

Food Recall Manual



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

FOREWORD

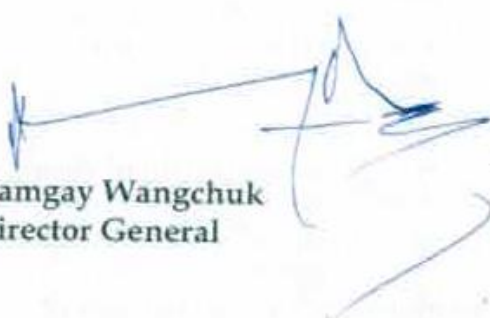
Food Recall is a fundamental tool for the management of risks in response to Food Safety Events & Emergencies. It is an important link in ensuring food safety to the consumers backed by Regulatory control on the Food Service Operators.

Effective National Food Recall Systems rely on Food Business Operators (FBOs) to take action to recall food under the guidance and oversight of the competent Food Safety Authority. Food Business Operators are important stakeholders in the Food Supply Chain and have the primary role and responsibility to ensuring the safety of the food products. FBO's need to understand that if they believe or, have reasons to believe that the food product, which they have processed, manufactured, imported, distributed are not in compliance with the food safety norms, they have the responsibility to initiate the procedures to recall and withdraw the food in question from the market in collaboration with BAFRA.

The purpose of this Manual is to provide direction, operational guidance and procedures with respect to both Industry and National Recalls of Food in Bhutan. It is primarily for the use of Government officials, but will also provide useful information for Food Business Operators.

This Manual is expected to facilitate the effective withdrawal of food products which have been identified as unsafe. It provides guidance on how to establish a written Recall Plan for carrying out Food Recall in order to ensure the hygiene, safety and quality of food to protect the health of the consumers.

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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Food Recall Guidance Manual

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Food Recall Guidance Manual

Introduction

Where there is reason to believe that a food may pose a health risk and/or be non-compliant with a legislative requirement, a food safety investigation to determine the source of a food safety problem, (e.g., whether a hazard (physical, chemical, and/or biological) or other contravention exists) will be done. If the investigation confirms a hazard and identifies the source, the appropriate risk management action (e.g., industry recall, detention, seizure, public advisories) will be implemented.

Purpose

The purpose of this manual is to provide direction and operational guidance, definitions, policy and procedures with respect to both industry and national recalls of food in Bhutan. It is primarily for the use of government officials but will also provide useful information for food businesses.

Industry Recall

An industry recall is a risk management action implemented by a food business to control or reduce a risk associated with a marketed food product. Food businesses should initiate a recall once they become aware of a potential health risk or non-compliant food or at the direction of a food inspector designated by Bhutan Agriculture and Food Regulatory Authority” (BAFRA).

Definitions

Correction

Means adjustment or relabeling of a defective food product without its physical removal to some other location.

Direct accounts

Means food businesses that purchased food(s) directly from the recalling company.

Effectiveness check

Effectiveness checks are intended to verify that consignees received the information pertaining to a recall and they took appropriate action.

Industry Recall

Means a food business’s removal from further sale or correction of a marketed food or food ingredient. Industry recall of a suspected or known defective or hazardous food may be initiated for a number of reasons such as:

- presence of a toxic or hazardous substance that could cause serious injury or death

- misinformation as to the product (presence of unlabelled ingredients that could result in anaphylactic shock, unacceptable ingredients);
- results of process deviations that could result in a hazard in the final product;
- consumer or other complaints of illness or injury due to consumption or use of a particular product.

There are two other types of product removal or disposition actions:

- **Product Withdrawal** is removal from further sale or use of a marketed product that does not contravene legislation. Note: Most product withdrawals are for quality reasons.
- **Stock Recovery** is removal or correction of a non-compliant product that has not reached consumers or that has not left the direct control of the recalling firm.

Food Inspector

Means the BAFRA food inspector responsible for liaison and overseeing an industry recall (e.g., communication with food business, initiating effectiveness checks, verification of public communications).

