

# Department of Food Science

## *Food Processing*

FSE 99-21

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### Developing a Recall Plan

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This material is intended to be a guide to the major points which should be covered in a recall plan. **It is the responsibility of the manufacturer to construct the appendices to this outline to produce an adequate recall plan.**

A commercial processor engaged in the processing of acidified foods is required by 21CFR108.25 to prepare and maintain a written recall plan. Guidelines for product recalls are contained in 21CFR7. This plan will provide a current procedure for implementation, including:

- notifying FDA of any recalls
- a procedure for distributors to follow to recall products which may be injurious to health
- a procedure for identifying, collecting, warehousing and controlling products
- and a method for determining the effectiveness of any recalls.

Recall is a voluntary action taken by manufacturers and distributors to remove food which is in violation of laws administered by the FDA. FDA may request a recall, but cannot order one without a court order. Product recovery is

only classified as a recall when the product is violative.

#### **Product Identification**

Each batch or production lot of the product will be properly coded as described in Appendix A. This code will allow the product lot to be identified as to date, batch product personnel production records, and ingredient records.

#### **Records**

Records are key to the recall plan and must be maintained for three years. They include:

- Records of examination of raw materials, packaging materials, and finished product along with any supplier guarantees or certifications (Appendix B).
- Processing and production records showing adherence to scheduled processes, including records of pH measurement and other critical factors (Appendix C).
- A log of all departures from scheduled processes, actions taken to rectify them, and disposition records of the portion of product involved (Appendix D).
- Records of initial distribution of the finished product adequate to facilitate separation of food lots which may have become contaminated or otherwise unfit for use (Appendix E).

## **Notification**

Persons to be notified in the event of a recall include FDA, key company personnel, and distributors. Prepare a list of names and phone numbers (Appendix F).

In the event of a recall, the media may also need to be notified. Only one employee should be assigned the duty of spokesperson. Others should refer questions to him.

The notification shall include the product, container size, and code of affected lots. The extent of the hazard and the level of the recall will be as determined by FDA. On the basis of this determination, FDA will approve the recall strategy. The notification will include instructions for consumers and distributors for product recovery and information feedback (Appendix G). The contact person should be listed on the notification form.

## **Product Recovery**

Plans for recovery include procedures for segregation of affected lots, storage, warehousing, and control. Procedures in place shall allow determination of the effectiveness of the recall (Appendix H).

The recall is concluded when FDA determines that recovery is adequate and there is no longer any threat to the public.

## **Some Thoughts**

Recall is time consuming and costly. It may and often has, destroyed a company's reputation. Careful control over production and processing is an absolute necessity to prevent the need for a recall.

In the event a recall is necessary, use the plan, paying close attention to the notification step, the use of designated spokespersons, and good communications to all involved. Careful planning will allow the processor to implement the recall in a timely, organized fashion with a minimum of confusion. This will help to minimize the public health consequences and losses to the company.

**Appendices** (you need to develop these and include them in your plan)

- A. Product coding
- B. Raw materials records
- C. Processing & production records
- D. Departures from scheduled processes
- E. Records of initial distribution
- F. Key contacts and phone numbers
- G. Sample notification form
- H. Plans for recovery of recalled product and evaluation of effectiveness.