

Chapter 10

DEVELOPMENT OF A RECALL PLAN

1.0 WHAT IS A RECALL?

- 1.1 When is a Recall Necessary?
- 1.2 What is the Facility's Role and Responsibility?

2.0 TRACEABILITY – THE BACKBONE OF RECALL

- 2.1 What Traceability is and Does
- 2.2 Traceability and the Production Team
- 2.3 Linking Information Throughout the Chain
- 2.4 Defining Traceability Policies

3.0 RECALL PROCESS

- 3.1 Visualizing the Recall Process
- 3.2 How to Develop a Recall Plan

4.0 STOPPING DISTRIBUTION AND CONTROLLING PRODUCT WITHIN THE FACILITY

- 4.1 Communication Plan

5.0 CHECKING THE EFFECTIVENESS OF COMMUNICATIONS

- 5.1 Mock Recall

6.0 CUSTOMER COMPLAINT FILES

- 6.1 Recording Complaints
- 6.2 Investigating Complaints
- 6.3 Corrective Actions
- 6.4 Illness or Injury Complaints

7.0 RECALL FORM TEMPLATES

8.0 SOURCES OF INFORMATION

1.0 WHAT IS A RECALL?

Recall is the process of quick and efficient removal of questionable food from the supply chain and reaching consumers.

All food recalls have the following aims:

1. Stopping the delivery and sale of the product(s) in question;
2. Informing the appropriate regulatory agencies, such as the Canadian Food Inspection Agency (CFIA); and
3. Timely removal of the product from the marketplace.

The manufacturer has final responsibility for removing products of concern from the marketplace. Manufacturers must remove such products before they cause damage or injury. With a good system for traceability or tracking and a carefully prepared action plan, a recall is likely to be successful. It may also cost the facility less money.

1.1 When is a Recall Necessary?

Any food safety emergency can trigger a recall. Examples include:

- Willful or intentional product contamination;
- Human error (including failure of the prerequisite programs);
- Mislabeling;
- Industrial accidents;
- Pesticide contamination;
- Foodborne illness outbreak;
- Packaging defects; and
- Real or threatened product tampering.

There are a number of sources to use to check these concerns. Sources may vary as to their usefulness at fully understanding the problem.

Sources include:

- Consumer Complaints – Consumer complaints can be sketchy or unclear. They may not provide much detail. Always ask those making the complaint for specific information including the product code, dates, where they bought the product, etc.
- Distributor or Retailer Complaint – Often these complaints are just as unclear as consumer complaints. Distributors or retailers usually tell the facility about a concern when they see repeated complaints about the company or products.
- Suppliers – Suppliers may find something wrong in their own products. A supplier's internal inspections may lead them to recall their own products throughout the supply chain.
- Internal Inspections – Deviations that breach critical control points, or prerequisite programs, can reveal products that don't meet standards. End-product testing may also alert facilities to problems.
- Government Inspectors or Agencies – The Canadian Food Inspection Agency (CFIA) carries out numerous food safety projects and inspections every year. Problems may be found through random testing, inspections or investigation of consumer complaints.
- Health Authority Illness Investigations – Alberta Health documents all outbreaks of foodborne illness. If they are able to track outbreaks to a specific product or lot number, this information can be used to trigger a recall.
- Tampering Threats – No matter what the source of a tampering threat, always track this information completely so the facility can confirm possible affected products.

No matter where the information comes from, take any complaint that involves a health hazard seriously. Check it immediately.

1.2 What is the Facility's Role and Responsibility?

Product recalls are a shared responsibility. Industry, government, and consumers all have roles to play to ensure the rapid, efficient recall of unacceptable product.

However, it is the responsibility of the facility to ensure product safety.

If the potential of a food safety hazard exists, it is the facility's duty to work with the CFIA. This is true even if the processor is not a federally registered facility.

Tell the CFIA immediately if the facility believes their products may put consumers at risk. This includes products the facility has made, processed or sold. Telling the CFIA immediately allows for a quick, efficient and thorough recall.

Facilities are generally responsible for:

- Suggesting the scope or size of the recall;
- Preparing and giving out all communications; and
- Deciding what to do with the recalled product.

Be prepared to supply the necessary regulatory agencies (CFIA, Alberta Health Services, or Alberta Agriculture and Rural Development) with the following information:

- A detailed description of the problem;
- The name, brand, size and lot codes affected;
- Details of complaints received and any reported illness;
- Where the product has been distributed or shipped (locally, provincially, nationally, or internationally);
- When the product was distributed;
- Example label(s) of the product(s) in question;
- The total amount produced and distributed;
- The name, phone number or other contact information (email, cell number) of the facility's after hours representative.

Sometimes the media (TV, radio, newsprint) communicates to consumers the need to recall a product.

The more detailed and specific this information is, the better. The CFIA may need this information to develop a complete risk management plan for a recall.