Recalling food business

Means the food business that initiated an industry recall. It is usually the company that has primary responsibility for the recalled food (e.g., importer, processor), but it may also be a distributor or retailer.

Recall Classification

Recall classification outlines the consequences of exposure to a food borne hazard. Factored into the classification decision will also be the target population for the product (i.e., children, elderly, general public), whether any illnesses have occurred from use of the product, the ease of product identification, and the amount of product that is presumed to be in the market place.

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

The classification of the recall will also include the **depth of the recall** extended into

the food distribution system, such as to the manufacturer/importer, the distributor, retail, including hotels, restaurants and institutions or consumer.

Recall Program Framework – Industry Role

Industry Recall Plan

Food businesses should:

- Prepare and maintain a detailed written plan¹ that will permit a rapid and effective food recalls. For small food businesses, they should have a simple plan.
- The plan should be known to all persons involved and should include:
 - identification of all internal and external personnel involved in or to be notified of the recall;
 - functions and responsibilities of involved persons;
 - a method of ensuring that a recall can be put into operation at any time, during and outside normal working hours;
 - the means of notifying and implementing a recall and of deciding its extent;
 - a procedure to control products in transit, product distributed and returned stock;
 - provision for the disposition of recalled product;
 - a means of assessing the progress and effectiveness of the recall;
 - a fit for dispatch certificate to certify the finished products
- The plan should also identify the other aspects of food manufacturing and processing that will facilitate a recall including:
 - The use of appropriate coding during manufacture or preparation of food products will permit positive lot identification and facilitate effective recall of those lots if be required.
 - Maintaining product distribution records, preferably by lot, will facilitate location of products that are being recalled. These records should be maintained for a period of time that exceeds the shelf life and expected use of the product.

Communications

The recall plan should outline the communications approach and methods (e.g., telephone, SMS, facsimile, e-mail, telex or special delivery letters) for promptly notifying each of its direct accounts and the BAFRA food inspector about a recall.

The plan should outline the general contents of the food business's recall communication:

¹This recall plan will be subject to assessment by BAFRA inspectors during food business inspections.

- the product of concern;
- the reason for the recall, including some indication of the hazard;
- that sale or use of the recalled product should cease immediately;
- where applicable, the requirement to notify other food businesses in the distribution chain about the product being recalled, and for those food businesses to notify subsequent recipients;
- any instructions regarding corrective action, disposal, storage or returning the recalled product including refunding the cost of the recalled product

Purchaser Notification

The recall plan should include requirement for food businesses that purchased the recalled food to immediately carry out the instructions of the recalling company and, where necessary, extend the recall to the next level, whenever a recall notification is received.

Public Notification

The recall plan should include general instructions on preparation and issuing a news release to inform consumers, when required. The purpose of notifying users is to alert them of a serious health or safety hazard (A template is provided in Annex 1).

Effectiveness Checks

Effectiveness checks by the recalling firm should be included in all recall plans. They are carried out to verify that consignees have received notification about the recall and have taken appropriate action. The recalling company may conduct their effectiveness checks through personal visits, telephone calls, faxes, letters, or a combination thereof.

The recall plan should include how the food business will document and maintain records of any effectiveness checks for subsequent review by government officials.

Stock Control

The recall plan should include procedures that the recalling food business will use to ensure that recalled product is properly identified and segregated until a decision is made for the recalled lot (disposal, return to manufacturer or correction). It is essential that the recalled product does not find its way back into the market unless it meets legislative requirements.

Follow up

The recall plan should include follow up processes to address the source of the problem that caused the recall and the recall process itself. The food business shall review its procedures and practices to ensure that the problem that caused the recall has been addressed to prevent its reoccurrence.

Recall Program Framework - Government Role

Government officials play a key role within an industry recall. They provide coordination during national recalls, between all appropriate government organisations (e.g., national, city corporations); oversee the operations of the recalling firm (e.g., recall notices, public communication, monitoring the recalling firm's action and all followup).

