

## **PRODUCT RECALL**

### *What is a food recall?*

Food manufacturers use many controls to make sure that the products they produce are safe. Sometimes, for many different reasons, a product may be manufactured and sold which may make some people ill or injure them, or is in violation of the legislation. When an unsafe or violative food product has left the control of the manufacturer, it must be removed from the market. Not all violations imply a recall. This process of removing the product is called a “recall”. If your firm has imported a product that is unsafe or violative and you have sold the product to someone else, you must recall the product.

### *What is the goal of this guide?*

Ask yourself these questions.

“If you needed to remove a product from the market right now, would you be able to do it?”

“Would you be able to remove the product quickly?”

“Would you be able to remove all of the product?”

The goal of this guide is to provide you with an overview of how to develop a recall plan and how to action that plan in the event of a recall. It will assist you in identifying unsafe products that you have received and sold.

### **MAKE A RECALL PLAN**

Recalling a product is a planned action. This section of the guide describes how your firm can develop a written recall plan prior to having a recall. This will help you remove unsafe or violative product(s) that your firm has imported and sold, from the market quickly and efficiently.

There are eight basic elements that should be included in your recall plan. All of these elements must be included; each element plays a specific role and provides a different benefit to your firm.

Recall Management Team

Complaint File

Tracing of Products and Suppliers

Distribution Records

Recall Product Records

Recall Procedures

Recall Effectiveness Procedures

Testing the Recall Plan

## **1. RECALL MANAGEMENT TEAM**

### **Benefits**

When an unsafe food product has been identified it must be removed from the market quickly. Identifying persons in your firm and assigning recall duties to each person will allow you to action your recall plan smoothly. You can be assured that all of the procedures are covered. Also, many recalls happen after regular work hours so you must be prepared to contact people outside of the office/plant. The list of people who make up your team should be reviewed and updated on a regular basis.

**Description**

Your team should include people responsible for:

Decision making

Quality assurance / technical advisory

Media communication

Complaint investigation

Contacting accounts

Contacting the regulatory authority

Legal Counsel

Your recall management team document should include the following:

RECALL MANAGEMENT TEAM				
NAME	ALTERNATE PERSON	BUSINESS PHONE	AFTER HOURS PHONE	RESPONSIBILITIES DURING RECALL
Person's name and position in the firm	a replacement individual in the event that the person is not available			the duties of the person during a recall

**2. COMPLAINT FILE****Benefits**

If you receive a complaint, it is important to record the complaint information, complete an investigation at your storage facility, and contact the regulatory authority. Early action on your part may enable you to discontinue distributing the product until it is determined that the product is safe.

**Description**

There are three main parts to the complaint file:

Recording of the initial complaint information

Investigation at your storage facility

Action taken for the specific product

**Recording of the Initial Complaint Information**

The complaint should be recorded by a designated individual(s). It is important to include enough information so that the manufacturer of the product can start an investigation of the problem immediately. This may include but is not limited to:

Complainant details

name, address, telephone number (s) of the complainant

What is the problem with the product, e.g. chemical taste, allergic reaction, illness, object in the food

Product details

package type and size

product name

identifying codes

does the complainant have a sample of the product?

Retail Details

name and address of store

date of purchase

Illness and Injury Details

when was the product consumed (date and time)

has the product been consumed before

number of persons consuming the product

number of person(s) ill

names and ages of the person(s) ill

amount of product consumed

time the person(s) became ill

symptoms of illness in order of occurrence

physician consulted / physician name, contact number, date of contact

current status of illness

description of injury

current status of injury

Has the complaint been referred to anyone else?

### **Investigation at the Storage Facility**

It is important when you receive a complaint to make sure that the problem with the product did not result from activities at your storage facility. Investigate the complaint fully. **If you determine that the problem was caused by activities in your storage facility, contact the regulatory authority immediately.**

Record in your complaint file:

the name of the person at your firm who investigated the complaint

date and time of the investigation

investigation findings

other products which may be affected by the problem

### **Complaint Referral**

If you determine that the problem was not caused at your storage facility, refer the complaint immediately to the manufacturer who produced the product.