Role of Government Agencies

The Canadian Food Inspection Agency deals with all product recalls, along with help from Health Canada (providing health risk assessments). This falls under the Canadian Food and Drug Act and Regulations.

The CFIA may take the lead role in investigating and coordinating food safety emergency responses, or it may choose to have the facility keep them fully informed. Regional health authorities or provincial inspectors may also take part in the recall process. This will depend on the situation. All these regulatory agencies are available to help the facility, for investigations and recall activities.



The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588>

2.0 TRACEABILITY – THE BACKBONE OF RECALL

Traceability is the backbone of any quick and efficient recall. Using recorded information to trace a food item is absolutely necessary. This helps to decide where the product is in the supply chain.

Recorded information to trace includes the food item's:

- History
- Application
- Use
- Location

Being able to track a food item forward or backward through the supply chain can help control costs by reducing the amount of product recalled or destroyed.

Food safety and traceability are both very important issues for governments and industry. Numerous programs to introduce tracking and tracing methods in the food supply chain are underway worldwide.

'Traceability' and 'Product Tracing' are both used to describe such procedures. Since traceability is most common, that is how it will be referred to in this chapter.

It is impossible to give an exact cost for setting up a traceability system. This depends on the technology used. It also depends on the information recorded and what is involved in making the product. Location, customer base and the length of supply chain also affect cost.

2.1 What Traceability is and Does

Generally, traceability systems are record keeping procedures. They show the route a raw material took from the supplier. This includes the supplier's steps to produce the product. It also includes the supply chain from distributors or customers, to consumers.

Any traceability system includes:

- Identification of units / batches of all raw materials;
- Identification of units / batches of all finished products;
- Information about when and where the product(s) were used, transported or sold; and
- A complete system to link this information.

Note that trade items are tracked routinely for availability, inventory management and logistical purposes.

Traceability is a 'reactive' – or after the fact – food safety tool. It lets manufacturers and agencies follow the path of a unit and/or lot of products downstream. It tracks these throughout the supply chain, as they move between different companies or customers.

In order for it to be effective, a traceability system must identify where a particular supply chain unit came from. Check records held by previous owners in the supply chain. Units are usually traced for purposes such as recall and complaints.



See Form F.18: Supplier/Customer Contact List.

A traceability system's goal is to:

- Manage risks related to plant/animal health issues (e.g. BSE, genetically modified materials);
- Promote informed consumer choice by offering label information on product quality and ingredient history;
- Create trust in the marketplace with fair trade practices (e.g. show that organic products really are organic); and
- Improve product quality and processes (e.g. better inventory tracking systems).



Can-Trace identifies industry requirements for a national whole-chain food tracking and tracing standard. Can-Trace's goal is to develop a standard to set up traceability based on international standards. It's a voluntary program developed by Canadian industry. To help the facility develop programs, check out Can-Trace's resources (Traceability Evaluation Tool), standards (Canadian Food Traceability Data Standard) and other materials (Can-Trace News, press clippings, and more) at www.can-trace.org.

2.2 Traceability and the Production Team

The main responsibility for traceability falls on the facility's manufacturing team.

Manufacturing happens when raw materials are blended, formed and processed. Remember, each raw material in a product has a history. Tracking lets the manufacturer understand how this history affects the product.

However, the manufacturing team does not work alone. Traceability requires a collaborative effort by the whole production team. Other key players may include:

Research and Development – These staff members are the facility's 'gatekeepers.' They are responsible for finding out how good suppliers are at tracing their own product. They can help shed light on the suppliers' tracking systems before raw materials enter the facility.

Purchasing and Receiving – These staff members must understand the importance of traceability information to a facility. It's their job to make sure this information is collected upfront, before materials enter production.

IT or Management – The facility's IT or management need documentation systems to internally track ingredients. They will coordinate these systems with suppliers so that the operation's information needs are met. It's important that the facility can easily get hold of this information and understand it.

Operations Staff – These staff members create the link between raw ingredients and finished products. They will record information to trace materials through the production process. They must understand the importance of this information and know where to find it.

Shipping Staff – Shipping staff are responsible for creating the link between product information and the customers. They need to understand the importance of recording production dates for all materials shipped. These staff members make up the last step in the production chain.

Train all key staff on traceability. The right information in the tracking system upfront helps create positive end results.

2.3 Linking Information Throughout the Chain

Traceability requires not only getting information but also using this information.

If a food safety issue is caused by raw materials, traceability back to the supplier increases chances of correcting the problem. It also helps prevent this problem from happening again.

Track ingredients throughout the production process:

- When an ingredient enters production, record its lot number; and
- Link it to a formula or to production information.



