

It's all about managing food.

Food Recall Plan Template For Food Distributors

What to Do In The Event Of a Product Recall

Every Food Distributor and Food Manufacturer must track the products they manufacture and distribute. Food Decision Software Inc. (FDS) has taken all the applicable information regarding product recalls and recall planning and has summarized it so you can create your own Recall Plan.

What is a Food Recall?

Food producers use many controls to ensure the safety of their products. Despite their best efforts, however, sometimes unsafe food products, or those that do not meet legislative requirements, make their way into the marketplace. When an unsafe or violative food product has left the control of the manufacturer/distributor, it must be removed from the market. This process of removing the product is called a recall.

Any food recall has the following aims:

- Stopping the delivery and sale of the product in question;
- Informing the appropriate regulatory agencies; and
- Proper and timely removal from the marketplace of the product in question.

What is a Recall Program?

The ability to remove products from the market quickly and effectively is vital to every food producer and distributor. A recall program is a written action plan that is carefully constructed, tested and evaluated to ensure efficiency. It is the safety net that can prevent consumers from buying or eating a potentially harmful food product.

Having an efficient recall program may reduce a company's liability, while a non-existent or poor recall program can have serious economic and legal consequences. For a small processor or distributor, a recall can be a very traumatic experience. Being properly prepared for a recall can make the difference between a recall being a learning experience or a nightmare.

Parts of a Recall Program

A Distributors Recall Program can be broken into 8 parts. Each part plays a specific role and gives a different benefit to your company. These parts are often linked to other food safety programs that may be in place.

Downloading and Using the Available Templates

There are a number of templates that can be downloaded for the various portions of a Recall Plan. FDS has provided forms that can be completed using Microsoft Word®. By clicking in the gray field, you can maintain the form without the need for reformatting.

FDS has provided space for your applicable company logo and address. Delete the FDS logo and company address and add your own logo and address to each sheet you use. Please Do Not remove the disclaimer at the bottom of the templates.

1. Recall Team

Identifying recall team members and assigning recall duties enables the recall procedures to be conducted quickly and smoothly. The recall program should also identify the person who will coordinate the recall. The recall coordinator should have the authority to call upon other recall team members as needed to address the issues at hand. Because many recalls happen outside of regular working hours, after-hours contact information should be included in any recall team list.

Your team should include people responsible for:

- Decision Making
- Quality Assurance/Technical Advisory
- Media Communication
- Complaint Investigation
- Contacting Customers
- Contacting your regulatory body (FDA, FSIS or CFIA)
- Legal Counsel

Download the "**Recall Management Team Members**" template and enter the applicable names that will be on your Recall Team. Remember to add people as alternatives in the event the primary contact is not available at the time of the recall. If you need additional sheets, indicate at the bottom how many pages have been used.

The list of people that make up your team should be reviewed and updated on a regular basis. The person updating the list shall sign and date the pages.

2. Complaint file

When a complaint is received, it is important to record the details and start an investigation immediately. Early action on your part may enable you to identify potentially unsafe products and correct problems or enable you to stop selling/distributing the product until it is determined that it is safe.

A complaint file should consist of:

- Complainant Information This should include information about the person who made the complaint (name, address, telephone numbers, any illness or injury)
- Problem Details The problem with the product (allergic reaction, illness, object in the product, chemical taste, etc.)
- Product Details The product name, lot code or production date, package type and size, other identifying codes, is there a sample of the product.
- Retail Details name and address of the store purchased and the date of purchase
- How the Complainant stored and handled the product
- Detailed Illness Inquiry Find out as much as possible regarding when the product was consumed, how many persons are ill, ages of people that are ill, etc.

- Complaint Referred? Has the complaint been referred to anyone else? This could be Public Health, FDA, CFIA, FSIS, etc.
- Investigate the complaint and record the findings
- Ensure that all products that may have been affected are investigated by a trained person in your company
- Record the details of the investigation (persons name, date, findings, other products that might be effected).
- Take action based on investigation findings
- Contact the Manufacturer of your findings.
- Once all findings are in place, contact the appropriate government agencies to discuss and ensure your actions are correct.

Download the "Consumer Complaint Form" template and either have easy access to the form directly from your computer or have copies accessible. It is important to ask all the right questions. Having the form in front of you will ensure all the right questions are asked. There is a "Complaint Number" field on this form that must be completed. It really does not matter what the number is as long as it is used throughout the complaint and investigation process. A suggestion might be to include the day, month and year in the number and then maybe a sequential number (i.e. 041109 could indicate the 4th day of November, 2009).

Designated people within your company should be familiar with the "Consumer Complaint Form" and your staff should be made aware of who is responsible to receive the information in the event a consumer complaint is received. These people shall be placed on the "Recall Management Team Members List".

Download the "Complaint Investigation" template. This document is to be used by the person who is responsible for investigating the Consumer Complaint. Notice that the Complaint Investigation has a "Complaint Number" field. This shall be the same number as that identified on the "Consumer Complaint Form".

