment and/or vendor?
- Was any other product produced, sold or distributed using the same raw material, equipment, manufacturing procedures or other practices as those that resulted in the affected products?
- How many had consumed the non-compliant/implicated product? Number of individuals displaying acute symptoms of illness including severity from consumption of the non-compliant product? Potential long term health hazards from the non-compliant product?

2. Could any other products manufactured or imported have been affected? If so, what quantity of product? Under what timeframe? Which batch/lot?

- Was the same non-compliant product sold or distributed under other codes, other brands, or other sizes, other containers?
- Was any other product produced, sold or distributed using the same raw material, equipment, manufacturing procedures or other practices as those that resulted in the affected products?
- Is there any other product the food business manufactured or imported that may have been adversely affected? Storage? Transportation?
- How much has the non-compliant product been distributed/sold? Where has the non-compliant product reached?

3. Could other manufacturers/importers have been affected?

- Was the source of the problem raw material or ingredients? If so, how many other manufactures sourced that raw material or ingredients
- Was the source of the problem a result of equipment malfunctions, ineffective processes or procedures? If these are industry standards, there may be other food businesses with similar problems.
- Was the affected product shipped to other facilities for further processing? Did those manufacturing processes render the final product safe?

- Was the product imported by one or more firms? Whether for direct sale or for further processing?

Scoping Processes

- Fully identify the main product(s) that triggered the food safety investigation. (e.g., Vegetables, raw meat, spices, food products).
- Fully identify the hazard. (e.g., chemical, biological, physical).
- List known or estimated risk level (e.g. Health Risk 2, Health Risk 1, and Health Risk 3).
- Identify the likely cause or route of contamination (e.g., Contamination of raw material, Cross contamination during slaughter, poor sanitation practices, storage, and transportation).
- Assess the manufacturing processes, and timeframe (i.e., when the problem began and when it was corrected).
- Identify individuals displaying acute symptoms of illness from consumption of the non-compliant product?
- Determine the product infiltration in the community/market

Examples:

- An oven malfunctioned at 6am, which was identified at 10am and fixed by 11am: Impacts food cooked in that oven from 6 – 11 am.
- Presence of metal pieces in baked products from contaminated flour will impact all food businesses using that flour supplier.
- Inadequate sanitation of food contact surfaces (e.g., cutting tables, meat slicers) may affect all food production over many weeks, right back to the earliest known instance of inadequate sanitation.

By the end of this step there will be a list of suspected products including location of those products.

Risk management actions

The result of food safety investigations is a risk management action. These actions will be based on the facts of the investigation, and be consistent with the Food Act of Bhutan2005 and the Food Rules and Regulations of Bhutan 2007.

District level actions

Where the issue is restricted within one district, the risk management action maybe taken at the district level. This is particularly the case, where the food had

limited distribution and the food businesshas resolved the issue. In such instances, the OIC may implement risk management actions such as:

Immediate

- Recall[4], detention/destruction of products (within the district)
- Enhance inspection frequency

Longterm

- Increased education and training to valid license holders/food handlers

National Level actions

National level decisions reduce inconsistency and contribute to public confidence in the case of illnesses and more wide spread food safety problems. They also establish precedents that can be applied in the future. Risk management decisions warrants action at the national level when implicated food has;

- Wide spread distribution affecting several districts and more than one food business
- Poor compliance history for food handlers and food business
- Epidemiologically linked to an illness
- History of past outbreaks (linked to food /causative agent)
- Is an imported product

Multiple districts/national distribution

Where the food is in national (i.e., multiple districts) distribution, or if the food safety issue affects multiple food businesses or multiple foods or food ingredients, the risk management decision shall be taken at head officeinvolving a technical committee (if necessary) from relevant stakeholders. Risk management decisions associated with food illness outbreaksare also generally taken at the national level.

If the implicated food business cooperates with BAFRA in resolving the issues, BAFRA may implement risk management actions such as:

Immediate:

- Recall[3], detention of products across multiple districts
- Enhance inspection and/or sampling frequency
- Provide immediate public notifications (e.g., a food safety hazard alert)
- Alert INFOSAN focal point (BAFRA and Health)
- Notify international trading partners (both import and export)

[4] *See Bhutan Recall Manual*

- Co-ordinate multi-sector collaboration with relevant stakeholders
- Identify investigation team comprising of members from relevant agencies with required expertise

Long term:

- Increase education and training to food handlers

Where the food business has a history of problems, the district and head office should discuss the appropriate risk management actions to prevent the reoccurring problems. Where a food business has demonstrated by repeated food safety problems that it is unable or unwilling to comply with food safety requirements (i.e. persistent non-compliance), other risk management actions to prevent reoccurrence of problem should be considered such as:

- Seizure of affected products
- Suspension or revocation of registration
- Prosecution and/or injunction

Imported foods

Where the implicated food is an import, risk management actions can include:

- Recalls , detention of food or food ingredients
- Enhanced inspection of the importer against Good importing practices
- Notification of responsible authority in exporting country
- Deeming the food inadmissible (e.g., refusing imports or implementing temporary restrictions of imports) until the supplier or the competent authority can provide evidence and/or appropriate assurance the issue has been corrected,
- Deeming the food higher risk and requiring certification by the responsible authority in the exporting country,

Follow up:

Once the specific issue has been resolved, it is important to assess the food safety investigation. This assessment should identify both industry specific follow up and more general strategies.

For specific food businesses, the focus should be on reviewing the practices implemented to prevent further problems, are they working as designed.