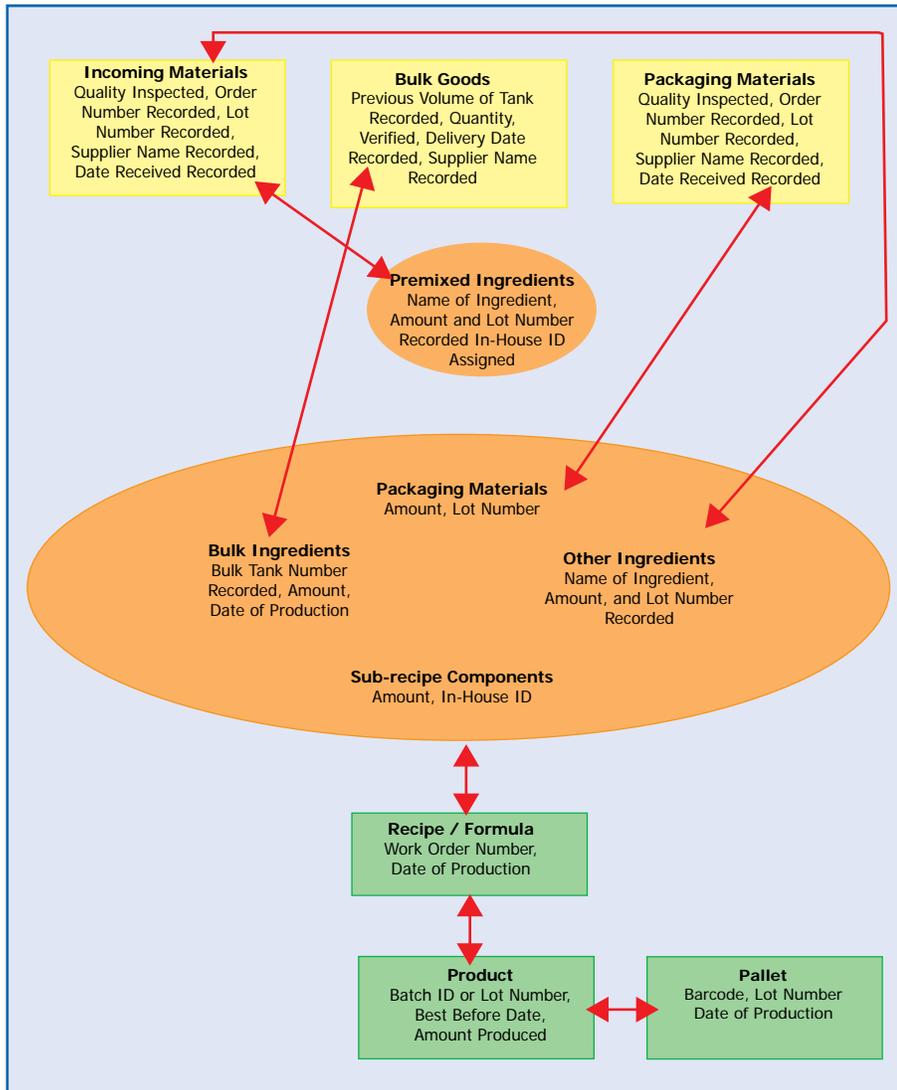
See *Form F.13: Raw Material Input*.

Give each production run an in-house lot number. This lot number can carry information such as:

- Expiry date;
- 'Best Before' date;
- Job or work order number; and
- Other useful or important information.

A good system will track every movement. It will track not only the product's movement, but also the movement of every part or ingredient in the product.

Figure 1: This diagram shows how information is linked within an in-house traceability system. It shows the flow from raw materials (at the top) to finished product (at the bottom).



2.4 Defining Traceability Policies

Most confusion in developing traceability systems is about defining the right unit size. Unit size includes:

- Batch
- Individual container
- Box of containers
- Volume of product

Often unit size is set according to how a particular process is managed. Each manufacturer must develop its own traceability policies.

Here are some key areas where decisions or policies must be developed:

- Continuous and Batch Processing – Processors must be able to safely separate and identify batches.
- Handling of Bulk Products – These products tend to be mixed with earlier deliveries. So even when they come with clear batch identification, forward traceability may not be possible.
- Rework – Just because rework is traceable does not reduce the chances of contamination. Contaminants can be spread over large amounts of production and over long periods of time. Any rework can seriously influence a product recall.
- Water Used for Processing – Water must be potable and water source traceable.

Each of these key processing areas must be addressed.

The more key information products carry with them, the better the chances of finding and removing them from the marketplace swiftly. Ideally, the facility wants traceability procedures that ensure the greatest safety for the product at the least cost to the operation.



GS1 Canada is a not-for-profit, industry led association. It develops, promotes and maintains global standards. It does so for the identification of goods, services, locations and related e-commerce communication. Check out the GS1 Canada website (www.GS1ca.org) to investigate standards, including the Canadian Food Traceability Data Standard. There are also other materials and services available to help a facility develop traceability programs.