Inspectors should:

- provide information to headquarters on recalls and updates as required until the recall is terminated;
- assure a liaison with the recalling company, reviewing their strategy and its implementation, and assisting in the preparation and consultation of news releases;
- initiate effectiveness checks, summarizing and distributing the results, including co-ordinate the allocation of resources.

Public Announcement

Recalling companies are encouraged to notify the government whenever a recall is initiated. The company may identify a need for a public announcement or a news release to be issued based on the risk and the risk control options. However, the government may decide to issue a press release on its own when:

- (a) The government considers it imperative that the recall receives wide coverage to protect the health and safety of the public;
- (b) the company refuses to issue a public announcement; and
- (c) the proposed public announcement is inadequate.

In all cases, the company will be given the opportunity to comment on the government public announcement.

Government Recall Effectiveness Checks

The government may carry out its own effectiveness checks in order to monitor the recall. A sample format is given at Annex 2. This is separate from the recalling firm's effectiveness checks. If the food business maintains detailed records, the government may monitor a recall by a review of the food business records. Alternatively, the government may undertake to carry out personal visits or telephone contacts with accounts. The level of effectiveness checks will depend on the risk to health and safety. Where there is little or no associated hazard or risk, the government may choose not to carry out any effectiveness checks.

Refusing to Recall

Where a company refuses to recall a product or the recall is deemed to be inadequate, the BAFRA should be prepared to take alternative measures which may include product removal, contacting all consignees to advise them of the hazard or potential hazard, or a public warning.

In addition, the government should also consider more stringent action such as seizure, prosecution and penalty for continued sale of a non-compliant product.

Termination of a Product Recall

A recall will be terminated when the government and the recalling company are in agreement that the product subject to the recall has been removed and proper disposition or correction has been made.

Summary Information on Recalls

The government is responsible for summarizing the results of the recall. A list of product recalls will be made available to the public & industry on request or may be made available by other means within 30 days of the recall.

Follow up

The BAFRA shall also review information to determine if the issue that resulted in a recall is an isolated occurrence (i.e., result of a food business process), or more wide spread (e.g., industry wide practices). If the problem is related to industry wide practices, the competent authority should determine if policy, program or perhaps legislative changes are required and discuss with relevant stake holders (if needed) to take appropriate action.

Recall Implementation Procedures

This section will describe the procedures associated with implementing an industry recall, particularly with respect to government actions.

The **Food Inspector** is the primary contact with the recalling firm, and is responsible for providing the industry information to district office, and providing industry with direction from the BAFRA. The Food Inspector will work closely with district OIC to coordinate distribution of information to national headquarters and other implicated districts or organisations.

Risk management decision: Initiation of industry recall

- **Food business:** As soon as the food business determines to recall a food or food ingredient, they should contact the nearest BAFRA offices.

- **BAFRA:** As soon as BAFRA determines that a food recall is required to manage a food safety issue, the food inspector must contact the firm to request a recall. A verbal notification shall be followed up with written confirmation.

Recall Implementation

Confirmation of Recall

To document the recall, the Food Inspector shall write (e.g., email, fax) to the food business confirming the scope of the recall, the recall classification, the regulatory contravention (when applicable), the time frames for action, and the summary of any discussions with the firm.

The Food Inspector shall have all information on the food being recalled including:

- the name and address of the recalling firm
- the company spokesperson for the media (if company wishes)
- area of distribution of the product
- distribution date (s)
- copies of the product label
- brand name
- common name
- package type, net content, size, weight and/or special marks or features
- date codes, lot codes,
- expiry / best before / use by (dates)
- information on production data, quantity of production and reasons for recall.

The Food Inspector should provide information to the OIC, who will work with the focal officer for food safety to coordinate the recall and distribute the information.

Verification of the Food Business Recall Plan and Procedures

The Food Inspector will review the food business recall procedures, which will be adapted from the food business's recall plan (See p 6). This review should be done on the site of the food business. However, in some instances, and in the interest of time, the food business and Food Inspector may agree that the information be sent electronically to the BAFRA office for review. After review BAFRA should immediately get back with confirmation.