If the investigation outcome suggests that you have sold or distributed an unsafe or violative food product, it is your duty to contact your regulatory agency immediately, as they can assist with the investigation and the collection of information to help make the right decision. The person responsible for this task must have the authority to contact the regulating authority and the Manufacturer of the product(s) in the event this is warranted.

At this time, a file must be created of the complaint and investigation.

3. Recall Contact List

A recall program should contain a contact list with the names, phone and fax numbers of the appropriate regulatory agencies. As there are local contact numbers for regulatory agencies, we have provided the website links so you can find those applicable to you.

Food Safety and Inspection Service (FSIS) Index of local offices and Phone numbers

http://www.fsis.usda.gov/Contact_Us/Office_Locations_&_Phone_Numbers/index.asp

Canadian Food Inspection Agency contact #'s in case of recall

http://www.inspection.gc.ca/english/fssa/recarapp/recarappe.shtml#rp

The contact list should also contain the phone and fax numbers, after hours contact information, primary contact and email address of all your suppliers and customers. Every company you distribute to should be listed on this document.

Download the "Recall Contact List" template. If you do not have a compiled list of names of Customers, Suppliers, and Regulatory Agency's, complete the list and keep it up to date. Someone in your organization shall be responsible for maintaining the list.

If you have access to lists of Suppliers and Customers with the applicable information, you can take copies of those lists and attach them to this list so a complete listing is readily available.

WinFDS Built-in Functionality – Generating a list of all your Suppliers and Customers is part of the functionality built into WinFDS. Being able to generate a report that lists the Supplier who delivered the product and all Customers that have been shipped a specific product with specific lot number is also part of the functionality built into WinFDS.

4. Traceability

Being able to determine which products need to be recalled allows you to limit the scope of a recall. If the specific affected products cannot be identified, you will need to broaden the scope of the recall, often recalling more products than necessary, which results in more financial losses. If the products are incorrectly identified, another recall may be necessary.

As a Distributor, traceability of products involves record-keeping procedures that provide you with the information of products that have been received and distributed.

To develop a traceability system:

- Link the products you receive from each Supplier.
- Link the products you have received to the accounts you have distributed the product(s) to. This can be achieved by including the lot codes sold to each customer on distribution records.

Each manufacturer and distributor should develop their own traceability policies. The more key information products can carry with them, the better the chances of finding and removing them swiftly from the marketplace.

If you do not have a system that allows you to track products received from a Supplier, you can download the "**Product Receipt Record**" template. This document will give you the ability to enter all the products that you want to track from your Supplier. It provides space for information such as Supplier, PO Number, Date Received, Product Code, Quantity, Lot Number and Expiry Date. Using this form will allow you to track your products as they are received.

As with the "**Product Receipt Record**" template, the "Product Distribution Record" template provides you the ability to track products that are shipped to your Customers. If you do not have a system that allows you to track products shipped to your Customers, download the "**Product Distribution Record**" template. It provides space for information such as Customer, Customer Order Number, Date Shipped, Product Code, Quantity Shipped, Lot Number and Expiry Date. Using this form will allow you to track your products as they are shipped.

If products are sold through a retail area, it is not necessary to know the amount sold to each individual customer. However, it is your companies' responsibility to know the amount of product sold through the retail system.

WinFDS Built-in Functionality – Maintaining the traceability path from receiving goods to knowing exactly how much product was sold/distributed and how much is still in the warehouse is part of the functionality built into WinFDS

5. Recalled Product Records

It is beneficial to develop recall product records to ensure that recalled products are controlled and do not get into the hands of Customers. Such records should include the name of the product being recalled, the amount, the date the product has been recalled and the corrective action taken for each product.

Download the "Recalled Product Receiving Record" template. This document will provide the ability for you to enter all the applicable information necessary when a recalled product is received back into your facility.

6. Recall Procedures

Every recall plan should contain a step-by-step explanation of what to do when a product needs to be recalled. Following this plan will help ensure that important steps are not overlooked during this time of crisis. Recall procedures should be readily available and should explain product coding, product traceability, and distribution records. Develop all necessary forms to be used in case of a recall, as well as a media release form if necessary.

The steps in any recall are similar for all products. For each recall, the Manufacturer should:

- Identify the concern
- Assemble the recall team
- Notify your applicable regulatory agencies
- Identify all products to be recalled
- Segregate (put on hold) affected products that are in your control
- Prepare a distribution list
- Prepare a press release (if necessary)
- Notify customers (informing them what to do with the recall products)

- Control recalled products and decide what to do with them
- Dispose of recalled products
- Fix the cause of the recall

Download the "Distributor Recall Procedure" to use when a recall occurs. The checks within the document will ensure that no steps during a recall have been overlooked.

As each Distributor has their own method of coding and distribution, a document was not created indicating your specific Recall Procedures. However, we have listed what should be included in the document.