For industry wide problems, more general strategies may be considered such as:

1. New industry education or guidance (e.g., food business employee training)
2. Development of new industry guidance documents to enhance compliance with food safety requirements

3. Readjustment of inspection programs, strategies
4. Enhanced education materials for targeted groups (e.g., physicians, schools)

Annexure 1 – Food Safety Complaint form

Part 1
To be completed by complainant

Recording district/competent authority				
Complaint number		Date of reception		
Complainant name		Contact information	Village	
			Gewog	
Consumer	Yes/no		District	
Food business	Yes/no		Country	
Other			Phone #/SMS	
Evidence			email	
Complaint description				
Symptoms (e.g., illness, injury)				
Implicated food(s)				

Part 2: Detail Food Safety Complaint

To be completed by BAFRA Official

Recording district/Competent Authority				
Complaint number		Date of interview		Phone/in person
Name (s) of person			Relation to complainant	

interviewed				
Implicated food description				
Type of food			Domestic/ Imported	
Brand name				
Vendor (Name, address)				
Date (s) purchased				
Date used				
Description of product	Raw/cooked	Refrigerated/shelf stable	Size	Quantity purchased
Description of usage				
Other comments				
Sample (s) available	Opened package Yes/No	Other packages yes/no	Samples taken Yes/No	
Sample submission form (number)*		Analytical results		
For official use only				
Assess the information	Is complaint valid? Yes /No If no, Close complaint	If yes, is it caused by complainant's actions Yes/No, If yes, Close complaint	If no, Investigate vendor and transportation of food	

*Sample submission form number provides the linkage between sample and analytical reports and complaint form.

Part 3 – Vendor Investigation/ Interview form
To be completed during investigation

Recording district/Competent Authority				
Complaint number		Date of interview/ Investigation		
Name (s) of responsible FBO/person			Title/Designation	
Implicated food				
Lots	Date Purchased	Quantity purchased	Quantity sold	Quantity remaining
1)				
2)				
3)				
4)				
Storage conditions				
Transport conditions				
Warrantee (if any)				
Other complaints				
If so, action taken				
Other comments				
Sample (s) available	Yes/No	Samples taken	Yes/No	
Sample submission form (number)*		Analytical results		
For official use only				
Assess the information	Is complaint valid?	If yes, is it caused by vendors	If no, Investigate food business (producer or importer) of food	

	Yes /No If no, Close complaint	actions Yes/No, If yes, undertake full inspection of vendor, determine follow up action Close complaint	

Part 4: Traceability form

Using the processes outlined in this manual and the appropriate inspection manuals, undertake a food safety investigation. Document all of your findings

Recording district/Competent Authority			
Complaint number		Date of interview	
Food business		Address	
Responsible person	Name Title		
Inspection date	Link to inspection report		
Samples available	Yes/no	Samples taken	Yes/no
Link to sample report numbers		Analytical results	
Complaints received	Yes/No	Action taken to resolve complaints	

Other information				
For official use only				
Conclusion of food safety investigation				

Annexure 2 – Food borne illness investigations

This Annex provides guidance on illness and other investigations.

Outbreakinvestigation

Investigation of food borne illnesses requires an epidemiological investigation in order to determine the probable cause which is generally carried out by physicians or epidemiologists. The inspector's role in such instances is to investigate the source of the food.

Where there is a single illness, it is likely that the inspector will interviews the person who was ill. The interviews are to assess whether the illness could be a result of food, water or environmental transmission.

Information to gather

Ask about and record all information about meals and snacks eaten seventy-two hours before onset of illness. The food, even the meal, which precipitated the illness, might not be obvious. The type of illness will sometimes give a clue.

- If the first and predominant symptoms are nausea and vomiting, concentrate questions on foods eaten recently.
- If the first and predominant symptoms are diarrhoea and abdominal cramps, foods eaten six to twenty hours before onset of illness are suspect.
- If diarrhoea, chills and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.

Sample Collection

Samples are an important tool in investigating food borne illnesses, and will provide more information on possible causes or sources of the illness or outbreak.

CAUTION: When investigating food borne illnesses, never taste anything, and handle all food, including samples very carefully, both to protect yourself and to prevent any possible cross contamination.

Based on the interview information, determine which foods are most suspectsand which samples should be collected. If there is any doubt, it is better to collect more samples of suspect product. The determination on analysis can be made later on return to the laboratory, in consultation with laboratory personnel and other experts.

When preparing to sample:

- Check storage areas (e.g., refrigerators, cupboards) for suspect food, as left over or ingredients may have been stored for future use and subsequently forgotten.
- Check garbage for discarded foods or containers.

- Check preparation and finished storage areas (e.g., retail shelves, restaurant kitchens, distribution areas). If suspect food is found, take action to prevent distribution or serving.
- Check the availability of food from the suspect meal, if no foods remain:
    - collect samples from similar foods that may have been prepared subsequently
    - Collect ingredients or raw items used in preparing the suspect food.

Examples of articles that are normally collected include:

1. Remaining portions of all suspect foods;
2. Parent stocks of suspect foods;
3. Insecticides, rodenticides, or other poisons that may be involved.
4. Suspect food containers such as cans, bottles, etc.;
5. Utensils or materials used in the preparation and storage of the suspect food;
6. Table scrapings and food residues from equipment such as slicing machines, cutting boards, etc.

NOTE: Collection of clinical specimens such as vomit, stools, swabs of nasal and throat passages or open sores or lesions of food workers should be the responsibility of government or private physicians.

Sampling material and equipment should be discussed with the laboratory to ensure that appropriate technique and procedures are used. Where only small amounts of food or ingredients remain, such as bits of leftovers, empty containers with adhering particles, collect all or as much as possible by scraping from utensils, equipment or containers. Also consider collecting the empty containers. Where there are sufficient quantities to allow for random sampling, samples should be taken in accordance with the direction in the sampling plans.

Sample Handling

Record the temperature of the room, refrigerator, or warmer in which the food was stored, and record the temperature of the food that remains after a sample is collected.

Samples of products frozen at the time of collection should be maintained frozen until analysed. Samples of perishable foods, which are not frozen at the time of collection, should be cooled rapidly to a temperature of 4oC and maintained at this temperature if they can be analyzed within eight hours. If analysis cannot be started within eight hours, and you suspect microbial contamination, contact your servicing microbiology laboratory for proper handling procedures.

If the suspect food is a commercial product, examine the original package or container for coding information to identify the place and time of processing.