The Food Inspector shall review the following food business documents:

- The notice of recall to be sent to direct clients and the follow up

communications, where direct accounts fail to respond

- The draft news release (if required)
- The list of direct clients for the recalled food(s)
- The food business's instructions to correct or dispose of the recalled foods
- The food business's plans for conducting effectiveness checks

Notice of recall

The recall notice should clearly communicate (i.e., is brief and to the point) to all direct accounts (consignees) all pertinent information about the recalled food including:

- The firm recalling the food
- A full description of the food product being recalled,
 - the product, size of the affected lot(s), lot number(s), package and case code(s), and/or UPC codes and any other pertinent descriptive information to enable accurate and immediate identification of the product
- the reason for the recall and the hazard involved,
- Confirm that the product is subject to a recall
- Provide contact information of the recalling firm that can be used by the direct account
- Pertinent instructions:
 - Confirm receipt of the recall notice
 - Further distribution or use of any remaining product should cease immediately
 - Forward notification of the recall, including pertinent instructions, by the food business to their direct accounts, if the food was further distributed,
 - Specific action that must be taken with respect to the product (e.g., segregation, return to supplier).
 - Reporting requirements including how much of the product remains in the food business's possession, the action taken on the product and how much of the product had been further distributed
 - Provide instructions for refunding the purchase cost for recalled product that is returned by consumers or still within the food business's control.

Note: It is the Food Inspectors responsibility to verify that irrelevant qualifications, promotional materials, or any other statement that may detract from the message are removed from the recall notice.

The News Release (Public Warning)

Where the food business or the competent authority determines that a news release or public warning (See Annex 2) is required, the Food Inspector should work with

the food business on the public notification to verify that the facts are accurate, and the notice clearly communicates the issue to consumers.

Principles for public communication:

- Information provided to the public must be timely, accurate, clear, objective and complete.
- Information should foster open dialogue, build a climate of trust, credibility and understanding by being open and transparent about food safety issues and recalls, including facts, evidence and information

Transmission

As determined by the recall plan, a recall notice can be communicated by telephone, fax, E-mail or other appropriate measure. Telephone calls or other personal contacts should be documented in an appropriate manner.

Distribution list

The recalling firm must develop and provide an accurate consignee list detailing who received the affected/recalled product for the specified time period (e.g., 24 hours, last week, last month, last year). This distribution list must be provided to the Food Inspector and include the following information in a clear and legible form:

- the names of consignees, addresses, contact name, telephone numbers (this should include after hours contacts).
- a contact person for each consignee (if available), after hours contacts
- the date product was shipped to the firm and the amount of product shipped.

Additional information such as the quantity of the product and the date shipped to each consignee should also be requested, however, however the food business may need more time to submit this information.

Where a product specific distribution list is not be available, particularly in the case of smaller food businesses, a list of all direct accounts who may have received the products must be provided.

It is the responsibility of the recalling food business to identify their direct accounts; it is the responsibility of those direct accounts to provide subsequent distribution lists. It is particularly important to identify manufacturers, where the food was used as an ingredient for further production, as this will require investigation to determine, if the product containing the recalled food must be recalled or if there hazard was minimised or eliminated in the processing step.

Affected Product Removal/Correction / Destruction

The recalling food business shall take action to ensure the recall has been effective in removing the product from the marketplace. This means having a strategy to deal

with affected product and assessing the effectiveness.

The Food Inspector shall verify that the recalling food business strategy for dealing with the affected product to ensure that it includes the following:

- Halting the sale & distribution
- Segregating the affected product from other product, to ensure no confusion, and minimise the potential for inadvertent use or resale, redistribution of the recalled product
- Action, if appropriate, to be taken to remediate the affected product (e.g., recondition, relabelled, destroyed). Note: this action should be reviewed by and concurred by BAFRA

Documentation

The food business shall verify and document the effectiveness of the recall. This should include a combination of:

- Reviewing the quantity of product distributed, confirming the quantity of product returned.
- Reviewing the number of direct accounts who received the product, and the number of direct accounts who returned the product
- Validating by phone and/or in person the completeness of the recall.