3.0 RECALL PROCESS

The steps in a recall are usually the same for all products.

For any recall, the facility must:

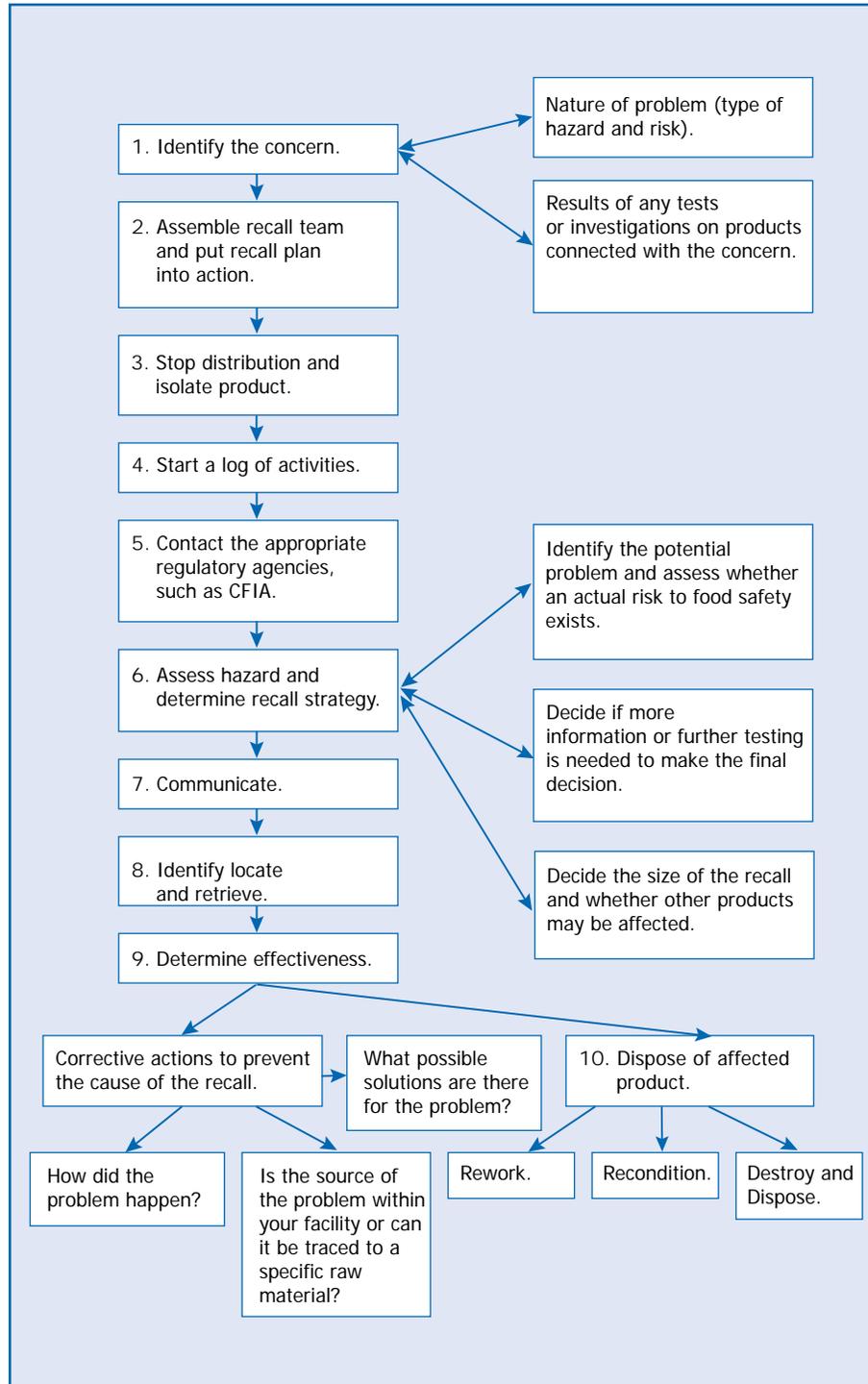
1. Identify the concern or problem;
2. Assemble the recall team and put into action the recall plan (Steps 3 - 11);
3. Stop distribution and isolate the product(s);
4. Start a log of activities;
5. Contact the appropriate regulatory agencies, such as the Canadian Food Inspection Agency (CFIA);
6. Assess hazards and decide on a recall plan;
7. Communicate;
8. Identify, locate and retrieve the affected product(s);
9. Determine how well the recall is working;
10. Get rid of the recalled product(s); and
11. Fix the cause of the recall.



The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588>

3.1 Visualizing the Recall Process

Recall Step by Step



Step 1 – Identify the concern or problem.

There are a number of situations that can lead to recalls. Some cause bigger problems than others. However, all such situations can threaten consumers in some way.

