

Retracing your steps

With the advent of new food safety laws, traceability has become a serious issue for the food industry. Dennis Brandl of the World Batch Forum describes how a new system can meet these guidelines.

Product traceability is a mainstream requirement for many manufacturing industries. Material traceability has always been a regulatory requirement in the pharmaceutical and biotechnical industries, and due to litigation issues it has recently become necessary for consumer products too. In Europe, the Health and Consumer Protection Directorate (178/2002) will take effect on 1 January 2005. In the USA, the Bioterrorism Act (USA Public Law 107-188) is already in effect. These regulations were put in place to allow government agencies to address food scares quickly, and to mitigate the possibility of bioterrorist attacks. The basic concept of these regulations is that it should be possible to identify every ingredient in any food, and to trace the ingredients back to their sources. This means that food producers must maintain records that identify the ingredients for each product, and detail the original sources for each ingredient that goes into a product.

Label law

In addition to bioterrorism and food safety issues, several countries have also developed mandatory labelling laws for foods containing ingredients derived from GM crops. To comply with these labelling laws, food manufacturers must be able to document the genetic purity of both GM and non-GM ingredients. This can be accomplished by preserving the identity of a crop from seed to final product, or by tracing back from the final product to the initial crop.

The Bioterrorism Act demands a type of traceability known as 'one up and one down'. This means that food producers must keep track of where they obtain their raw materials, and of where they subsequently ship their product. However, this is a complicated procedure, because ingredients are often split or combined during food production. For example, the end product in a store will probably have come from several different raw material lots, which in turn came from several different sources. The main issue of traceability is to determine exactly which lots go into a final product. Until now, recipes and production schedules have not had to specify which raw material lots are to be used, and picking the appropriate material for each batch has been entirely at the discretion of the operator.

Information upon request

According to early US FDA guidelines, if there is a problem with a product the producer must submit information outlining exactly what was in the product and where the raw materials came from. The manufacturer must reply within four hours of the request. The EU directive requests that the information must be made available

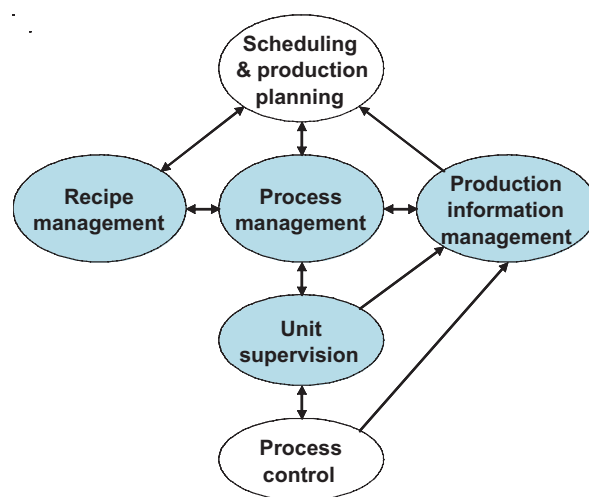


Figure 1. The S88 cactus activity model

to competent authorities 'on demand'. The timing is critical. In the case of food contamination, it can mean the difference between safe recall and disaster. Unfortunately, these high-speed information demands cannot be met cost-effectively with paper-based tracking systems.

The ISA 88 batch control system is the most popular model for batch and flexible manufacturing. The S88 system defines standards for batch manufacturing terminology, recipe representation, batch information and structures for equipment control. However, there have been concerns about the need to purchase process automation equipment to observe the S88 standard.

Path of production

The S88 batch control system standard provides a formal model for identifying and capturing the materials used in production, and a strong foundation for building food traceability into the manufacturing process. The S88 standard defines the activities that should occur in a manufacturing facility in order to properly capture production data, and to make that data available for storage, analysis and archiving (see Figure 1). The shaded activities are defined by the S88 standard and are important for food traceability. The recipe management activities are important because they specify how to manage, control and define the list of ingredients in a food product. Production information activities are vital because they define how to collect the production data related to the production of each

