

## Traceability for Consumer Safety and Process Improvement

**The trace quantities of ingredients in a batch of nutraceuticals emphasize the rising importance of traceability in all steps of production process. Tracking and tracing of all ingredients that go in to the batch, batch itself, and who the batch is proving to the consumer vital safety and company reputations.**

Traceability is a vital element of product safety in terms of identifying and controlling contamination incidents. Increasing pressure from regulations, such as the U.S. Food & Drug Administration (F.D.A.), Regulations or Bioterrorism Act, force suppliers in several industries to ensure traceability on a one-up/one-down principle, but not dictate the methods.

The purpose of tracking and tracing helps managers answer a variety of questions:

- Does this shipment contain what we ordered?
- Is the physical flow of my goods optimized?
- Would I have the information I needed if there were a recall or withdrawal?

The companies are free to choose the control methods. Some manufacturers comply using paper-based systems; others may require full networked computer and barcode systems to effectively meet requirements.



Traceability requirements are linked to legislative demands that any product placed on the market shall be fit for purpose and not injurious to health. As a risk management tool, traceability allows businesses and authorities to withdraw products identified as unsafe. It also:

- Minimizes costs incurred by making recall more effective
- Allows targeted action to prevent recurrence
- Assists in problem diagnosis, passing on liability where relevant
- Promotes customer confidence and brand protection
- Optimizes production efficiency and quality control (stock control, material usage, and origin/characteristics of products).

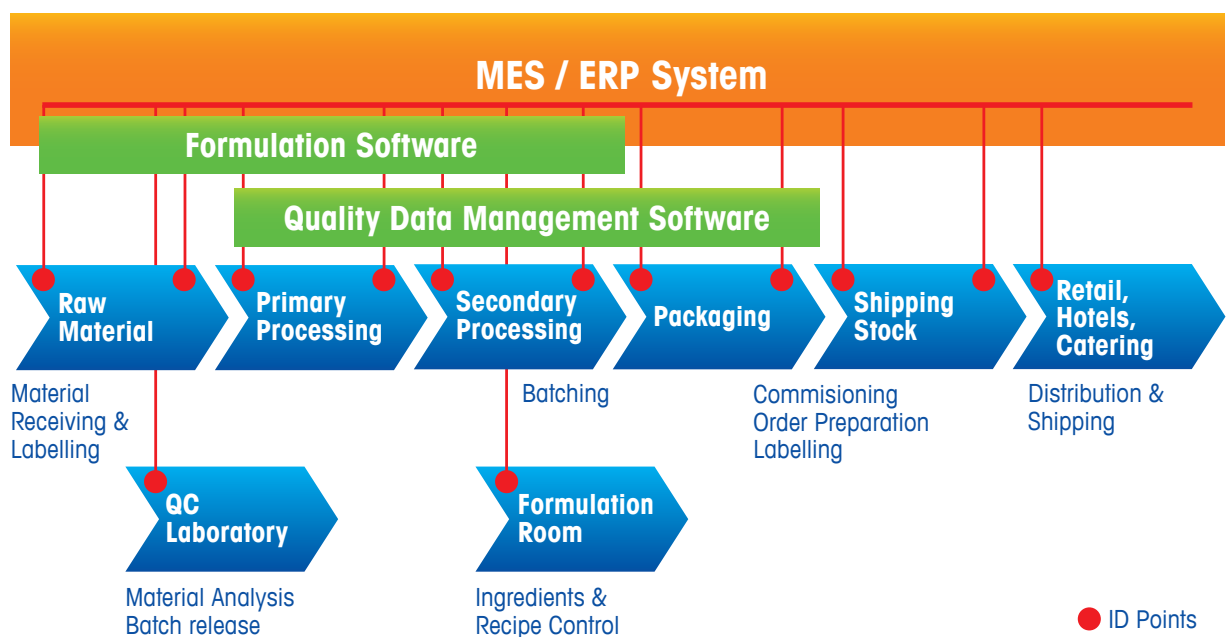
Some general principles to consider when designing or changing an existing traceability system include making sure that it:

- Covers all stages of production, processing and distribution
- Identifies raw materials suppliers

- Identifies which components have been used in which product
- Identifies supplied customers
- Identifies which products and intermediates have been disposed of (verification of destruction may be required)
- Ensures products supplied to customers are adequately labeled or identified to facilitate traceability, and
- Provides details to authorities on-demand in a timely manner.