The following are possible triggers of a recall:

- Allergens;
- Communicable diseases (e.g. E. coli, Salmonella, Listeria);
- Foreign materials that are not part of the regular food manufacturing process;
- Damaged packaging (e.g. broken seals, faulty seams, etc);
- Notifications from suppliers;
- Tampering or tampering threats; and
- Undeclared or unintended ingredients.

The following information is important to help identify and assess each recall:

- Type of hazard;
- Type of risk; and
- Test results or investigations on products relating to the cause for the concern.



See Form F.16: Recall Hazard Assessment Form.

Step 2 – Assemble the recall team and put the recall plan into action.

Immediately assemble the facility's recall team. Everyone has a role with the process. The sooner the team is assembled the smoother the process can flow.

Put into action the facility's recall plan ensure that all the necessary activities are being performed. Document all activities.

Step 3 – Stop distribution and isolate the product within the facility.

As soon as the facility becomes aware of a problem, immediately stop all further production and/or distribution of the product. This will help to narrow down the problem. Label any suspect product as 'ON HOLD.' Keep this label until it's known whether it's safe or connected with the problem.

The size of a recall will vary from small quantities to large amounts of product. A good product coding system and traceability program makes it easier to narrow down affected product. The easier it is to narrow down the problem, product loss and costs are minimized.

Step 4 – Start a log of the activities.

Record keeping helps the manufacturer prove due diligence. For food recalls, record keeping is particularly important. Record all actions, including decisions and reasons for them. At least one member of the recall team should be named as record keeper. That person should keep an accurate diary of all activities connected with the recall.



See Form F.15: Recall Activities Log.

Step 5 – Contact the appropriate regulatory agency.

Communication is very important and it starts within the plant. Once the required facility staff are aware of the situation and have set aside the recalled product within the facility, broaden communication to include the regulatory agencies.

First, contact the Canadian Food Inspection Agency (CFIA) to ensure that the action or decision is correct. The CFIA staff can help with investigations. They should be notified of all food related health and safety actions taken on a recall, or on a possible recall. Each region in Canada has a CFIA Recall Coordinator who can reach the right CFIA staff.



See Form F.1: Authority Recall Information Form.

Step 6 – Consider the hazard and decide on the recall plan.

Once the CFIA has been contacted, consider the hazard of concern and decide on corrective actions. If the CFIA becomes involved, the Office of Food Safety and Recall (OFSR) will decide the recall classification for the situation. However, the facility, along with the CFIA representative (if one is assigned), is responsible for doing an initial assessment.

This initial assessment will:

- Identify the potential problem and decide whether there is an actual risk to food safety;
- Decide whether more information or further testing is needed to make the final decision; and
- Determine the size of the recall and whether other products are affected.

The OFSR uses the information from this initial assessment and gives the recall a risk classification if necessary. Depending on the classification or level of recall, the CFIA has required actions. The CFIA representative will explain these requirements and communicate the next steps of the recall process.



See Form F.16: Recall Hazard Assessment Form.

Step 7 – Communicate.

The key to any successful recall is communication. Depending on the class of recall, the facility may have to communicate not only with customers, but also with media. From the start, make sure this communication is truthful and accurate. Make it clear and to the point. Different situations require different levels of detail.



The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588>



See Form F.10: Notice of Recall.

The facility is responsible for notifying all customers or accounts. Notify anyone that may have received the affected product.

Prepare a written notice with all necessary related information. Before handing out this notice, the CFIA may need to approve a draft.

As part of communications, always ask customers to confirm that they received the notice. Ask customers also to confirm they have taken action.

Follow up with customers and make sure they received the notification if the facility does not receive an answer. Keep ongoing records of all these activities.



See Form F.2: Communications Log.

Step 8: Identify, locate and retrieve.

Once all customers have been contacted, develop a plan for recovering and disposing of affected product.

Just as it's important to keep track of amounts manufactured and shipped, it is also very important to keep records of all returned product. This gives the facility a cross-reference that can reveal how well the recall is working.



See Form F.12: Production Numbers Record, and Form F.7: Defective, Suspect and Recalled Product Receiving Form.

Step 9: Determine the effectiveness of the recall.

The first step in assessing a recall's effectiveness is to make sure communication is working. The CFIA will also check up on how well the facility's recall communication is working and will do spot checks with customers. They will find out whether notification was received. They will also check on whether product is still available for sale and, if so, why.

If the CFIA has not become involved, it's a good idea for the recall team to undertake these activities.



See Form F.8: Effectiveness Questionnaire.

The second step in assessing a recall's effectiveness is accounting for all affected product. Require customers to document how many units they had at the time of receiving the recall notice. This will provide the recall team with numbers to compare against production figures.

Depending on how much time passed between product distribution and product recall, some recalled product may have been sold. Therefore, it may not be possible to get all the affected product back.

