** MONTANA WHOLESALE FOOD**

**Food Recall Plan GUIDELINES**

Rev 11.14.14

The purpose of this document is to assist food processors in developing a food recall action plan. A recall plan is a written document to ensure that specific foods are removed from commerce that may be injurious to health.

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Acidified food and low-acid canned food processors are required by Montana rule ARM 37.110.101 (1) (p)/21CFR108.25 (e) and 21 CFR 108.35 (f) to create and maintain a written recall plan. The food processor must ask the distributor to follow the recall plan.

The following criteria must be part of implementing a food recall plan:

1. **Product identification**
2. **Notification system**
3. **Product collection**
4. **Product storage**
5. **Product control/security/deposition**
6. **Recall effectiveness assessment**

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| **Product Identification**  **The recall plan must include a method to identify the product that needs to be removed from commerce.**  Acidified food and low-acid canned food processors are required to keep records about products they create. These records may be used to identify the product.  Some of the required records include use of a log to document critical factors for each food batch or lot. Every batch or lot must be properly coded on the log and package label. The batch code must include items that identify the establishment, production year, production day and packaging period per ARM 37.110.101 (1)(u)/21 CFR 114.80 (b) and ARM 37.110.101 (1)(t)/21 CFR 113.100 (a). |
| **Notification system**  **The recall plan must include a method to notify the Food and Drug Administration about a food recall, and ask any and all product distributors to follow the recall plan.**  The notification plan should include:   * Organization names (product recipients, local health officials, state health officials, FDA, media outlets, etc.) * Personnel names * Personnel job titles * Telephone numbers * E-mail addresses * Physical addresses of organizations * Mailing addresses of organizations * Assignment of roles and responsibilities for personnel   Most of the time, a written media release is the most effective way of notifying consumers about a recall. Written recall notices issued to the public should be done in cooperation with the FDA, local or state health officials. The media release should include the following:   * Product name * Product photo * Batch code * Description of the hazard * Instructions to the public on how to return or dispose of recalled product that is in their possession * Company contact information |
| **Product collection**  **The recall plan must include a written method about how recalled products will be collected.**  Written details must be stated on the plan regarding how reasonable efforts will be made to remove the recalled products from commerce. In addition, any products still under the firm’s control must be segregated from other foods and stored in a secure manner.  This part of the plan should include:   * Description about how consumers will be notified to return or dispose of recalled product that is in their possession * Description about how retailers will be notified to return or dispose of recalled product that is in their possession * Names of carriers that will retrieve product from the marketplace (trucking companies, fleet vehicles, personal vehicle, etc.) * State how recalled products that are being transported back to the firm will be documented and marked * State how recalled products that are being transported back to the firm will be segregated from other foods * State how products that are still within the firm’s control will be documented and marked not for sale |
| **Product storage**  **Recalled products must be stored in an area that is segregated from other foods.**  This part of the plan should include:   * Statement whether the designated storage area is on or off-site from where the food is being manufactured * Statement whether an exact designated storage area will be determined at the time of a recall * Who determines where the recalled products will be stored * How records about a specific recall will be stored |
| **Product control/security/deposition**  **Recalled products must be secured and controlled to prevent re-entry into commerce.**  This part of the plan should include:   * Description about who has access to the recalled products * Description about who has access to the recall records * Description of disposition decisions (e.g. non-human consumption use, destruction or reconditioning) * Statement about who at the firm determined final disposition of products * Documentation of final disposition decision * Record of what regulatory authority reviewed and approved of the final disposition decision |
| **Recall effectiveness assessment**  **The recall plan must include a method to assess the effectiveness of the recall.**  This part of the plan should include:   * Documentation that all distributors received notifications * Documentation that the public was issued notifications * Documentation that all recalled products within control of distributors was returned or disposed * Documentation that all recalled products within control of the manufacturer received proper final disposition * Criteria by which the recall will be deemed a success or failure * Improvement plan for recalls deemed to be a failure * Documentation that the regulatory authority approved the termination of the recall |

**CONTACT INFORMATION TEMPLATE**

**DATE**

**FIRM CONTACTS**

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| Name | Title | Telephone | Address | E-mail | Responsibility |
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**REGULATORY CONTACTS**

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| --- | --- | --- | --- | --- |
| Name | Title | Telephone | Address | E-mail |
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**DISTRIBUTION CONTACTS**

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**MEDIA CONTACTS**

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| Name | Title | Telephone | Address | E-mail |
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**ASSIGNMENTS TEMPLATE**

**Quality Control:** responsible for identifying significant deviations in quality manufacturing parameters that warrant a recall

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| Name | Title |
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**Complaint Patterns:** responsible for identifying patterns of consumer and distributor complaints that lead to a recall

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| Name | Title |
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**Initial Products List:** responsible for identifying and creating an initial list of all products that must be recalled, and what distributors received the product

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| Name | Title |
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**Management Approval:** responsible for deciding whether to recall products

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| Name | Title |
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**Recall Manager:** responsible for coordination of all recall activities, and assignment of responsibilities

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| Name | Title |
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**Recall List Maintenance:** responsible in maintaining, updating and securing recalled product list

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| Name | Title |
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**Regulatory Authority Notification:** responsible for notifying the appropriate regulatory authority about the recall

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| Name | Title |
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**Distributor Notification:** responsible for preparing and issuing written recall notice to all distributors

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| Name | Title |
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**Media Notification:** responsible for preparing and issuing written recall notice to media and press outlets

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| Name | Title |
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**Product Collection:** responsible for ensuring recalled products are collected and transported

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| Name | Title |
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**Product Storage:** responsible for ensuring recalled products are correctly stored and secured

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| Name | Title |
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**Product Deposition:** responsible for determining final deposition of recalled product

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| Name | Title |
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**Recall Effectiveness:** responsible for assessing success or failure of recall, and initiating improvements in recall system

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| Name | Title |
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**Media Release REcall Models**

**Allergens**

[http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm%20)

**Clostridium botulinum**

[http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm%20)

**E. coli 0157:H7**

[http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm%20)

**Listeria monocytogenes**

[http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm%20)

**Salmonella (all serotypes)**

[http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm%20)