Collect additional packages bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum, leaks, or other conditions. Be as specific as possible in requesting the type of analysis.

For report form suggest using the template developed by WHO

http://www.who.int/foodsafety/publications/foodborne_disease/Annex_6.pdf

Annexure 3: Potential Sources of Contamination

Processing Sources

As ingredients and raw materials may be a source of pathogens or contamination, during the food business inspection,

- determine and document the source of all ingredients and raw materials
- determine if any warrantees were provided by the supplier. If so, note the need for follow up with the suppliers.
- document ingredients storage (e.g., location, conditions, temperature)
- determine which ingredients were added before, and which were added after any cooking or heat processing.

As faulty processing could be the source of contamination, therefore validate the processes, and check temperatures of foods during processing. During the food business inspection

- assess the processing requirements, where parameters are consistent with processing
- determine the time and temperature involved in freezing, thawing, cooking or thermal processing, hot and cold holding, chilling, reheating, and any other steps in the processing operations.
- Verify the records and documentation of all the processing steps.

As packaging materials could be the source of the problems, verify the packaging material is food grade, that it is appropriately protected during storage.

Pests

Pests are a possible contamination source and can be an indication of poor hygiene, sanitation, food storage, handling and preparation practices. These pests may include rodents, flies, cockroaches or others that:

- Occur around human settlements.
- Occur indoors as well as outdoors.
- Are attracted to potential sources of pathogens (garbage, drains, excrement, etc.) and to human food.
- Travel back and forth between possible sources of pathogens and food or food contact surfaces.

During the food business inspection, evaluate whether pest(s) are a contributing factor to the problem. Are there any pests present? Or is there any evidence (e.g., excreta, urine, gnawing) of pests?

Where pests are a potential source of contamination, collect specimen if necessary to determine whether the pest is the source of food borne pathogens.

Raw Meat

Raw poultry, pork, and other meats are often contaminated. Where meat is a potential source of contamination, samples of meat and poultry, meat scraps, residues on floors, and other equipment can be helpful in tracing the primary source.

Sampling of meat products and swabbing food contact surfaces of equipment (e.g., tables, cutting boards, slicing machines) may establish or trace the source of contamination. Samples or swabs may also be taken from air filters, drains, vacuum sweepings, food scrap piles, dried deposits on equipment, and dead ends of pipe lines which may reflect the presence of organisms previously in the establishment. It is important to follow sampling protocol/best international practices during collection of the samples and also follow laboratory instructions.

Poor sanitation

Poor sanitation is a key consideration in a food safety investigation. Poor sanitation may be a cause of food borne contamination or a contributing factor. The food safety investigator should evaluate the cleanliness, manner, and frequency of cleaning the food business/ premises, and in particular the equipment and food contact surfaces and verify relevant records. Examine if there are possible routes of cross-contamination between raw and cooked foods.

Also verify if there is any chemical contamination, including poor storage, usage or rinsing of cleaning chemicals.

Workers/Food handlers

Workers can be a source of food borne pathogens, thus it is important to investigate employee hygiene practices, including food safety training. Poor hygiene practices among food workers (e.g. not washing their hands), continues to be a major contributing factor for contamination and food borne illness. Employee attendance and sick leave records may provide information as to the health status. Ask about illnesses, particularly respiratory (e.g., coughing, sneezing) or intestinal (e.g., diarrhoea, vomiting).

A separate interview for all persons involved in processing, preparing, or storing of the food will provide valuable information. Ask questions in a sequence that discloses the flow of food from the time it was received, through preparation and distribution.

Employees may fear criticism or dismissal if they are perceived as the source of a problem. As a result, employees may not accurately describe their actions, thus it is important to assess the reliability and completeness of their description. Reliability may need to be confirmed through other interviews, while completeness can be confirmed through asking the question in several ways to seek more details. Be alert for inconsistencies among the various responses. Validate the descriptions by watching the operations.

Annexure 4: Food Safety Risk Assessment

Once sufficient information has been gathered, the inspector in consultation with officer in-charge and focal food safety officer should determine whether a food safety risk assessment (FSRA) is needed. While the assessment is based on scientific analysis, the intent of an FSRA is to address the questions with respect to harm for this particular food safety investigation. While not all food safety investigations will require FSRA's, recording and documenting all the information required is good practice.

While the basic steps of a FSRA are identified below, it is also recommended to refer to the FAO/WHO Guide for application of risk analysis principles during food safety emergencies:
http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf

Basic Steps

1. Clearly define purpose:
    a. What is the trigger?
    b. What is the scope of product(s) to be covered by the FSRA?
2. Preliminary investigation (usually completed before FSRA request):
    a. Collect pertinent information to assist in completion of FSRA.
    b. Summarize details surrounding the product of concern.
    c. Analysis information, if available.
    d. Reported illnesses/reactions?
3. Hazard Identification – Predominantly a qualitative process to determine which potential hazard(s) identified present a significant health risk to consumers:
    a. Identify biological, chemical or physical agent that may be present and capable of causing adverse health effects.
    b. Determine whether a health hazard exists or has the potential to exist.
4. Hazard Characterization:
    a. What is the potential severity of adverse health effects?
    b. What is the potential duration of adverse health effects?
5. Evidence – Scientific evidence that contributes to exposure assessment:
    a. Positive lab results.
    b. Strong epidemiological link between product and human illness.
    c. Product attributes which may be amenable to pathogen proliferation.
    d. Other supportive information.
6. Exposure Assessment:
    a. Dose-Response Assessment.
    b. Level of contamination.
    c. Likelihood of Occurrence.
    d. Hazard Exposure Characterization: Quantitative/qualitative evaluation

of potential exposure (dietary information, level of contamination).

e. Information on product distribution, intended use, consumer habits, target populations, high-risk populations, etc.

7. Risk Characterization:

a. Determine likelihood of occurrence of illness as a result of consumption of the product.

b. Based on steps 2-5, classify the level of risk as Health 1, Health 2, Health 3, or other (no risk).