- An explanation of how your products are coded
- An explanation of how your product traceability is performed
- An explanation of how you receive products and how the traceability codes are maintained
- An explanation of how you ship products and how the traceability codes of products being shipped are maintained.

Download the "Communications Log". This document shall be used during a recall to document every call that is made to every effected Customer and Regulatory Agency.

The "Notice of Recall" and "Press Release" can be downloaded. The "Notice of Recall" template can be used as your fax document. As discussed above, each effected Customer shall at a minimum be called and sent a fax of the recall. If the product recall was a result of something that happened in your facility, a Press Release might be required. We have provided the applicable information that is required in the Press Release.

7. Recall Effectiveness

A company recalling a product is responsible for notifying all customers who bought the affected products. They should also verify that all customers have stopped the distribution of the affected products, and that all recalled products have been returned to the Distributors' control or other designated area as instructed in the recall notification.

In order to ensure all effected Customers know of the recall, an "**Effectiveness Check**" questionnaire can be downloaded and used. This document is used to contact each Customer to ensure they have received notice and are aware of the recall.

8. Testing the Recall Program

Mock recalls test a company's ability to recall products without actually recalling them. Mock recalls are strongly suggested and should be tested on a regular basis. The goal is to be able to identify every affected lot, know exactly where it is and know who to contact to bring it back. A mock recall can be an eye-opener: some Distributors discover that they are not as prepared as they thought.

Mock recalls should test both product-tracking and your internal recall process.

Results of the practice must show that a Distributor is able to handle a recall situation (a 95-100% efficiency rating). If deficiencies are identified, correct the problems and retest the program with another mock recall.

Download the "Mock Recall Record" and use it during every Mock Recall. They say "Practice makes Perfect". You want to be ready in the event that your company has to perform a recall.

Which Government Agencies Deal with Recalls?

Depending on if you are in the United States or Canada will depend on the Government Agency that will deal with product recalls.

In the United States – The United States Department of Agriculture Food Safety and Inspection Service (FSIS), deals with product recalls for meat and poultry in the United States. For egg products and all other products the U.S. Food and Drug Administration (FDA) deals with all other products. The FDA or FSIS may take the lead role in investigating and coordinating food recalls, or just require that the processor ensure they are kept informed.

In Canada - Under the Food and Drug Act and Regulations, the <u>Canadian Food Inspection Agency</u> (<u>CFIA</u>), with help from <u>Health Canada</u> (which provides health-risk assessments), deals with product recalls for all food processors/distributors in Canada. The CFIA may take the lead role in investigating and coordinating food recalls, or just require that the processor/distributor ensure the CFIA is kept informed.

All of these regulatory agencies are also available to help with investigations and recall activities.

Recall Decision

Recalls are usually initiated by the manufacturer or distributor of the unsafe product, sometimes at the request of the regulating agency. These are called voluntary recalls because they are initiated and carried out by the manufacturer or distributor without a regulatory agency order.

If a processor or distributor refuses or chooses not to conduct a recall, the regulating agency may order the processor or distributor to conduct the recall.

Recall Classification

There are three levels of food product recalls. The classifications identified by the US and Canada are the same and indicates the relative degree of health risk posed by the product being recalled:

Class I

A situation where serious adverse health consequences (possibly even fatal) may result if the product is consumed. A public alert is usually issued.

Class II

A situation where a health hazard might exist but the probability is remote. A public alert may be issued.

Class III

A situation where the consumption of the product is not likely to cause health problems. A public alert is not usually issued.

References

Food Safety and Inspection Service (FSIS) Index of local offices and Phone numbers: http://www.fsis.usda.gov/Contact_Us/Office_Locations_&_Phone_Numbers/index.asp

FDA's Regulatory procedures Manual (Chapter 7):

http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf

Recall for Provincial Meat and Poultry Processors:

http://www1.agric.gov.ab.ca/\$department/newslett.nsf/all/fss14804

The Canadian Food Inspection Agency - Food Recalls: Make a Plan and Action it! Manufacturers' Guide: http://www1.agric.gov.ab.ca/\$department/newslett.nsf/all/fss14804

The Canadian Food Inspection Agency - Food Recalls: Make a Plan and Action it! Distributors' Guide: http://www.inspection.gc.ca/english/fssa/recarapp/rap/dgguide.shtml

Health Canada: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/proces-eng.php

Disclaimer

The information provided in this document has been compiled from a number of reputable sources that have granted FDS permission to use all or part of their information. FDS has in its best effort compiled the information to provide a much needed process for producing Food Recall Plans. The following companies and Government Agencies shall not be held responsible for any information used from their sources to compile this procedure:

- Food Decision Software Inc. (FDS)
- United States Food and Drug Administration (FDA)
- United States Department of Agriculture Food Safety and Inspection Service (FSIS)
- Alberta Agriculture and Rural Development
- The Canadian Food Inspection Agency (CFIA)

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