Examine the seriousness of the situation. Examine how much of the affected product is not accounted for. The facility may have to issue a public warning about the product.



See Form F.11: *Product Reconciliation*.

Step 10: Dispose of affected product and put in place corrective actions.

When all of the related products have been returned, decide on how to deal with affected product. There are three options available:

- Rework
- Recondition
- Destruction and disposal

The CFIA or another appropriate regulatory agency should first approve any decision regarding recalled product disposal. Use the Activities Log to record the action taken for each product.



See Form F.15: *Recall Activities Log*.

Step 11 – Fix the cause of the recall.

If it has not already been done, determine the cause of the recall and decide on a solution. To show due diligence, the manufacturer is responsible for ensuring that all reasonable steps have been taken to prevent similar recalls in future.

Depending on the cause of the recall, the CFIA may return to the facility later to check on corrective actions and to see if they are working.

3.2 How to Develop a Recall Plan

Once the recall process is understood set up a plan that prepares the facility in case a product recall is needed. Put this recall plan in writing. The plan must show how a facility will make sure that unsafe product is recalled quickly and effectively.

The recall plan must have procedures and policies to be followed in regard to:

- Raw material tracking throughout the production process;
- Product coding;
- Customer complaint files;
- Situation analysis and ways of informing relevant government agencies;
- Stopping distribution of products within the facility;
- Distribution records and distribution record systems;
- How to inform customers, and public (if necessary) about the recall; and
- Roles of recall team members.

Raw Material Tracking

Recalls can be started in various ways.

Ask the following questions:

- Is the recall team prepared to act upon a recall by one of the raw material suppliers?
- If an investigation of a complaint finds a problem with one of the raw materials, can the recall team decide which products may be affected?
- Can the recall team follow raw materials throughout the production process to know what products are affected and which are not?

As explained, traceability is the backbone of the recall process. With a good traceability program in place, it will be easy to narrow down what needs to be done during any recall. It also may help reduce related costs.

Julian dates are three digit codes used to show the manufacture date.

Product Coding

All products should be coded correctly and easy to understand. The identified recall team member will use this information to tell customers what products are associated with any recall activities. Any recognizable method of coding is acceptable. Letters are often used to single out the month a product was packed (e.g. Jan, Feb, etc.).

Correct record keeping of these codes lets the recall team trace the cause of consumer complaints. It also helps control distribution and inventory. It ensures product rotation, and if necessary, helps in carrying out a recall.

Record an explanation of the product coding system within the recall plan. For example, define what letters are used to signify the month, and what order the information is being recorded in (e.g. month/ day/ year, day/month/year, etc.).

HOW SHOULD I CODE MY PRODUCT?

Since it should be possible to identify the product by the year and day it was packed, 'Best Before' dates make sense for product coding. They allow for ease in tracing back the product to the exact date of production. If the facility decides to use this type of coding, it is also important to have some form of batch coding. This helps to identify between several batches processed on the same day. If more than one processing facility is involved, each facility must be shown. Be sure to code all cases and individual containers so they can be read easily. And remember that whatever code is used, the facility will need to be able to explain it to both the customers and/or regulatory agencies.



4.0 STOPPING DISTRIBUTION AND CONTROLLING PRODUCTS WITHIN THE FACILITY

It is in a facility's best interest to immediately hold back all affected recalled products that are still in its control. They should also prevent any further distribution of this product.

This is most easily accomplished by giving one member of the recall team responsibility for conducting an in-house stock assessment. Ensure they isolate any stock that may be related to the problem.

The most efficient way to isolate stock is to identify the product(s) through signs or labeling. These should indicate clearly that the product is 'On Hold.'

When labeling product this way, it is important to maintain control. The sign or label should have the following information:

- 'On Hold' marked clearly;
- Date that the action was taken;
- The initials or name of the person placing the product on hold; and
- Statement that no product is to be disposed of without clearance from the recall team or management.

When the problem and affected lot numbers have been found, develop a plan for recovering this product from distribution. Keep accurate records to help limit the recall and to help produce information accurately and quickly.

The record system should allow for creating a distribution list. This list should give both the specific product codes and lot codes.



See *Form F.5: Distribution Status Record – Sales*, and *Form F.6: Distribution Status Record – Shipping*.

The distribution list should include:

- Name of customer and address (including city and province);
- Type of account (e.g. manufacturer, distributor, retailer, restaurant, etc.);
- Product name and lot code;
- Primary contact at the account;
- Telephone number, and other contact information (email, fax, after-hours phone number); and
- Amount of product shipped to the customer.



This information could be gathered from Form B.11 - Shipping Record and Form F.18 - Customer Contact List.

However, the identified recall team member may need to reference other documents to ensure all effected product is accounted for and customers are notified.

For these records to help in a recall, make sure those responsible for the information have enough training. They must understand why the information is important and why it needs to be recorded.

