One of the more challenging elements in a traceability and recall system is the ability to track and estimate usage of bulk materials. This is particularly important when there is a food safety or raw material contamination issue associated with these materials, as it will impact the amount of finished product that must be recalled.

Any facility that uses bulk materials as ingredients in its process must have a system in place to allow personnel to identify and track those materials in the case of a recall event. Mock recovery exercises should be conducted to verify that the system works, that the site can execute the recall procedures, and that the system and personnel can indeed account for the raw materials and finished products involved as part of the recall. The time to find out that there are issues with identification of bulk raw materials and the products that they have been used in is not during an actual recall.
Material Traceability

SO WHAT DO I HAVE? One of the most important aspects of bulk traceability is to account for how much material you received, the lot number of the material received, what day it was received, and which silo or tank the material was transferred to. The lot numbers of the material should be documented on bills of lading, certificates of authenticity (COA) or other shipping documentation provided by the raw material supplier. The date received should be included in the plant receiving documentation in addition to the silo or tank into which the material was offloaded.

The amount (in weight or gallons) of product going into the bulk storage tank must be known. This can be taken from either a meter that records the gallons of liquid going into the tank or through the use of scale tickets of the trailer when loaded and empty to know the weight going into the dry storage bin.

If scales or meters for measurement of liquid materials are not readily available at the site, the amount of material delivered should be included as part of the shipping documentation provided to the facility by the bulk raw material supplier. In the case that raw material supplier documentation is used, facility personnel should verify that all materials were delivered to the facility by inspecting the tanker interior to ensure recall accuracy.

WHERE DOES TRACEABILITY BEGIN? So when do you start the recall process? That depends on the type of material received. Unless you offload into a clean and empty bin, you need to consider that there will be commingling of materials within the tank or bin.

For recalls of liquid materials, traceability typically will begin from the day that the liquid being traced was received on site. This will ensure that the finished products manufactured with the commingled materials are included in the recall exercise.

For dry materials, estimation of the time of use may differ. In the case of grain, flour, sugar and other commodities, bins usually will hold more than one lot number of product. Solid materials will be in layers in the bin. The site will need to know the feed rates from the bulk bins and the time and day that the product was unloaded into the bin. This will allow them to estimate the amount of product metered out and estimate, with a reasonable degree of accuracy, the time that they started with that lot and the time that it was fully used and the next lot in the bin was started.

Most sites also will recall an additional percentage of the materials at the front end of the lot being recalled to account for commingling of the product when it was placed into the bin.

WHERE DID IT GO? So where did the material go and where was it used?

In order to maintain traceability of bulk materials, it is important that the facility’s batch and lot code tracking system includes the silo or tank where materials come from, as well as the time and date that production empties the silo or tank and begins drawing materials from the next vessel. It would be rare for a facility to have only one silo or one tank for storage of bulk materials.

Lot number tracking should allow the facility to trace the lot of material back to the date it was received. Also, by using the flow rate of the bins and the amount of materials received, an estimate of when the lot was used in the process and when quantities were exhausted can be calculated.

If materials are used as ingredients on multiple production lines, then the scope of the audit will include many finished products. If the site reworks materials or if materials are donated, maintain samples of them and keep damage logs from the warehouse that can be consulted to ensure all finished product and work in process is accounted for.

For sites such as mills that handle bulk raw agricultural commodities such as grain, there are no exceptions for recall and
Material Traceability

traceability of these materials. Bioterrorism regulations require that personnel be able to go one step forward and one step back in traceability of materials. In the case of materials that are received directly from growers, the farm where the material was received from — in addition to the field that the material was harvested from — should be considered a part of the traceability program.

In addition to knowing how much of what went into which elevator bin, part of the process in the mill is to clean the grain or commodity and make it into an edible food ingredient. Traceability and recall procedures also will need to take into consideration shrinkage and loss of material as part of the cleaning and milling process.

If grain is fractioned into different materials that are sold to different facilities for different purposes (i.e. finished flour is sold to a bakery and by-products are sold to feed manufacturers), then all of the materials that are produced with the suspect grain will need to be identified as part of the production documentation so that all materials produced with suspect grain may be identified. Estimations of shrinkage and loss of materials will vary on the mill and the crop. Reasonable estimates will need to be calculated, in addition to a reasonable cushion for commingling of grain in the bins, when defining this part of the recall and traceability program.

WHEN SHOULD IT END? The determination of the end of a bulk ingredient recall is effected by many factors. However, for the purposes of the written recall and traceability program, a reasonable estimate of when the material is exhausted and commingling of product is no longer a factor should be used to determine the amount of materials to be recalled on the back end of the process.

Factors that should be considered to estimate the termination of the recall should include, but are certainly not limited to, the amount of material commingled in subsequent lot codes of materials added to the silo or tank where the affected product was stored and/or the cleaning cycle where the tank was completely emptied and cleaned, which creates a finite break in the process.

For bulk liquid material where commingling in the tank occurs, common language included as part of traceability and recall of these materials includes the lot in question, plus the next lot unloaded into the tank to ensure that any commingled product would be accounted for in the next lot of liquid. If the reason for the recall involves a significant risk, the site may choose to recall any materials from the day that the material in question was received until a defined break and clean cycle has occurred for that material.

Typical recall programs for dry commodities such as grain, flour and sugar will define a percentage of material to be recalled as part of production after the lot in question has been exhausted to account for commingling of material. Where there is a regular cleaning schedule, such as for flour bins where cleaning occurs on a regular basis to break the insect life cycle, the recall end may be determined by this break and clean cycle, since any possibility of commingling of materials would come to an end.

However you define the “end” of the recall, there will be exceptions. Severity of the issue and potential for illness, injury or even death of the consumer will impact and may expand the scope of the material recalled to ensure that any materials that could cause harm are accounted for.

OTHER IMPORTANT CONSIDERATIONS. The accuracy of the recall process is affected by the accuracy of the measuring device. If you rely on meters, scales or other methods to help estimate the amount of materials used, then regular calibration, verification and preventive maintenance of these devices will ensure accurate and complete traceability.

Once the program is defined, it is critical that the facility conducts a mock recovery exercise to assure that the recovery of bulk materials is accurate and can be conducted in a timely manner. Most recall programs define a time period and amount of product and raw material that must be recovered within that time period. Recovery of products manufactured from bulk raw materials should be no exception.

Practicing the recall procedures for bulk materials will help personnel identify holes in the program or issues with estimation material usage in a non-critical setting. Issues identified as part of the mock recall and traceability process should be identified and addressed so that personnel can be confident that the program is viable and that product produced with these materials can be identified and removed from the market should the need for a recall arise. AIB