The food business shall maintain records confirming that each account was contacted including:

- the date contacted, the method of contact, e.g. by telephone, fax and/or E-mail, and the name of the contact
- the response from the direct account including
 - confirmation of the recall by themselves and transmission to their direct accounts
 - confirmation of the amount of product they received, the amount forward to their direct accounts and the amount on site at the time of the recall
 - the action taken by each account, (e.g. halted sales, segregated product)

The Food Inspector should request that the food business documentation be summarised in a report form and submitted within a specified timeframe.

Time frame for reporting contact records to the Food Inspector is generally:

- within 48 hours for Class 1
- within 5 days for Class 2
- Class 3, to be determined on a case-by-case basis.

Follow up

The Food Inspector shall verify that the food business has undertaken appropriate follow up after completion of the recall. This includes:

- Ensure correction or disposition (rework, re-label, export, destruction, etc.) of the recalled product
- Review and correction of the processes or procedures to minimise or prevent future health hazards, non-compliance.
- Assess and review any problems with recall procedures and adjust recall plan as needed.

The lead inspection shall review the results of the recalling food business's recall activities; this activity is most effective when conducted on-site and is likely to include a review of documentation such as confirmed recall notices, receipts of returned product, telephone call reports and email confirmations.

Government Coordination

BAFRA shall ensure coordination among government organisations. This should ensure that the information with respect to the recall is provided to all ministries, by fax, email or phone as soon as available. If the product was exported, the food safety officer will provide international trading partners with information on the recall

The information provided should include:

- Recall classification
- Recall notice
- Public (news release)

As the Food Inspector receives the distribution list, the information about direct accounts should be sent to the districts in which they are located. This is particularly important for products subject to a class I recall.

The Food Inspector should continue to provide information to all districts about the implementation of the recall. In addition, as required, the Food Inspector may request assistance in further verification of recall products.

This may take the form of Government effectiveness checks, or where the industry recall has been ineffective, government recalls.

Government effectiveness checks

The purpose of the verification process is to assess the effectiveness of the recall measures taken by the recalling food business and other associated food business (i.e. distributors and retailers).

- Verification that the affected product has been controlled by removal from distribution and recovered.

- Verification that the corrective/disposition action for the affected product(s) has been evaluated and appropriate and acceptable, e.g. destruction, disposal, relabeling, over sticker, rework.

Developing the Effectiveness checklist

The Food Inspector should determine the types of consignees included in the list (e.g., distributor, retailer, further processing).

- If the list contains distributors or manufacturers, the appropriate BAFRA district office(s) should be immediately notified, so that distributors can be contacted to obtain a detailed list of retailers.
- If there are manufacturers in the list, separate food safety investigations would be initiated at each food business.

The Food Inspector should provide the list of direct clients, notice of recall, the public warning (if applicable) and any other information required to complete the effectiveness checks. It is also important to outline actions to be taken, when informed that a direct account was not informed of the recall. This should include ensuring the Food Inspector and the recalling firm are advised, so they can take appropriate action.

District inspectors assigned to undertake recall verification activities will:

- Review the recalling firm's distribution lists,
- Contact the direct accounts that are distributors and obtain those direct accounts (these should be provided to the Food Inspector, to be incorporated into the effectiveness checks)
- Investigate all food businesses that used the recalled food that as a raw material or ingredient (food safety investigation manual) to determine if the processing reduced or eliminated the hazard.

Recall effectiveness checklists can be found in Annex 2

The Food Inspector should, in consultation with OIC, prepare a recall effectiveness evaluation plan, including numbers and recommended time frames for completion. The plan will then be forwarded to districts where products have been distributed.

Estimate the actual number or best estimate of firms that may have received and/or distributed the recalled product, based on the distribution list provided by the firm and the distribution lists provided by the direct accounts.

- For Class 1 recalls, a minimum of 10% of onsite visits should be made to conduct effectiveness checks. Another 10% should be contacted by phone.
- For Class 2 recalls, 10% of clients should be contacted, with 5% contacted in person.