8. Complete documentation:

a. If applicable, support FSRA by indicating the Act, Rules or Regulation.

b. Identify which section of the Act or Rules and Regulation was violated.

c. Identify any unknowns.

9. Potential re-assessment of issue, if new relevant information becomes available.

Health risk classification outlines the consequences of exposure to a food borne hazard.

- Class I Hazard is a situation in which there is a reasonable probability that the use of, or exposure to, a food or food product will cause serious adverse health consequences or death.
- Class II Hazard is a situation in which the use of, or exposure to, a food or food product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III Hazard is a situation in which the use of, or exposure to, a food or food product is not likely to cause any adverse health consequences; the food or food product is in contravention of an Act or Regulation.

Health risk classifications form the basis of recall classifications.

ANNEXURE 5: STANDARD OPERATING PROCEDURE FOR INVESTIGATING FOOD CONTAMINATION AND/OR FOOD BORNE ILLNESS OUTBREAKS

Introduction

Consumers have a right to access safe and suitable food and a responsibility to store and prepare purchased food safely. The food industry has the responsibility to produce safe and suitable food. However, no system is perfect, and when issues arise, they can result in food borne out breaks.

Food borne illness can have impact at various levels, affecting the health of individuals, families, and impacting the viability of food businesses. This Standard Operating Procedure outlines the roles and responsibilities in the event of an outbreak. It complements the detailed guidance established in the Food Safety Investigation Manual.

Scope

There are generally two situations in which this SOP will be implemented

1. Illness(es) with suspect, but no confirmed link to a specific food
2. Contaminated food with no link to confirmed illnesses

SOPs have been developed for each of these situations as well as an illustrative flow chart.

Illness (es) with suspect but no confirmed link to food

Where food borne illnesses are identified but there is no confirmed link to food, the Department of Public Health, Ministry of Health will lead investigation. BAFRA will collaborate with the public health and medical officers to investigate and confirm (if possible) a linkage to the contaminated food or water.

Once a cluster of illnesses is identified, the information will be shared between district OICs, and OIC will report to food safety focal officer with as much detail as possible. The food safety focal officer will call a coordination meeting and/or call among relevant BAFRA officials (e.g., OICS of all implicated districts), Chief laboratory officer, and Chief RQO and Head of BAFRA to review all information and determine incident command team within BAFRA is needed.

If yes, the incident command teamshall be constituted and will:

1. Meet as and when required to discuss the information from the public health, medical officers.
2. Provide direction to food safety officers to investigate any potential food linkages, including,
    a. taking samples, prioritizing the samples and assessing and reporting on the results
    b. investigating food businesses
    c. provide support to the district level public health and medical officers.
    d. Decision on the risk management (recall, further processing, ban notice, detention etc.)
    e.
3. As part of the incident command team, the food safety focal officer will liaise with the public health and the medical officers, sharing any information with incident command team.

If no incident command team is formed, the food safety focal officer, will continue to monitor the illness outbreak. The food safety focal officer will be responsible for sharing information and, as necessary, will recommend another coordination meeting to revisit the need for an incident command team.

Until a link is made to specific food, BAFRA will have a support role, providing sampling and analytical support to Public Health and Medical officers investigating the illness outbreak. Guidance and direction on sampling food and other support initiatives can be found in Annex 2 of the Bhutan Food Safety Investigation manual.

Illness linked to a food

On confirmation that the illness has been linked to a specific food, BAFRA will undertake a food safety investigation.

National level

The food safety focal officer will either convene the incident command team or call a coordination meeting and/or conference call among relevant BAFRA officials (e.g., OICs of all implicated districts, chief laboratory officer, and Chief RQO and Head BAFRA).

The objective is to:

1. Review all available information about the contaminated food, the distribution and food settings

2. Assess the need for an incident command team involving relevant stakeholders and constitute one based on the requirement chaired by the head of BAFRA.
3. If the incident command team is not already in place, decide whether one is required,
    a. If no incident command team is needed, the food safety focal officer will continue to work with the district OICs to coordinate information gathering, and provide direction on the recall process
4. Make a decision on whether a recall is required, or other risk management actions.

Where an ***incident command team*** is formed, it will include the food safety focal officer, the OICS of all implicated districts, chief laboratory officer, and Chief RQO and either the livestock or plant focal officer if implicated food is a livestock or plant product respectively and the communication officer (ICS), Ministry of Agriculture and Forestry. The incident command team is responsible for:

1. Keeping the medical officer and public health head office informed about the contaminated food, such as distribution, and if any further illnesses are associated with the contaminated food
2. Have regular meetings/calls to review the available information from all sources, districts, laboratories, medical/public health officers.
3. Make recommendations to the head of BAFRA on risk management actions
4. Provide direction and technical information to guide district actions including sampling, analysis, food safety investigations and other risk management actions (e.g., detentions, seizures, recalls)
5. Provide input and direction on media communication
6. Provide direction to the Food Safety laboratory with respect to prioritizing sample analysis.
7. Recommend /Mobilize resources as deemed necessary.

As part of the incident command team, the **food safety focal officer** will be responsible for coordination and management, and will

1. Maintain an incident file that contains all headquarters documents pertaining to the food safety outbreak, including decisions by the incident command team.
2. Coordinate and share all information with the OICs in the implicated districts and the Food Safety laboratory.

3. Liaise with international contacts (i.e., competent authorities), if contaminated food was imported or exported.

Food Testing Laboratory

1. Participate in the incident command team to advise on samples to be taken, procedures, numbers, and analysis,
2. Prioritize analysis based on direction from the incident command team
3. Report the results

Media officer

Media strategy:

1. Information must be timely, accurate and consistent
2. All information passed to the media should be cleared with incident command team (ICT)
3. The ICT should identify a media spokesperson
4. The media officer should communicate regularly with media counterparts in other agencies
5. Communication should be maintained with all appropriate media outlet

Objective:

1. Facilitate case findings through enhanced reporting of cases
2. Inform public about avoidance of risk factors for illness and about appropriate preventive measures
3. Maintain public & political support for disease investigation & control
4. Minimize the appearance of conflicting information from different authorities
5. Liaise with media and provide consumers with information to educate and create awareness on the importance of food safety, updates on the risk management actions, not create panic to the public.