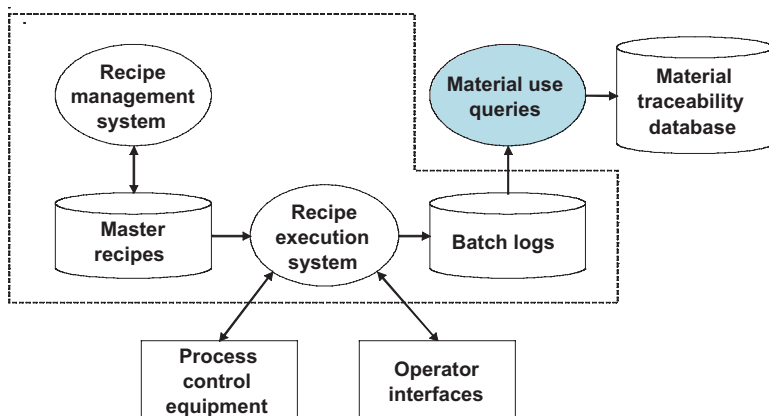


Figure 2. Using S88 for food traceability

batch. The process management and unit supervision activities describe how to execute recipes in order to create batches.

The S88 standard does not require the use of automated control equipment, such as PLC or DCS systems. The initial implementations of the S88 standard usually included automation of control, so there was some confusion as to whether the standard only applied to automated systems. The models defined in the S88 standard were designed to describe fully manual, semi-automated, and fully automated production facilities. Most S88 implementations have been retrofits on existing production facilities, using manual controls. These implementations have demonstrated that there is no need for capital equipment investment prior to fitting the S88 standard.

Recipe control

Several commercial batch control systems have special implementations for manual control processes. These systems send instructions to operators, directing them to perform actions specified in recipes (such as adding materials, starting motors and removing material). The commercial systems then automatically collect production information and put it into a batch log. Systems following the S88 model allow last-minute decisions regarding materials to be recorded, and store the information in electronic logs for later analysis.

The first requirement of food traceability is to identify the ingredients in a product. This is achieved by using recipes. Recipes include both the ingredients (the formula) and the manufacturing instructions (the procedure). The formula lists all the ingredients and amounts needed for a nominal batch. This ingredient list must be made available to authorities, if requested. The authorities do not need to see the entire recipe, so amounts and manufacturing procedures can still be treated as private corporate information. Most commercial systems can provide simple recipe reports that meet the regulatory requirements for ingredient lists.

The second requirement of food traceability is to trace the actual lots used during production. This is accomplished by using commercial batch control systems along with a set of database queries against the batch logs, which only pull out relevant information (see Figure 2). Fortunately, all major commercial batch system tools have followed S88 models and provide databases that contain a batch log.

The material traceability database can be operated within the batch control system database, in an MES database, in an ERP database or in an external database. However, there are good reasons to have an external material traceability database, or to include it as part of an ERP database. Records for all foods intended for processing into non-perishable foods have to be retained for two years after the date of creation. Since the time between production and a data request is random, information about each batch may need to be maintained for longer than most MES or batch control systems are designed to handle. Also, the final batch details may not be known at the time of production. For example, if a raw ingredient is only available in season, an entire year's demand must be processed in a limited time. Usually, the manufacturer will create unlabelled products. Labelling will be completed only after the sales order is received and confirmed, often after the material has left the manufacturing system. In this case, the final traceability will be a combination of information from the batch control system and the ERP system. Most commercial batch control systems also have special modules for connection to ERP systems, which are designed to process the material lot information required for food traceability.

Vital ingredients

The ISA 88 batch control system standard should be applied in food and beverage manufacturing to meet the requirements of the Bioterrorism Act and EU regulations on food safety. The ISA 88 model provides an effective mechanism to meet the USA FDA four-hour response and EU on-demand requirements for food traceability. Commercial batch control systems provide an effective starting point, because they include recipe management and production information management services. The S88 models can be effectively applied to manually controlled systems and do not require additional automated control equipment. Usually, S88 implementations can use existing HMI and SCADA system displays, minimising the need for new computers. The S88 model provides two major elements required for food traceability: ingredient lists and lot traceability. A database of material lot usage can easily be created from the batch logs, providing the information needed to account for traceability.

Due to the abundant availability of commercial systems, applying the S88 standard to food manufacturing will lead to reduced product variability and better utilisation of existing equipment. The S88 standard is a viable solution for food manufacturers because it does not require significant capital investment, meets the ingredient list and lot traceability requirements, and improves manufacturing efficiency. ●