- For Class 3 recalls, effectiveness checks are determined on a case by case basis, and can include verification at the next inspection visit, as there is little or no health risk.

If there direct accounts which sell to susceptible populations likely to be affected by the recalled product (e.g., hospitals), they must be verified higher frequency, although the determination as to frequency is generally made on case by case basis.

Where the account contacted by an inspector has not received or taken action on the information, instruct immediate compliance with the instructions provided in the Notice of Recall. Immediately advise the Food Inspector of the deviations encountered who will contact the appropriate recalling firm

Verification results should be submitted via E-mail, fax, or phone. Verification activities should be given a high priority by all districts; however, there may be circumstances that delay the verification and/or reporting activities (e.g., other food safety investigations) that must be reported to the Food Inspector. In most cases, government verification results should be reported within a period of:

- Class 1: within a week
- Class 2: within 2 weeks
- Class 3: as established on case by case situation

As districts report on their verification activities, the Food Inspector should maintain a detailed summary of results in order to identify the effectiveness of the food business recall(s). This should identify recall process deviations with respect to the % of firms contacted by inspectors:

- How many consignees were contacted by the recalling firm or its direct accounts? (Process deviations, i.e., Notice of Recall not received within the established time frames, a secondary distributor did not provide notification)
- How many consignees had taken action as per the recall notice? (Process deviations – recalling firm's effectiveness check was not completed, problems not addressed)
- How many consignees were not notified of the recall but became aware of the recall by the media,
- How many consignees still have the product(s) on sale (Product deviations – i.e., recalled product remains available to the consumer).
- Identify action taken after the government notice
- Determine the effectiveness of the recalling firm's activities.

Some problems may be based on problems within a consignee (e.g., the product was removed in a store but was re-shelved by mistake) or based on problems with the recalling firm's processes (e.g., no notification). Determination of the effectiveness or ineffectiveness of the recall should take into account both the number and the nature

of the deviations.

Effective recalls

- The recalling firm's process can be considered effective if:
 - 98% of accounts contacted by inspectors received the notice of recall
 - 98% of those accounts took appropriate action, either on reception of the recall notice or on follow up by the recalling firm

Where recall is deemed ineffective, the recalling firm should be asked to repeat the recall in appropriate area/region. Inspectors should consider what measures could be taken with respect to consignees who received the information but did not take appropriate action.

Ineffective recall

If at any time during the verification of the recall, the recall effort is determined to be ineffective, it is important the Food Inspector discuss the situation with the responsible firm, to determine what action the responsible firm intends to take to improve its recall effort, such as issuing additional recall communications, etc.

If, after having notified of the ineffectiveness of their recall, the responsible firm is unwilling or incapable of extending or modifying its recall, the recommended actions to be taken (e.g., public warnings, product seizures or other appropriate legal and/or compliance actions)

Follow up – government

Follow up activities include:

- Verification that the recalling firm's recall strategy/plan/procedure is revised, as required and reviewed to determine its acceptability
- Where the recall identifies a new issue involving other manufacturers, consider need for policy/standard revision.
- Where industry wide trends are identified, consider further food safety investigations to ensure issues are adequately addressed

Government Implemented Recall

Where a food business refuses to implement an industry recall, the competent authority will assess all risk management options. Particularly for Class 1 recalls, the government may decide to contact all consignees to require them to remove the product from sale. This is generally accompanied by a public notice.

Distributors and wholesalers may also be asked to recall the product. In such instances, all other risk management actions should be considered with respect to the originating firm that refused to recall the food. This could include suspension or revocation of the food business licence under the Bhutan Food Act 2005; seizure of products within the plant and possibly prosecution.

Annexure 1:Public notification templates

Examples of wording for public alerts is provided below.

Allergy alert

Thimphu, (DATE) –The Bhutan Agriculture and Food Regulatory Authorityand (Company Name) arewarning people with allergies to (allergen) not to consume (product). The affected product(s)may/does contain (allergen) which is/are not declared on the label.

Affected product(s) description: (Brand name, Product name, Size, lot number, Manufacture date, Expiry date, other) and area of distribution.