Food Safety Investigation implementation

OIC's in affected districts will be responsible for managing the implementation of the food safety risk management actions and food safety investigations at the district level

OIC's will identify personnel required for implementation including:

1. All OIC's and food inspectors in the affected districts
2. As needed, other BAFRA inspectors or public health officials.

Responsibilities:

1. Investigate the source of the food contamination

2. Carry out inventory of the implicated food (stock, sold, place, etc)
3. Oversee the implementation of risk management actions.
4. Ensure the contaminated food has been removed from the market
5. Liaise with district medical/public health officers with respect to further illnesses
6. Report to the incident command or the food safety focal officer on regular basis
7. On- going communication with public and food business on the importance of food safety.
8. Request resources and staffs from the nearest districts in the event of food safety emergency
9. Seek support from the other relevant stakeholders (custom, trade & police in event of destruction, ban and seizures)

Closing the incident and Follow up

Upon receiving recommendation from the Incident Command team, the Head of BAFRA (chair of the incident command team) will declare the food safety emergency over.

All implicated district OIC's will submit a detailed report on the food safety activity carried out during the food safety emergency.
The Incident command team will review all reports and determine:

- With respect to BAFRA's response, assess what went right, what could have been better, and if needed, recommend improvements to the Head of BAFRA.
- If the reports indicate there is a similar problem across many food businesses that contributed to the outbreak, assess if BAFRA should develop industry guidance to address this issue, and if so make a recommendation to the Head of BAFRA.

Food safety investigation into contaminated food with no confirmed illnesses

District level

Where contaminated food is identified within a district, the food has been widely distributed but there are no confirmed illnesses, the food inspector will:

1. Provide as much detailed information as is known at the time to the OIC,
2. Will take sample of identified contaminated food (??)
3. Will lead food safety investigation team

4. Provide information on the investigation to OIC, on a regular basis

The OIC will

1. Will form food safety investigation team and initiate food safety investigation
2. Inform all district OICs and the food safety focal officer
3. Contact the local medical officer to determine whether there are any reports of illnesses or complaints.

National level

The food safety focal officer will call a coordination meeting and/or call among relevant BAFRA officials (e.g., OICS of all implicated districts, chief laboratory officer, and Chief RQO and Head BAFRA)

During the meeting, the officials will

1. Review all available information about the contaminated food, the distribution,
2. Make a decision on whether a recall or other risk management action is required and whether an incident command team is required,
    a. If no team is required, the food safety focal officer will continue to work with the district OICs to coordinate information gathering, and provide direction on the recall process
    b. If team is required form incident command team.

Where an ***incident command team*** is formed, it will include the food safety focal officer, the OICs of all implicated districts, chief laboratory officer, and Chief RQO and either the livestock or plant focal officer if implicated food is a livestock or plant product respectively, the media officer and other relevant stakeholders,

The incident command team is responsible for:

1. Informing the department of Public health, Ministry of Health about the contamination, to determine if any illnesses might be associated with the contaminated food
2. Advising the national medical officer about the contamination, to determine if any illnesses might be associated with the contaminated food
3. Have regular meetings/calls to review the available information
4. Make recommendations to the head of BAFRA on risk management actions
5. Provide direction and technical information to guide district actions including sampling, analysis, food safety investigations and other risk management actions (e.g., detentions, seizures, recalls)
6. Provide input and direction on media communication

7. Provide direction to the Food Testing Laboratory with respect to prioritizing sample analysis.
8. Recommend/Mobilize resources and inputs as deemed necessary.

As part of the incident command team, the **food safety focal officer** will be responsible for coordination and management, and will

1. Maintain an incident file that contains all headquarters documents pertaining to the food safety outbreak including decisions by the incident command team.
2. Coordinate and share all information with the OICs in the implicated districts and the Food Safety laboratory.
3. Liaise with international contacts (competent authorities), if contaminated food was imported or exported.

Food Testing Laboratory

1. Participate in the incident command team to advise on samples to be taken, procedures, numbers, and analysis,
2. Prioritize analysis based on direction from the incident command
3. Report on results and provide scientific advice on the implications of the results.

Media officer

Media strategy:

1. Information must be timely, accurate and consistent
2. All information passed to the media should be cleared with incident command team (ICT)
3. The ICT should identify a media spokesperson
4. The media officer should communicate regularly with media counterparts in other agencies
5. Communication should be maintained with all appropriate media outlet

Objective:

1. Facilitate case findings through enhanced reporting of cases
2. Inform public about avoidance of risk factors for illness and about appropriate preventive measures

3. Maintain public & political support for disease investigation & control
4. Minimize the appearance of conflicting information from different authorities

5. Liaise with media and provide consumers with information to educate and create awareness on the importance of food safety, updates on the risk management actions, not create panic to the public

Food Safety Investigation implementation

OIC's in implicated districts will be responsible for managing the implementation of the food safety risk management actions and food safety investigations at the district level

OIC's will identify personnel required for implementation including:

1. All OIC's and food inspectors in the affected districts
2. As needed, other BAFRA inspectors or public health officials.

