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## Fda food recall plan template

FDU Guidance Document:Food Processing Plans, Allergen Control Plans and Recall Plans New Regulations on Processing and Recall Plans in Part VI, Title 51, L.A.C. (updated 2011) New Regulations on Allergen-Control Plans in Part VI, Title 51, L.A.C. (updated 2020); 21 CFR 117 Subpart B For General Manufacturing Firms Processing Plans: Plans must be written, implemented, and maintained up-to-date with any changes made to the firm's operational procedures. Plans must be available for review by your inspector upon request. Plans must include the following elements: list of steps in process, including potential biological, physical, chemical, or radiological hazards that may be introduced at each step; description of controls used to address the hazards listed above; description of methods used to monitor the controls noted above; records of corrective actions taken as a result of monitoring above; and records of changes to plan as a result of corrective actions documented above. NOTE: If a HACCP plan is currently in use, a separate food processing plan is not required. Allergen-Control Plans: Plans must be written and available for review by your inspector upon request. Plans must address the presence of the eight major food allergens in ingredients and finished foods. Plans must address workflows and circulation of products throughout the facility. Plans must address materials stored in morgue areas, pending QC approval, in-process products, and products in storage awaiting distribution. Recall Plans: Plans must be written and available for review by your inspector upon request. Plans must have a provision to notify your inspector and/or the Central Office staff of the Food and Drug Unit in the event of a product recall. If goods are shipped interstate, additional provisions must be made to notify the local or regional federal Food and Drug Administration office. Plans must include the following elements: identity of products including brand name and lot/batch code; reason for recall; date and means of discovery of the reason; total affected product produced and amount estimated to be in distribution; list of consignees that may have received affected product; contact information for the firm's recall coordinator; and, proposed strategy for conducting the recall, including media notifications, method of evaluating whether the recall needs to occur at the level of wholesale distribution, retail distribution, or the consumer; method of checking the effectiveness of the recall, including follow-up store visits or telephone/email contacts; method of determining whether changes to the plan are warranted by the results of the effectiveness checks. Additional Resources for Processing Plans There is no perfect analogue to a processing plan, but it is similar to a HACCP plan or a food safety plan focussed on process-related hazards and controls. In this context, the Food Safety Plan Builder tool from FDA may be a useful starting point. Additional Resources for Allergen-Control Plans Additional Resources for Recall Plans Example: dental hygienist It's all about managing food . food Recall plan Template For food Manufacturers 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. It's all about managing food. Food Recall Plan Template For Food Manufacturers Tags: Food, Plan, Template, Manufacturers, Plan template for food manufacturers Information 1 It's all about managing food . food Recall plan Template For food Manufacturers 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. 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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 Manufacturers Recall Program can be broken into 10 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 .3 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. 2 - 11. This document is distributed by food Decision Software Inc. for use by all food Distributors and food Manufacturers without the need of consent as long as this disclaimer is not removed. 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.4 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.5 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. 3 - 11. This document is distributed by food Decision Software Inc. for use by all food Distributors and food Manufacturers without the need of consent as long as this disclaimer is not removed. Complaint Referred? Has the complaint been referred to anyone else?6 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 Supplier of your findings (if applicable). Note: If the product is a raw material. - 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.7 A suggestion might be to include the day, month and year in the number; and then maybe a sequential number ( 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.8 The person responsible for this task must have the authority to contact the regulating authority 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 4 - 11. This document is distributed by food Decision Software Inc. for use by all food Distributors and food Manufacturers without the need of consent as long as this disclaimer is not removed. Canadian food Inspection Agency contact #'s in case of Recall #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.9 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.10 If the products are incorrectly identified, another Recall may be necessary. As a Manufacturer, traceability of products involves record-keeping procedures that provide you with the information of products that have been received and distributed. Additional traceability procedures that show the route a raw material took from the supplier through production to the final product, and then on to customer/distributor are also necessary. To develop a traceability system: Link the products you receive from each Supplier. Link all ingredient lot codes to finished product codes: If a raw material has caused a food safety issue, being able to trace it back to the supplier will increase the chances of correcting the problem and avoiding it happening again. When an ingredient enters production, record its lot number and link it to a formula or production information. If you use rework, link the ingredients of the rework to the finished products. Carryover product from one lot to another can compound the traceability of a product. 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