There have been no.... reported illnesses associated with the consumption of (this/these) product(s).Consumption of this (these) product(s) may cause a serious or life-threatening reaction in persons withallergies to (allergen).

The (Name the company) is voluntarily recalling the affected product(s). TheBhutan Agriculture and Food Regulatory Authority is monitoring the effectiveness of the recall.

For more information, consumers and industry can call:
(Company name and phone number);

Food Safety Alert

Thimphu, (DATE) – The Bhutan Agriculture and Food Regulatory Authority and (Company Name) are warningthe public not to consume (product) because the product may be contaminated with (name the pathogen/toxin/hazard).

Affected product(s) description (brand name, product name, size, lot number, Manufacture date, Expiry date,other) and area of distribution.

There have beenno. of reported illnesses associated with the consumption of this (these) product(s).

Food contaminated with (name the bacteria, toxin, hazard) may not look or smell spoiled. Consumption of contaminated foodmay cause serious and potentially life-threatening illnesses. Symptoms may include (examples of symptoms, illness or injury), including potential permanent effects (e.g., seizures, strokes, kidney damage)

The (Name the company) is voluntarily recalling the affected product(s)from the marketplace.The Bhutan Agriculture and Food Regulatory Authority is monitoring the effectiveness of the recall.

For more information, consumers and industry can call:(Company name and phone number)

Annexure 2 – Recall Effectiveness

Review of industry distribution information

The Food Inspector should be working closely with the recalling firm with respect to distribution information. The inspector should request information with respect to product distribution and direct accounts. Preparation in advance of meeting with the recalling firm either in person or on the phone will make the process more effective. Questions should not provide the respondent with a “desired” answer – so to the extent possible should be open ended.

The intent is to understand if the recalling firm is capable of providing a detailed list (names, phone numbers etc.) within the time lines; the estimated number of consignees who are selling or could have received the recalled product; where the product was distributed. Some key questions include:

Distribution process:

- “Please describe how your product is distributed
 - how orders are taken?”
 - “How does the product flow from your location to the stores?”

Area of distribution

- “How far is your product distributed?”
- “Clarify the geographical distribution by provinces?”
- “Do you export the affected product?” If yes. “To which countries?”

Direct clients

- “Who are your direct clients? Do you know which of your clients received the products?
 - Are they retailers? Distributors, hospitals? Manufactures?
 - Are any cash and carry outlets?
 - “Was the product sold to public directly
- Approximately how many retailers sell the recalled product?” “How did you determine this number?”

Distribution list

- “How would you be preparing the list of your accounts for this product?”
- “Would you be contacting ALL your clients and how?” or a subset of clients
- “How quickly you can get the list of your accounts to us?”

Government Effectiveness Checks Procedures

Inspectors should follow a similar process in undertaking verifications procedures to

ensure consistency and clarity in communicating with industry. It is very important to record all the information and responses. The following steps should be used.

- 1) Ensure all reference documents are readily available (e.g., news release, recall notice, labels, blank effectiveness form)
 - a. For a site visit, ensure you take all reference documents with you with extra copies of documents that can be left with the firm.
- 2) For a site visit, inspect the shelves, to determine if the recalled product is on the shelf.
- 3) Call the consignee (Phone call) or Ask to meet with a representative of the firm (Site visit)
 - a. Identify yourself and ask to speak with a person responsible for product recalls
 - b. Ensure that the person you are speaking with has the authority to respond to product recall notifications and/or was involved in recall activities.
- 4) Explain the general purpose of your call/visit - "A product recall has been initiated; and this call/visit is intended to determine the effectiveness of the recalling firm's efforts. Your store was included in the distribution list provided to us by the recalling firm."
- 5) Initiate a discussion about the recall
 - a. "Please tell me about the recall notice?" Let the person describe the situation. If they cannot provide the information, it is appropriate to follow-up with specific questions, e.g. "Are you aware of a product recall conducted by recalling firm x of product y?"
- 6) If the person can provide information on the recall, seek further details:
 - a. "When and how did you become aware of this recall? Who " –
 - b. If notified by fax or letter, ask if a copy can be faxed or read to you and verify the date of receipt. If by telephone, who called you?"
 - c. Key is to compare the information on the notice of recall provided to consignee and the official notice of recall, including action requested by the recalling firm.
 - d. Was any of this product distributed to your clients (e.g., is company a distributor or wholesaler)? If so, have you taken any measures to relay the recall information to your clients? When, how and by who was this done?" If the client was notified by fax or letter? Could you provide me with a list of your clients? And could a copy be faxed to me or read over the telephone?"
- 7) Seek information with respect to product information and action:
 - a. "What happened once the notice was received?
 - b. "What quantity of the product did you have available for sale (e.g., on the shelves, in stockroom) when the notice was received from the recalling firm?"