Responsibilities:

1. Investigate the source of the food contamination
2. Carry out inventory of the implicated food (stock, sold, place, etc)
3. Oversee the implementation of risk management actions.
4. Ensure the contaminated food has been removed from the market
5. Liaise with district medical/public health officers with respect to further illnesses
6. Report to the incident command or the food safety focal officer on regular basis
7. On- going communication with public and food business on the importance of food safety.
8. Request resources and staffs from the nearest districts in the event of food safety emergency
9. Seek support from the other relevant stakeholders (custom, trade & police in event of destruction, ban and seizures)

Closing the incident and Follow up

The Head of BAFRA (Chair of incident command team) will declare that the food safety emergency is over upon receiving recommendation from the Incident Command team,

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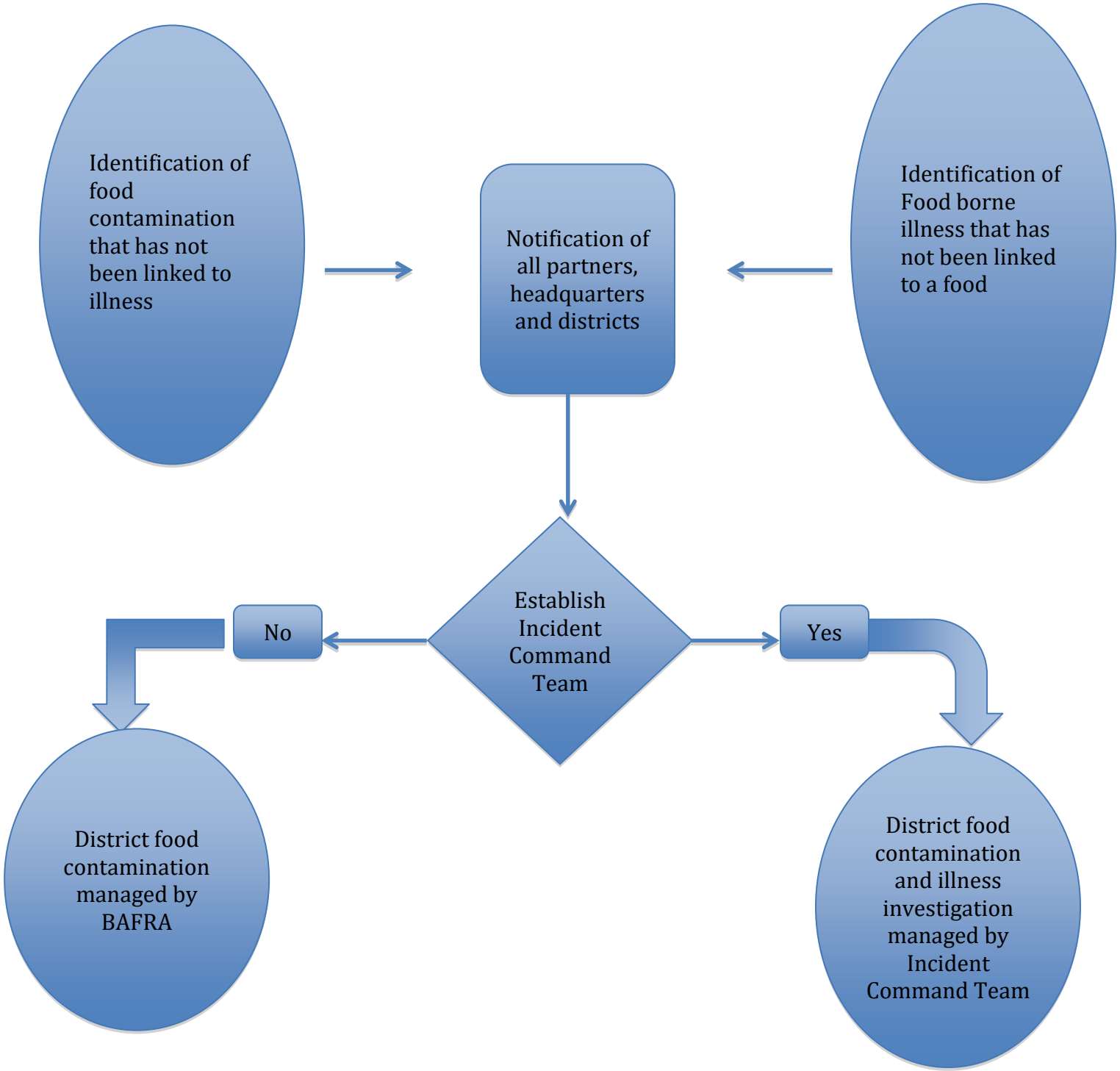
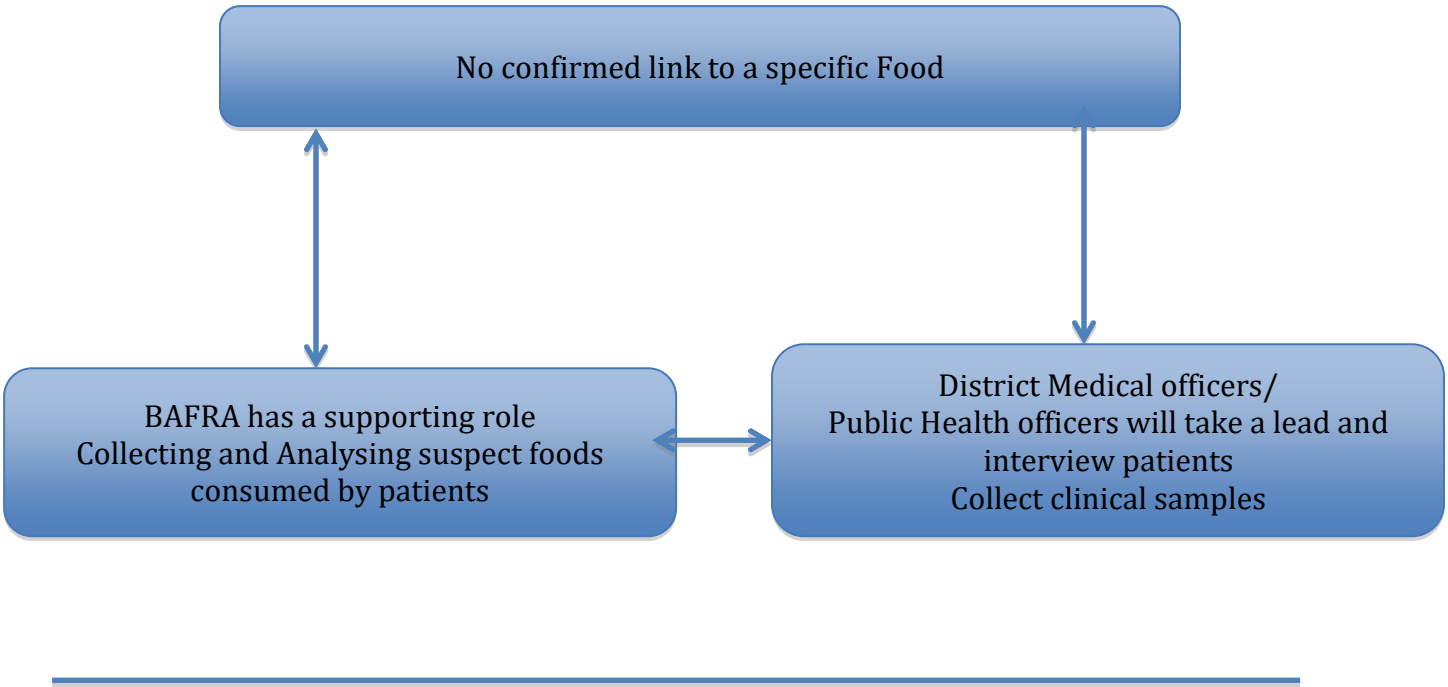
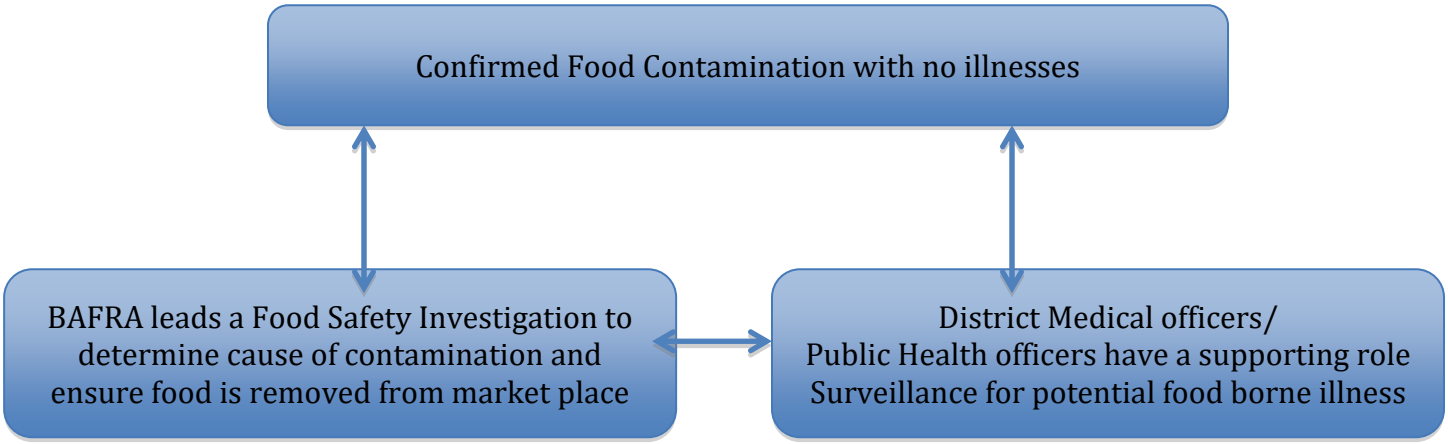
All implicated district OIC's will submit a detailed report on the food safety activity carried out during the food safety emergency. The Incident command team will review all reports and determine:

