By Mark Foukes

A Survival Guide to Traceability & RECALL

Is your plant prepared in the event of a product recall?

Every food plant should include Traceability and Recall Programs in their Quality System. These programs are managed separately, but are integrated in the event of a recall. They are quite different in their requirements, yet both must be thoroughly understood and implemented to be effective.

A solid Traceability Program is necessary in order to minimize the financial loss of a recall. Without a good Traceability Program, more product than necessary may need to be recalled in order to ensure that all suspect product has been captured.

A Recall Program is necessary so that a plant is prepared to effectively and efficiently remove product from the marketplace if necessary. In the event of a recall, a plant will have to provide information to the appropriate regulatory agency. A recall will require a plant to provide information about the severity and magnitude of the problem to regulatory agencies, customers, and possibly, the public, as well as identify the suspect product (traceability) and remove it from the market. Recall is a legal term. Therefore, the Recall Program must recognize the legal requirements of a recall effort.

As recent as December 9, 2004, the Food and Drug Administration (FDA) published in the Federal Register its Final Rule implementing the "recordkeeping" and "records access" provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which amended sections 301 and 704(a), and added section 414 of the Federal Food, Drug, and Cosmetic Act (FDCA). In this Rule, legal requirements have been established for the information that must be included in the Traceability Program and the FDA's legal access to this information if there is reasonable belief that a food poses a threat to human or ani-

mal health. These requirements must be reviewed and included in Traceability and Recall Programs.

TRACEABILITY PROGRAM. What follows is a brief description of the key components of a high-quality Traceability Program.

1 Document lot numbers of incoming ingredients and primary packaging.

The first part to a Traceability Program is to ensure that all incoming raw materials, including ingredients, packaging materials, and processing aids, are identified. Raw materials received should have a manufacturer's lot code. These codes must be retained in a manner that identifies supplier and date of receipt. This is often accomplished on a Receiving Log or simply by retaining receiving paper work, such as bills of lading that include a date and signature.

Once received, the supplier's lot code may be used for ongoing documentation of usage, or the receiving plant may decide to assign an internal code. One benefit of using a plant-assigned code at the time of receipt is the ease it provides for plant personnel using the correct information at later stages in the process. Since suppliers use numerous lot coding schemes, a plant-developed program utilized for all receipts would be easier to use at the facility. Rather than training every employee to read and record all the different lot codes, using a plant specific lot system may reduce errors. Only personnel responsible for receiving would be required to read and understand supplier codes.

2 Record ingredient and packaging usage.

As ingredients and packaging materials are brought from the warehouse to the production area, it is important that a system is in place to record the lot numbers. An easy method is to have production workers record lot numbers of the ingredients and packaging material on batch tickets as they are used.

It is important to track rework. A lot number should be assigned to this material, as it would to any other ingredient. The lot number of the rework material can be listed on the batch ticket as it is used. Documentation of rework usage is an important component of the Traceability Program.

In addition, a breakpoint should be established for putting rework back into batches. Without a breakpoint, a single lot of an ingredient will appear in future batches because of the rework that has been added back into the product. Some argue that, after six dilutions, the amount of ingredient left in the rework is insignificant. However, most companies and regulators are not comfortable with this argument. For that reason, a predetermined schedule for discarding all rework should be established. A scheme used by some companies is to discard all rework at the end of every financial period. Since financial periods are for a predefined timeframe, often four weeks, this strikes a balance between the financial implications of a recall and the cost of discarding rework.

There is also the potential for ingredients and packaging material to be discarded without being used. For example, if the materials become damaged, they may need to be discarded. A record of discarded materials must be maintained. The record must include code identification and quantity. The same record may be used for excess spillage. One of the measurements of a Traceability Program is the ability to reconcile quantities received with quantities used. Discarded material can often account for many discrepancies in these quantities.

3 Mark finished goods with a traceability code.

Traceability codes are often referred to as lot codes or product codes. Because of the many different types of identification, it is suggested to use the term traceability code to describe all of these different practices. Regardless of the procedure used in a specific plant, every package and/or case of finished product must have a traceability code.

Some different examples of traceability codes are the shelf life or expiration date of the product, a Julian date, the production date, or even a specific code, such as sequential number, utilized by the plant. Regardless of the system used, it should provide the plant information on how to identify product. Additionally, the traceability code may define the quantity of product that can be separated in the event of a recall. For instance, if one day's production is a lot, as defined by the traceability code, then the minimum quantity that can be traced and recalled is an entire day's production.