- c. “What action was taken with this product?” “What did you do with the product that was removed” Once again let the person describe the activities and follow-up with specific questions, e.g., “While the product is segregated, until final disposal, how will you ensure that the product is not mistakenly returned to the store shelf?”
- 8) Other than retail sales to individual consumers, do you further distribute this product (act as a wholesaler...)? If so, have you taken any measures to relay the recall information to your clients? When, how and by who was this done? If the client was notified by fax or letter, ask to see a copy

If the firm has no knowledge of the recall, provide as much information as possible. If on the phone, read the recall notice, or provide a copy to the representative. Verify if the firm has received any of the recalled products, and if so, how much did they receive and how much is still available. Request the firm to remove it immediately from the shelves and action, as per the recall notice. Once the firm has confirmed that no further product is available for sale, provide a summary of the information to the Food Inspector.

Outcome:

At the end of the check make sure you have answers to all questions on the form and if there was a problem - cause is known and that the corrective action has been taken.

Recording Government Effectiveness Checks

Bhutan Agriculture and Food Regulatory Authority _____

District name _____ Recall information (Name of firm) _____

Inspectors name _____ Recall information (Product) _____

1) Name and Address of Food Premise ¹	2) Date/type of contact (yy/mm/dd) ²	3) Contact Name and Phone Number ³	4) Notification received and date (yy/mm/dd) ⁴	5) Supplier's Name and Phone Number ⁵	6) Recalled product available for sale ⁶	7) Recalled product action	8) Recalled product action	Further distribution

Notes: Additional comments

Summary	Total number of verifications		Effectiveness of recall			Distributors	
	On site	By phone	Notifications received (# of stores)	Product removed	Product remained on shelf.	# that contacted clients	# that didn't contact clients
Date/District							

- 1) Record the name and address of the food premise visited, including the city / town.
- 2) Record the date on which you conducted the visit or phone. Record “phone” or visit.
- 3) Record the name and phone number of the person at the food premise with authority on product recall notifications.
- 4) Notification received from recalling firm/supplier (Y/N): If they received notification by phone, fax or e-mail, record “Yes”. If notification was not received in any form, record “No”
- 5) Record the name and phone number of the supplier of the recalled product.
- 6) Recalled product offered for sale at time of visit/call:
 - a. If product is offered for sale, record “Yes” and the number of units found. Ask the store to remove the product from sale and segregate it appropriately. Proceed to question 7.
 - b. If product is not offered for sale, record “No.” and proceed to question 8
- 7) Ask how the recalled food will be handled and mark a) segregated by retailer; b. returned to supplier; c) relabelled.
- 8) If product was not available for sale at time of visit (verified physically) or time of call:
 - a. If recalled product is segregated and will not be mistakenly returned to the store shelves. Record “a”.
 - b. If product was returned to the supplier, review invoices/written documents. Record “b”.
 - c. If product was sold out at the time of notification, record “c”.
 - d. If the food premise did not receive the recalled product, record “d”.
- 9) Distributes further (Y/N) Ask the responsible person “Other than retail sales to individual consumers, do you further distribute this product (act as a wholesaler...)?” If the account further distributes, ask them to prepare a distribution list.

Notes/Additional Comments: Inspectors may add any additional comments at the bottom of the form