An ideal system fits into a company's normal work practice and enables quick and easy collection of relevant information.

A traceability system can be used to confirm that safety and quality checks have been performed and sufficient records have been retained for verification. This is particularly significant when investigating customer complaints and legal compliance. Any test results, such as microbiological testing, must also link back to original batches.



A growing number of consumer products must be supported by an electronic file containing documentation that demonstrates the product meets safety standards. This file becomes part of the traceability system.

It is good practice to use technical files even when it is not a specific legal requirement.

Meaningful documentation provides evidence of production history, such as:

- Incoming goods records and raw material quality checks
- Intermediate component records or mix recipes
- Warehousing and storage records
- Delivery orders to the final customer
- Records of any subcontracted work.

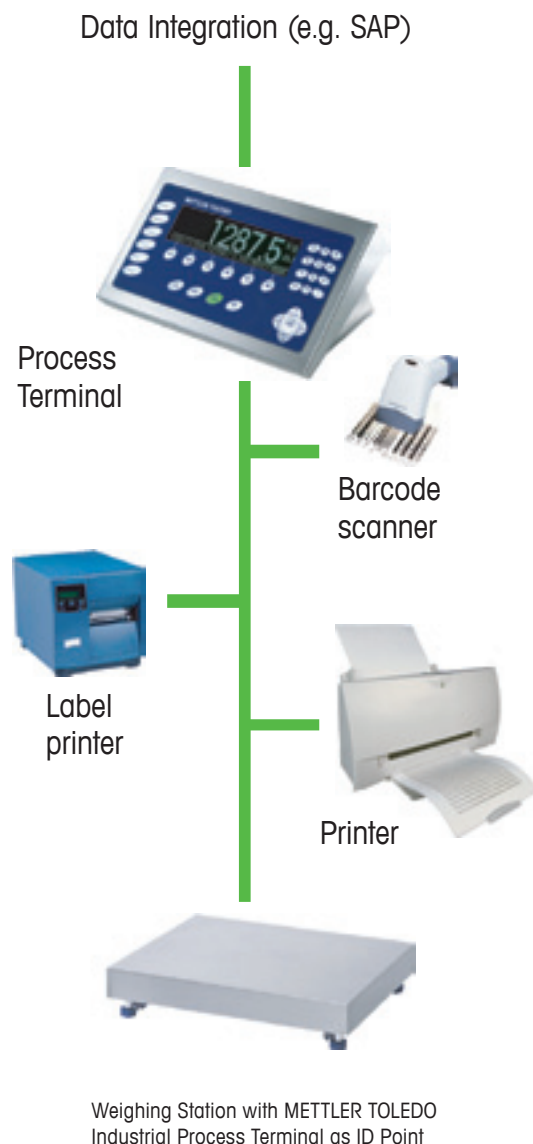
Additionally, if traceability is used for confirming that safety/quality checks have been performed, then the following documentation would also be required:

- HACCP or hazard analysis documentation
- Process records for manufacturing the finished product
- Operator instructions for the recording of batch codes for all raw materials, work in progress and finished products, and
- Personnel training records.

Legislation dictates traceability record retention time-frames related to product characteristics. For example, products with a shelf life of less than three months would need to be kept at least six months. Otherwise, general rules dictate a five-year retention minimum.

Enhance traceability in your operations:

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#### Mettler-Toledo AG

CH-8606 Greifensee  
Switzerland  
Phone +41 44 944 22 11  
Fax +41 44 944 30 60

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