Record in your complaint file:

the name of the person at your firm who referred the complaint to the manufacturer

the name of the person contacted at the manufacturing or importing firm

date and time of the referral

### **Action Taken**

Although the problem with the product may have been caused at the manufacturing plant outside of Canada, it is your responsibility to determine the action to be taken with the product. **Where the problem could be of a health and safety concern, you must contact the regulatory authority to ensure that your action decision is correct.** Once the decision has been made you should record:

what the action is, i.e., recall, no recall

instructions to give to your accounts regarding the disposition / return of the product

## **3. TRACING OF PRODUCTS**

### **Benefits**

Being able to identify which product(s) have to be recalled is a great benefit to your firm. It allows you to limit the scope of the recall and remove the product(s) from distribution

quickly and accurately. If you cannot identify a specific product(s) you may have to recall more product than is necessary. Furthermore, incorrect identification of all of the product during the first recall, may lead to other recalls. To do this, you must be able to trace the products that you have received and distributed.

### **Description**

To limit your recall to a specific product(s) you must:

Link the products you have received to each supplier

Distribution Records - link the products you have received to the accounts you have distributed the product to.

### **Receiving Records**

All products that you receive should be identified with a specific lot code. You should have a system in place that identifies and records the lot codes of each product you have received from each supplier.

For each supplier you should document:

the definition of a lot for each product

the parts and interpretation of the code(s) (obtained from the supplier)

a description of the system you are using to link the lot codes from the supplier to your shipping records

## **4. DISTRIBUTION RECORDS AND DISTRIBUTION RECORD SYSTEM**

Benefit

When the product is being shipped out of your storage facility into the distribution system, the lot codes of each product should be linked to the accounts receiving that product. This completes the link of the product from supplier - to your firm - to the accounts. Keeping this link is important; it enables you to limit your recall to the specific accounts that received the product being recalled. Your firm should have a record system which can generate these records accurately and quickly.

### **Description**

Your firm should be able to create a distribution list that is product **and lot code specific**.

This distribution list should include:

name of the account, street address, city, province

the product name and lot code

the type of account, for example: manufacturer (if you are distributing a product which is used in the manufacturing of another product), distributor, retailer

who to contact at the account

telephone number and other contact numbers consistent with the documented method of contact during a recall, e.g. fax number, e-mail address

amount of product shipped to each account

These distribution records should be kept for a period of time that exceeds the shelf life of the product. In some instances the period of time is specified in by regulations. Check with the regulatory authority to ensure that you are maintaining your distribution records for the correct period of time.

## 5. RECALLED PRODUCT RECORDS

### Benefit

For your own protection, keep records of products that you have recalled from your accounts.

### Description

Your recalled product records should contain:

a description of the product recalled: brand and product name, size, identifying codes