4.1 Communication Plan

The recall communication system can be set up in various ways. Whatever method is used, be sure to control all information released.

Most companies control information by using communication templates or guidelines. This helps to ensure that any written communication is clear and concise. It also shows the company is concerned.

If a recall involves a health risk, include a definition of this health risk in public communications or press releases. Also include some form of medical explanation. Provide some background on the situation. In this way the media are less likely to define the problem. They'll also be less likely to develop the information on their own.



Templates or guidelines for recall communication are available on the CFIA website <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588>

Keep in mind that different levels of information are required for different groups. Different forms of communication should be used when dealing with:

- CFIA
- Retailers and distributors
- Media
- Consumers

The facility is responsible for immediately notifying all accounts (customers or distributors) that may have received recalled product(s).

5.0 CHECKING THE EFFECTIVENESS OF COMMUNICATIONS

If the CFIA becomes involved it will check how well the facility's recall system is working. It will do so by random surveys of the customers. This helps the CFIA confirm that all affected product(s) are removed from the marketplace.

Where the CFIA decides that the recall efforts are not good enough, the recall may have to be repeated.

If the CFIA has not become involved, it's a good idea for the facility to do an internal or in-house assessment of the communication. This is most easily accomplished by using recall effectiveness checks. These checks involve phoning customers who may have received the affected product(s). Check to find out whether they received notice, removed the product from sale and that they understand the actions requested.



See Form F.8: Recall Effectiveness Check – Questionnaire.

In some situations companies use communication firms. This helps to remove some of the work associated with recall communication.

5.1 Mock Recall

The purpose of a mock or trial recall is to test how well the written recall procedures work. Every time there is a mock recall, the facility will learn a little more. A drill lets the facility adjust the plan before there is a real recall. The middle of an actual recall is not the time to test a recall plan. At this time the recall management team will likely be too busy with the actual recall.

A mock recall should be able to answer the following questions:

- Does the facility's system run smoothly?
- How easily can the facility trace and recover the recall products?
- Can the facility look at the lot identification records and find out what ingredients the recalled products have in common?
- Does the plan have the necessary information to work during extreme situations (e.g. if management is not available)?
- Does the plan let the facility recover and account for all affected products with the help of production numbers?
- Is the record keeping good enough to show where affected products have been shipped?

Every time the facility runs a mock recall, it will likely need to 'fine tune' the system. Almost all companies have to adjust their recall system several times.

Scenarios

When testing the recall system, consider using these scenarios:

Test the system forward from the raw ingredient level.

Example: "Our firm received a phone call from Supplier X telling us that ingredient ABC, lot number XXX, has been contaminated. All products related with this ingredient should be pulled from the marketplace immediately."

Test the system backwards from the finished product.

Example: "Our firm recently investigated a complaint. We found that product RQP in the XX-gram-size packages was unsafe. It should be removed from the marketplace immediately."

Test the system internally.

Example: "We recently received notification from our supplier that there may be a problem with ingredient ABC, lot number XXX. The supplier has asked us to put all associated products and ingredients not already distributed on hold until further notice."

If the facility finds shortcomings in the system, adjust the process.

At the end of each mock recall, let the recall committee suggest ways for improvement. Make the results of the mock recall available to all staff.

Record Keeping

As with an actual recall, maintain records during the entire mock recall process. These should include:

- All related recall records;
- A description of the test scenario;
- The date of the test;
- Problems found during the test; and
- Actions needed to correct each problem found (e.g. changes to recall plan, training, etc.).



See Form F.9: Mock Recall Record.

As with the recall plan, the facility should provide a procedure and documentation plan for mock recalls.

6.0 CUSTOMER COMPLAINT FILES

Customer complaint files are the most important part of record keeping relating to recalls. Be absolutely sure to record every customer complaint received. Investigate the basic cause of the complaint.

Accurate files of customer complaints let the facility identify trends or problem products and they help in choosing corrective actions.

The three parts of any customer complaint file are:

1. Recording the original complaint information;
2. Investigating the complaint and recording of findings; and
3. Corrective actions taken based on what the investigation found.

6.1 Recording Complaints

For each complaint, record the following information:

- Source of complaint and contact details;
- Separate quality and food safety issues;
- Description of the problem (e.g. illness, allergy, foreign matter, chemical taste, quality issue);
- Details of injury or illness (where applicable);
- Whether anyone else or an agency has been contacted (e.g. CFIA, Public Health);
- Product details including product name, package size, identifying codes; and
- Retailer information including store where product was bought and when.



See Form F.4: Consumer Complaint Form.

6.2 Investigating Complaints

Check into all complaints right away, no matter how small. Have a trained person in the firm investigate.

The goal of any complaint investigation is to answer the following questions:

- How did the problem happen?
- Is the source of the problem within the facility or can it be traced to a specific raw material?
- Does the problem affect any other products?
- What possible solutions are there for the problem?