4 Document traceability codes of the products shipped.

Traceability codes of all products shipped must be recorded. This is often included on the bill of lading. With the exception of

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companies that ship all of their product on a daily basis, every shipment leaving the plant must indicate the traceability identification of every item shipped. In addition, it is also beneficial to develop a means to quickly identify every customer that purchases each type of product. This will narrow the search through various documents when looking for specific traceability codes.

RECALL. What follows are the key components of an effective Recall Program.

5 The Recall Team

A Recall Program starts with identification of a team who will come together in the event that product must be removed from the market. The Recall Team has the responsibility of determining when a recall will be necessary, collecting information to allow the appropriate product to be identified, using the Traceability Program to determine where the product was shipped, and removing the product from the marketplace.

6 Team Member Roles and Responsibilities

The importance of setting up the Recall Team and assigning responsibilities before there is a crisis cannot be overemphasized. Following are some of the responsibilities that must be assigned:

- Correspond with the FDA. (This is usually the Recall Coordinator.)
- Correspond with the media.
- Contact legal council.
- Pull records used for tracking ingredients and primary packaging.
- Pull records used for tracking finished goods.

You should also determine who will be responsible for any recallable product remaining on-site and any that is returned to the facility.

While setting up the Recall Team, it is important to identify substitutes for all members. The size of the team may depend on the size of the business. Ultimately, the size of the team is each plant's decision. Once the program is tested, revisions may be made based on identified needs. Finally, since a recall is a legal issue involving a regulatory agency, legal council should always be included.

MOCK TRACEABILTY & RECALL. After developing comprehensive Traceability and Recall Programs into the plant's Quality System, the next step is to test the effectiveness of those programs.

7 Exercises for Traceability and Recall

Mock traceability and recall exercises are the best way to prepare the Recall Team and plant to handle this type of situation. Mock exercises are practice, like going to the driving range before playing a round of golf. There are two types of exercise that must be practiced. One involves the ability to trace product (Mock Traceability) and one involves the ability of the Recall Team to be contacted and function in a recall situation (Mock Recall).

For a plant with a mature Traceability and Recall Program, one ingredient and one finished product mock traceability exercise each year may be sufficient. If these programs are still in development, have been subject to substantial changes, or were found deficient during test exercises, additional testing may be required.

Many operations have placed a two-hour limit on trace exercises, which include assembling the team, presenting a scenario, identifying suspect product, and identifying where the suspect product has shipped. With this data, a reconciliation of figures is made. The total amount of suspect product must equal the sum of the product shipped and the amount still in inventory. Any discrepancies should be investigated and corrective actions recommended. According to new plant security regulations, plants must be able to complete a traceability exercise, both forward and backward as soon as possible and not to exceed 24 hours.

One of the most challenging trace scenarios that may be selected is to presume a harmful contaminant has been identified in a finished product. All lot numbers of raw materials used must be identified. This tests the backwards trace system. From that point, all finished products produced from these lots must be identified. This tests the forwards trace system.

In addition to the traceability exercise, plants should also test the ability of the Recall Team to come together and complete a mock recall exercise. The requirements of this exercise will include a traceability activity. However, the requirements of conducting a mock recall exercise are quite different from a traceability exercise.

The mock recall exercise will test the contact information and response of the team. It will allow the team to use its judgment to determine if a recall is necessary, identify which regulatory agencies must be contacted, ensure appropriate sample letters have been drafted and are available, and ensure that the person responsible for documenting recall activities is capable of doing so in an organized manner. During a mock recall, the Recall Team should document its Recall Strategy. It must include recall classification, depth of recall, action plan to coordinate the removal of product from the marketplace, and effectiveness reviews.

In determining the strategy, the following must be considered: evaluation of the health risk, ease in identifying the product, ease for the consumer to identify the health hazard, and amount of product remaining in the marketplace. These activities, which go far beyond traceability, often go unrehearsed and leave the team unprepared.

It may also be useful to vary components of the trace and recall exercises. Consideration should be given to using team member alternates in the exercises. This will allow all responsible personnel to test their knowledge and increase preparedness. The scenarios selected can also determine the level of difficulty. Trace scenarios involving bulk items and rework will increase the challenge. Mock traceability and recall exercises are an opportunity to find and correct weaknesses.

While trace and recall exercises may be viewed as an inconvenience to team members, testing these programs is the best way to ensure their effectiveness and to best ensure preparedness for an actual recall. Papers published by the FDA and USDA indicate that plants who practice both of these activities on a regular basis are prepared and can handle these situations. Those who do not practice both types find themselves unprepared during the actual event. **AIB**

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