the amount of product recalled

the date the product was recalled

what you did with the product, for example, returned to the supplier, destroyed

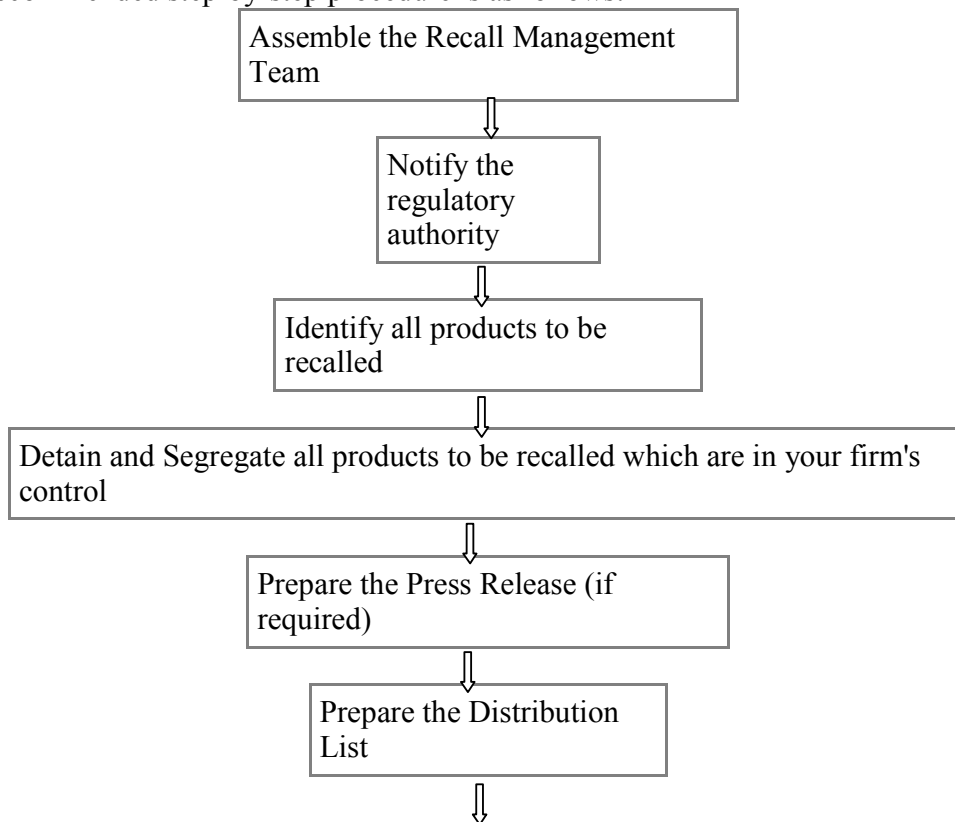
## 6. RECALL PROCEDURES

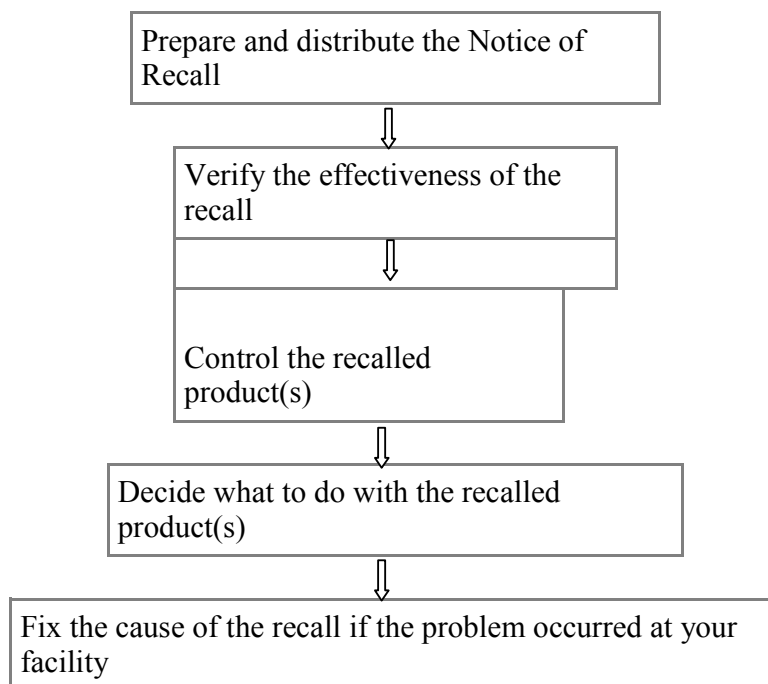
### Benefit

There are several activities that happen simultaneously during a recall. Having a step-by-step recall procedure will ensure that all of the activities are completed. This is the plan that you will action during a recall. A brief description of each of the recommended steps is included below.

### Description

The recommended step-by-step procedure is as follows:





## 7. RECALL EFFECTIVENESS PROCEDURES

### Benefits

Your firm is responsible for ensuring that all of the accounts that you shipped the recalled product to are notified about the recall. You must assess the effectiveness of your notification. The actual process of how to notify accounts is described in Tab 3 of this guide.

### Description

The recall effectiveness procedure includes a plan to assess the effectiveness of the recall.

Elements of the plan should include:

the number of accounts that were notified of the recall

the number of accounts that were contacted or checked to see if they had received the recall notification

method of confirming that the accounts were notified

a statement describing how you determine if your recall notification was effective

a statement of the recall notification effectiveness, i.e., satisfactory, not satisfactory

a statement of the corrective action to be taken where it is determined that the recall was not satisfactory

## 8. TESTING YOUR RECALL PLAN

### Benefit

During a recall, your firm's recall management team will be busy putting your recall plan into action. This is not the time to find out that your recall plan is not working or that the plan does not provide the information you need to remove the unsafe product from the market completely and quickly. Testing your recall plan before you have to do a recall, enables you to identify and correct problems in your plan.