See Form F.3: Complaint Investigation Form.

6.3 Corrective Actions

Once all the results of the investigation findings have been written down, decide on corrective actions. If the complaint relates to a product recall, contact the CFIA to ensure that the action plan is suitable.

Record the following:

- Who approved the decision;
- When the decision was approved;
- What corrective action was taken for affected products; and
- Whether the corrective action fixed the problem.



See Form F.3: Complaint Investigation Form.

6.4 Illness or Injury Complaints

If the facility receives a consumer complaint regarding possible illness or injury, take the following steps.

1. Direct the customer to the local public health authority or doctor for medical care. If a connection can be found between the product and the illness, the health region will forward the information to the CFIA. Health Link (1-866-408-5465) is the best resource to help the complainant decide where to report the incident.
2. Contact the appropriate regulatory agencies such as the CFIA. These agencies may send a representative to the plant to help find the source of the problem.

It's important that employees be considerate and helpful to anyone who claims injury or illness. Find out if the person making the claim has had any medical follow-up. Record all details of the complaint including where and when the product was bought, lot code, 'Best Before' date, how it was prepared, when it was consumed, and with what.

Whatever information the facility can get from the person(s) making the complaint will help the investigation.

If the facility can find some of the product in question (if appropriate), keep it refrigerated or frozen in case testing is needed. If the facility has records of test results already on hand, attach a copy to the complaint record.

Be sure to keep copies of all documents related to the particular product and code with the complaint record. If necessary, hand it over to the CFIA or health authorities.

Situation Analysis and Informing Relevant Government Agencies

The recall team is responsible for assessing the situation and for coordinating all parts of the product recall. The original assessment must be done in a timely manner. Find out the following information immediately:

- What is the potential problem and is it a food safety risk?
- Is more information needed (e.g. further testing, expert advice) to make a decision?
- Does the product need to be taken off the market while a complete review is done? Is it an emergency situation?

Notify the CFIA immediately if the facility thinks the products may be a risk to consumers. The Office of Food Safety and Recall (OFSR) determines how serious and what class the recall is.

The CFIA will provide the facility with a link to OFSR to speed up the process. These agencies have their own procedures for making decisions. This means the CFIA staff member working with the facility may not be the person making the final decision.

The facility must be able to supply the CFIA with the following information:

- A detailed description of the problem;
- The name, brand, size, and lot code(s) affected;
- Details of complaints received (especially any reported illnesses);
- The distribution of the product (including customers, dates, and amounts);
- Label(s) of the products that may be affected;
- Total quantity of product manufactured and distributed; and
- The name and number of the facility's after-hours contact.

This information allows the CFIA to develop a complete and correct risk management plan.

If there is missing information, keep a record of all the information that's been asked for. In doing so the facility will be prepared if it's necessary to contact the CFIA again.

7.0 RECALL FORM TEMPLATES

- F.1 Authority Recall Information Form
- F.2 Communications Log
- F.3 Complaint Investigation Form
- F.4 Consumer Complaint Form
- F.5 Distribution Status Record – Sales
- F.6 Distribution Status Record – Shipping
- F.7 Defective, Suspect and Recalled Product Receiving Form
- F.8 Effectiveness Check Questionnaire
- F.9 Mock Recall Record
- F.10 Notice of Recall
- F.11 Product Reconciliation
- F.12 Production Numbers Record
- F.13 Raw Material Input
- F.14 Sample Raw Material Input
- F.15 Recall Activities Log
- F.16 Recall Hazard Assessment Form
- F.17 Recall Management Team
- F.18 Supplier / Customer Contact List

8.0 SOURCES OF INFORMATION

1. Food Science and Human Nutrition Department, University of Florida, Gainesville. The Food Recall Manual. <http://edis.ifas.ufl.edu/pdffiles/FS/FS10800.pdf>.
2. Kaletunç, Gönül and Özadali, Ferhan. Understanding the Recall Concept in the Food Industry. Ohio State University Extension Fact Sheet. <http://ohioline.osu.edu/aex-fact/0251.html>.
3. Food Standards Australia New Zealand. Food Industry Recall Protocol 5th Edition (2004). http://www.foodstandards.gov.au/_srcfiles/5th%20FIPR_june04.pdf.
4. Canadian Food Inspection Agency Agriculture and Agri-Food Canada, and Canadian Council of Grocery Distributors. Supply Chain Food Product Recall Manual (2003 CFIA).
5. Canadian Food Inspection Agency Food Recalls: Make A Plan And Action It! Manufacturers' Guide (2001).
6. Electronic Commerce Council of Canada Tracking and Tracing of Food Products in Canada (2003). <http://www.can-trace.org/portals/0/docsTrackingAndTracingInitiativeWhitePaper.pdf>.