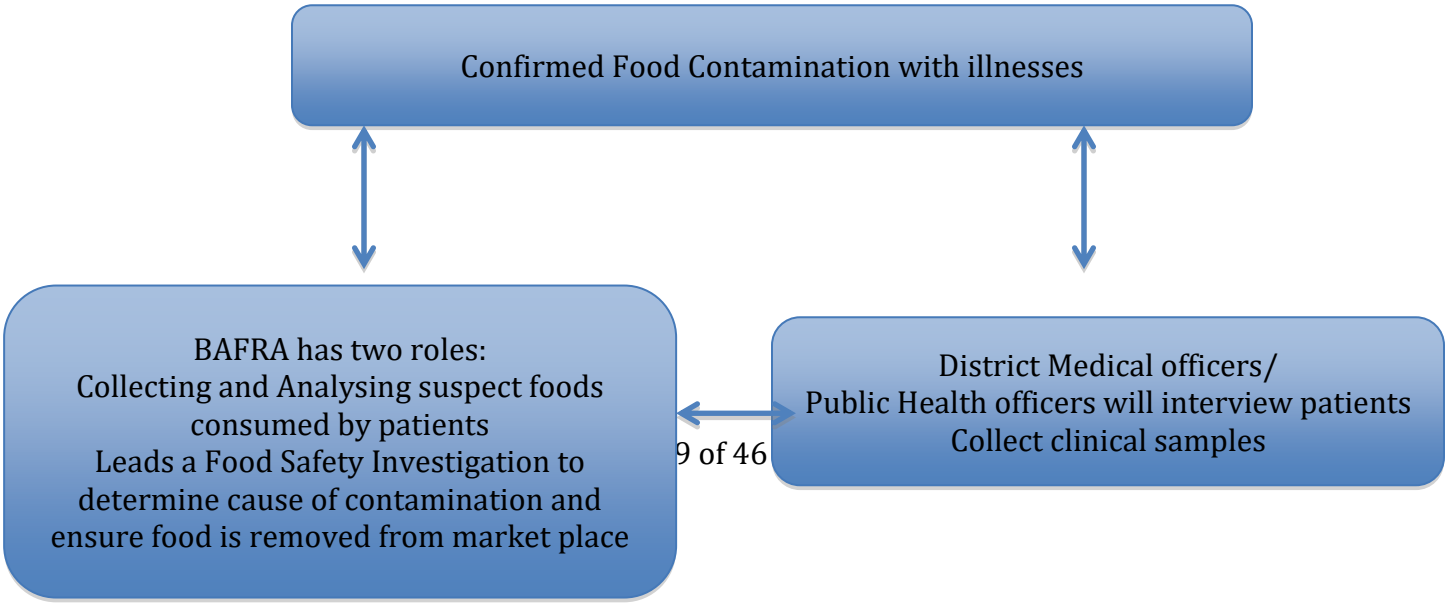
- With respect to BAFRA's response, assess what went right, what could have been better, and if needed, recommend improvements to the Head of BAFRA.
- If the reports indicate there is a similar problem across many food businesses that contributed to the outbreak, determine if BAFRA should develop industry guidance to address this issue, and if so make a recommendation to the Head of BAFRA