## **Description**

Your recall plan should be tested on a regular basis.

When you test your recall plan, pick a lot code of a product which you know has reached the consumer market. Then test your system and record:

a description of the test scenario, for example: “An investigation resulting from a consumer complaint of a problem with “Product AA” determined that the product was contaminated and that the product should be removed from the market immediately”

the date of the test

problems you identified during the test

for each problem you identified during the test, how you changed the recall plan to correct the problem.

## **ACTION YOUR RECALL PLAN**

Steps to an Effective Recall

### **Introduction:**

This guide described how your firm can develop a written recall plan prior to having to conduct a recall. These written elements form the basis for:

identifying health and safety concerns in your existing food safety systems

contacting and working with the regulatory authority

assigning recall duties to specific individuals in your firm to ensure that all parts of the recall are covered

tracing and identifying products which are affected by the problem

tracing product shipments

controlling returned product

checking the effectiveness of your recall

testing your written recall plan to ensure that it is efficient and effective.

All of these elements should be developed and documented prior to conducting a recall.

The goal of this section of the guide is to describe, in detail, each of the key steps your firm should take once it has been decided that a recall will be conducted. These recommended steps include the preparation of a Notice of Recall, and in some circumstances, a press release. Your firm should review these sections prior to conducting a recall so that you will be familiar with the document requirements and their purpose. It would be beneficial for your firm to maintain “templates” or to prepare sample documents that can be used as examples during a recall. This will speed up the process and ensure that all of the necessary information is included.

### **STEP 1: ASSEMBLE YOUR RECALL MANAGEMENT TEAM**

At the very beginning of the recall your firm must:

Make sure all members of the recall management team are informed of the decision to conduct a recall

Ensure that each member knows their responsibilities during the recall

### **STEP 2: NOTIFY THE REGULATORY AUTHORITY**

Notify the regulatory authority immediately when you suspect that your firm has imported and sold a product that may pose a serious risk to consumers. Provide the

regulatory authority with the following information:  
a detailed description of the nature of the problem  
the name, brand, size, lot code(s) affected  
details of complaints received and any reported illnesses  
the distribution of the product - local or national  
when the product was distributed (specific dates)  
label(s) of the product(s) which may be recalled  
the total quantity of product imported and distributed  
the name of your firm's contact with the regulatory authority  
the name and telephone number(s) for your firm's after-hours contact  
This information is pertinent for the regulatory authority to develop an accurate and complete risk management strategy.

### **STEP 3: IDENTIFY ALL PRODUCTS TO BE RECALLED**

It is your firm's responsibility to ensure that all products that need to be recalled are identified. In addition to those products directly affected by the problem, your firm must:  
determine if any other codes, brands or sizes of the same product are affected  
determine if any other products are affected

### **STEP 4: DETAIN AND SEGREGATE PRODUCTS TO BE RECALLED WHICH ARE IN YOUR FIRM'S CONTROL**

It is your firm's responsibility to ensure that products to be recalled that are in your firm's control are not distributed. Your firm must:  
determine the locations of the recalled product(s) e.g. on-site, at the plant, off-site storage  
determine the amounts at each location  
identify and segregate products to prevent distribution

### **STEP 5: PREPARE THE PRESS RELEASE (if required)**

The purpose of a press release is to alert the public that a product presents a serious hazard to health. Not all recalls require a press release; the regulatory authority will advise you when a press release is necessary. Where the regulatory authority is not in agreement with a press release prepared by your firm, the regulatory authority may issue a separate press release.

During this step, your firm must:  
decide who will prepare the press release, your firm or the regulatory authority  
if your firm decides to prepare the press release, include all relevant information  
complete the press release within two hours after being notified of the recall  
submit a draft of the proposed Press Release to the regulatory authority for approval

### **STEP 6: PREPARE THE DISTRIBUTION LIST**

Using your distribution record system, produce a **product and lot code specific** distribution list which:  
identifies the accounts that received the recalled product  
lists the accounts names and addresses, contact names and telephone numbers

identifies the type of account e.g., manufacturer, distributor, retailer  
**Provide the distribution list to the regulatory authority 24 hours.**

### **STEP 7: PREPARE AND DISTRIBUTE THE NOTICE OF RECALL**

Your firm is responsible for immediately notifying all of the accounts that received the recalled product.

**content of notice** - prepare a written notice which includes all relevant information  
**confirmation of receipt/ action** - ask customers to confirm that the notice has been received and action has been taken

**approval of notice** - submit the draft notice to the regulatory authority for approval. Where a Notice of Recall contains inaccurate information and/or is incomplete, the regulatory authority may require your firm to revise the Notice and reissue it.

**method of transmission**- Transmit your Notice of Recall to your accounts by the method stated in your distribution records system, e.g. fax, telephone, e-mail

**follow-up** - contact customers who have not responded to your request for confirmation of receipt of the Notice of Recall

**record-keeping** - keep records of those accounts which your firm has contacted and which accounts have confirmed that they have received the Notice of Recall

### **STEP 8: VERIFY THE EFFECTIVENESS OF THE RECALL**

verify that your accounts have stopped distributing and selling the recalled product(s) product(s)

verify that the recalled product(s) have been returned to the designated place(s) as stated in your Notice of Recall

It is the responsibility of the regulatory authority to follow up with some of your accounts to verify the effectiveness of the recall. Where it is determined that the recall was ineffective, your firm may be required to repeat the recall process.

### **STEP 9: CONTROL OF THE RECALLED PRODUCT(S)**

Your firm is responsible to ensure that recalled products do not re-enter the market.

separate and clearly identify recalled product(s)

reconcile quantities and monitor returned product(s)

record the recalled product(s) in your Recalled Product Records document

### **STEP 10: DECIDE WHAT TO DO WITH THE RETURNED PRODUCT**

The action to be taken on the recalled product should be approved by the regulatory authority.

decide on the action to be taken on the recalled product e.g., correction, re-export, destruction

find out if the regulatory authority wants to witness/verify that the action has been taken

verify that the action has been effective

record the action taken for each product in your Recalled Product Records document

## **STEP 11: FIX THE CAUSE OF THE RECALL**

As the firm that imported the unsafe product, it is your responsibility for ensuring that all reasonable steps are taken to prevent similar recalls in the future.  
put controls in place or revise existing controls to prevent similar problems in the future

### **COMMON PROBLEMS WITH RECALLS, POTENTIAL IMPACTS AND RECOMMENDED SOLUTIONS**

Listed below are some common problems, potential impacts and recommended solutions associated with some of the steps in the Recall Procedures.

#### **1. PRESS RELEASE AND NOTICE OF RECALL**

##### **Problems:**

the hazard is not clearly described  
the urgency of the recall is not clearly stated  
the key message is obscured by other information, e.g., advertising  
instructions to consumers are not clear

##### **Potential Impacts:**

distributors, retailers and consumers may not understand the seriousness of the hazard  
hazardous product may not be removed from sale or distribution in a timely manner  
consumers may use the recalled product before they are aware of the hazard  
the regulatory authority or the recalling firm may have to issue a second press release

##### **Recommended Solutions:**

state the hazard clearly e.g., Undeclared (Allergen) in (Product name)  
put the word **URGENT** in the title of the notice  
be brief and to the point, do not include promotional information  
tell consumers what to do with the product e.g., destroy, return to the store for a refund

#### **2. PREPARATION OF THE DISTRIBUTION LIST**

##### **Problems:**

the list is not provided to the regulatory authority within 24 hours after the firm is notified of the classification of the recall  
key information in the distribution list is missing e.g. contact names, addresses, phone numbers  
the list is not readable e.g, the print is too small or letters are not clear  
the list includes customers who did not receive the recalled product(s)

##### **Potential Impacts:**

recalled product which has not been removed from sale is not identified in a timely manner  
consumers may purchase and use the recalled product  
verification of the effectiveness of the recall may be significantly delayed

##### **Recommended Solutions:**

develop the ability to identify customers who received specific codes of product quickly  
develop the ability to prepare an accurate, complete distribution list within 24 hours