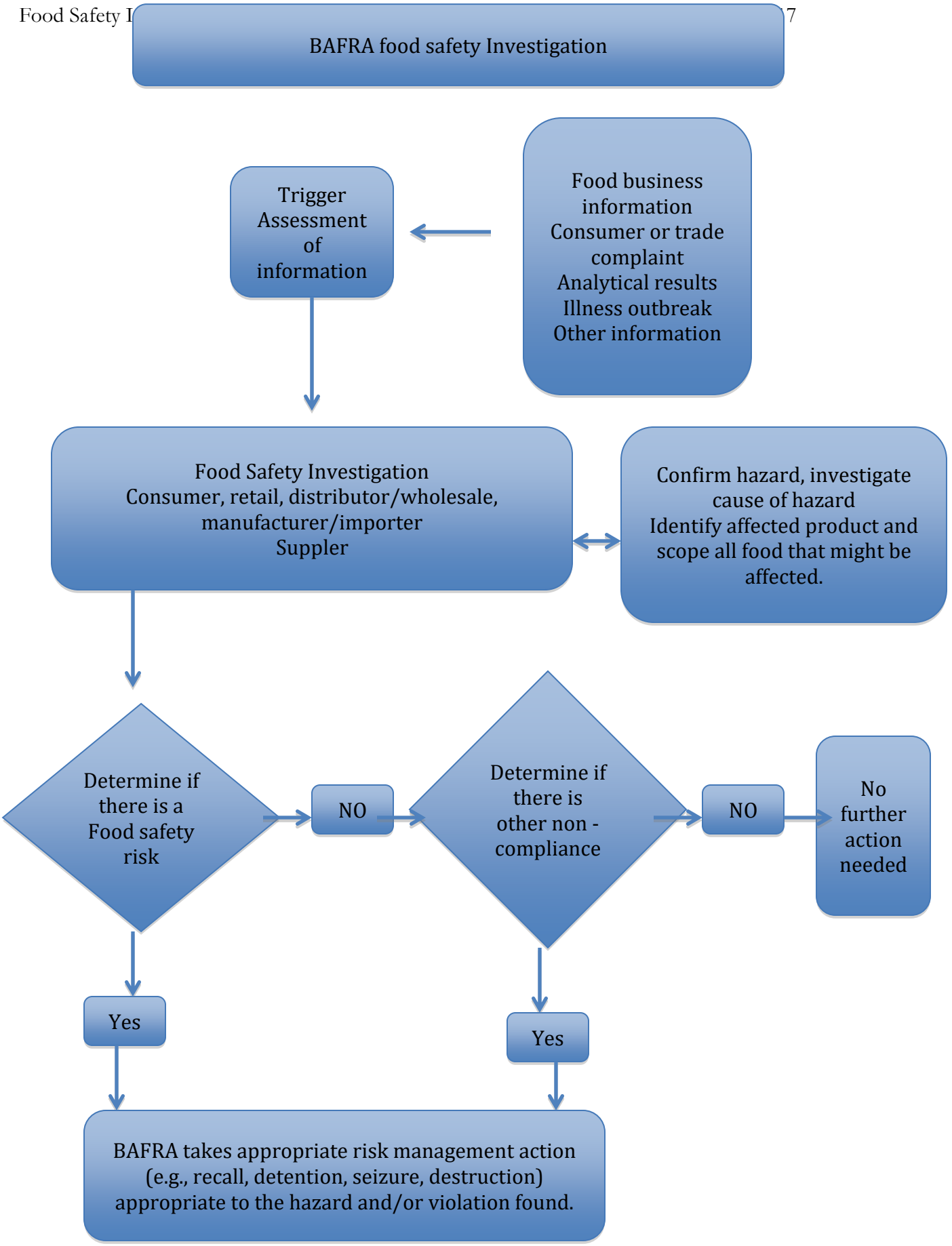
Bhutan Agriculture and Regulatory Authority – Food Contamination/illness flow chart




No confirmed link to a specific Food
BAFRA has a supporting role
Collecting and Analysing suspect foods consumed by patients
District Medical officers/
Public Health officers will take a lead and interview patients
Collect clinical samples


Confirmed Food Contamination with no illnesses
BAFRA leads a Food Safety Investigation to determine cause of contamination and ensure food is removed from market place
District Medical officers/
Public Health officers have a supporting role
Surveillance for potential food borne illness


Confirmed Food Contamination with illnesses
BAFRA has two roles:
Collecting and Analysing suspect foods consumed by patients
Leads a Food Safety Investigation to determine cause of contamination and ensure food is removed from market place
District Medical officers/
Public Health officers will interview patients
Collect clinical samples


BAFRA food safety Investigation
Trigger Assessment of information
Food business information
Consumer or trade complaint
Analytical results
Illness outbreak
Other information
Food Safety Investigation
Consumer, retail, distributor/wholesale, manufacturer/importer
Suppler
Confirm hazard, investigate cause of hazard
Identify affected product and scope all food that might be affected.
Determine if there is a Food safety risk
NO
Determine if there is other non - compliance
NO
No further action needed
Yes
Yes
BAFRA takes appropriate risk management action (e.g., recall, detention, seizure, destruction) appropriate to the hazard and/or violation found.

Annexure 6: US Food and Drug Administration Classification of Illnesses Attributable to Foods