#### **3. INFORMING THE REGULATORY AUTHORITY OF A RECALL**

##### **Problems**

regulatory authority is not notified of the recall  
regulatory authority is notified days or weeks after the problem is identified by the importer

**Potential Impacts:**

hazardous product may not be removed from distribution and sale in a timely manner  
consumers who purchased the product may use it before they are aware of the hazard

**Recommended Solution:**

notify the regulatory authority immediately if you suspect a product that your firm has manufactured and sold may pose a risk to the health of consumers

#### **4. IDENTIFICATION OF PRODUCT(S) TO BE RECALLED**

**Problems:**

all of the sizes, lot codes, brands of affected product are not identified  
other products affected by the recall are not identified

**Potential Impacts:**

hazardous product may not be removed from distribution and sale in a timely manner  
consumers may use the recalled product before they are aware of the hazard  
the regulatory authority or the recalling firm may have to issue a second press release  
the firm may have to conduct a second recall

**Recommended Solutions:**

determine and include all of the product manufactured from the time the problem started to the time the problem was resolved  
consider other products imported from the same manufacturing firm and produced on the same line or using a similar process

#### **5. NOTIFICATION OF CUSTOMERS**

**Problem:**

the firm decides to remove the product from the retail level without informing customers of the recall

the notice of recall is not written, the firm has no record of what was said to customers

the notice of recall is mailed to customers

customers are not notified until days after the recall was classified

customers are not notified

**Potential Impacts:**

distributors, retailers and consumers may not be aware of the hazard

distributors, retailers and consumers may not understand the seriousness of the hazard

hazardous product may not be removed from sale or distribution in a timely manner

consumers may use the recalled product before they are aware of the hazard

the regulatory authority or the recalling firm may have to issue a second press release

**Recommended Solution:**

inform all customers of the recall immediately and in writing

#### **6. CONTROL OF THE RECALLED PRODUCT**

**Problems:**

recalled product is accidentally shipped to customers

recalled product is sold to consumers

**Potential Impacts:**

retailers may sell the recalled product

consumers may purchase and use the recalled product

**Recommended Solutions:**

segregate and clearly mark recalled product(s)

take precautions to ensure that the product is not accidentally released

## **7. VERIFYING THE EFFECTIVENESS OF THE RECALL**

**Problems:**

the recalling firm does not verify that the notice of recall was received and action was taken

the recalling firm does not check to determine if the recall was effective

**Potential Impact:**

recalled product which has not been removed from sale is not identified in a timely manner

**Solution:**

implement the “Recall Effectiveness Procedures” described in the guide

## **GENERAL REFERENCE INFORMATION ON RECALLS**

**Definitions**

“Mandatory recall” means a recall where the Minister believes on reasonable grounds that a product regulated under an Act or provisions that the regulatory authority enforces or administers poses a risk to public, animal or plant health. The Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister.

“Product Withdrawal” means a firm’s removal from further sale or use of a marketed product that does not violate legislation administered or enforced by the regulatory authority. It is not considered to be a recall.

“Public Warning” is a news release that pertains to a specific food recall. The title of this form of communication is “WARNING”. The public warning is issued for those recalls requiring the recall of a product to the consumer level.

“Recall” (verb tense) means for a firm to remove from further sale or use, or to correct, a marketed product that contravenes legislation administered and/or enforced by regulatory authority.

“Recall” (noun tense) denotes the process of recalling the affected product and encompasses all tiers of the affected product distribution system.

“Recall Classification” means the numerical designation, i.e. Class I, Class II or Class III, assigned to a particular product recall to indicate the relative degree of health risk presented by the product being recalled.

“Recall Depth” means the level to which a recall is conducted (consumer, retail, distribution).

“Recalling firm” denotes a responsible firm that is accountable for the implementation of a recall.

“Stock Recovery” means a firm’s removal or correction of a violative product that has not been marketed or that has not left the direct control of the firm. It is not considered to

be a recall.

“Violative Product” is product that violates legislation administered or enforced by the regulatory authority.

“Voluntary Recall” means a recall that is initiated and carried out by the recalling firm without ministerial order.

**Recall Classifications**

“Class I” is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

“Class II” is a situation in which the use of, or exposure to, a violative 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 violative product is not likely to cause any adverse health consequences.