# THE BIOTERRORISM ACT: CATALYST FOR WORLD-CLASS INVENTORY MANAGEMENT IN FOOD AND BEVERAGE MANUFACTURING

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This paper describes how to leverage food safety regulatory compliance into world-class inventory management.

Since 9/11, bioterrorism has been a serious threat and concern in the USA and in many other countries. One of the most pressing concerns has been the safety of our food supply. In response, the United States Congress created the Bioterrorism Act and directed the Federal Drug Administration (FDA) to develop and enforce new additional food safety procedures. Even without the threat of bioterrorism, the recent and seemly unless episodes of food recalls supports the need for a well thought-out and stringent set of food safety regulatory compliance procedures. As the compliance requirements are examined in this paper, the reader will see that these new procedures require a high level of operational discipline and data accuracy. In turn, these procedures will keep the food supply-chain safe, create confidence, and lay the foundation for world-class inventory management. The outline for this discussion:

1. Food & beverage industry overview
2. Bio-toxin attack simulation
3. Bioterrorism Act overview
4. Record keeping (Lot-Trace) compliance overview
5. Where lot tracing is required in the supply-chain
6. Implied requirements
7. Leveraging the results into significant inventory reduction

## FOOD & BEVERAGE INDUSTRY OVERVIEW

Working on the assumption that not everyone reading this paper works in the food and beverage industry, or is knowledgeable on the industries dynamics, and for those that do, they may not have looked outside of their professional discipline to examine all aspects of the industry, a brief overview is appropriate.

The food and beverage manufacturing industry comprises of tens of thousands of companies, many small, and has many micro-vertical segments, and as in other industries, contract manufacturing has become more common. There is a wide range of sophistication ranging from those who are figuratively a step removed from cooking a meal for the masses, to food scientists who can manipulate the nutritional values of an ingredient, and build a recipe to target values. Home style cooking to nanotechnology, a remarkable range of sophistication and diversity. Viewed from the supply-chain perspective, the supply of ingredients, depending on the food produced is becoming more global and the velocity of product through the distribution chain has increased. This is good news for the supply-chain professional, bad for those responsible for protecting the public from tainted or corrupted food.

A respected magazine that serves the food and beverage manufacturing industry, Food Engineering, conducted an extensive survey to identify the top ten issues in manufacturing. Food safety was the top concern:

1. **FOOD SAFETY**
2. AUTOMATION
3. SKILLED LABOR
4. **PRODUCT TRACEABILITY**
5. SYSTEMS INTEGRATION
6. MAINTENANCE IMPROVEMENTS
7. SUPPLY-CHAIN INTEGRATION
8. INCREASED CAPACITY
9. EMPLOYEE TRAINING
10. IMPROVED CHANGEOVER

A quick analysis of the issues highlights the interaction or contribution that seven of these issues make to food safety. The diagram below depicts the relationships:

The adage, "the supply-chain is only as strong as its weakest link" highlights a critical issue in the industry. Most of the companies in the food supply-chain are small to medium size companies who operate off spreadsheets, ingenuity and hustle. Kudos for the entrepreneurial spirit but a concern for the strength and data integrity of the supply-chain in which data accuracy is critical to protect the public in the event of a recall for contaminated food.

Responsibility for food safety is not the exclusive domain of the FDA. The United States Department of Agriculture (USDA) is tasked with inspecting anything that contains animal protein at the point of processing the initial raw material. The USDA puts a resident inspector on the manufacturer's site, good for keeping the manufacturer alert to the food safety requirements. On the FDA front, there are typically no on-site inspectors.

Food manufactures, at least from a legal and FDA recommended level of practices are getting closer to the level of compliance requirements of the pharmaceutical industry for actual drug manufacturing. Just as there are Good Manufacturing Practices (GMP) for drug manufacturers, there are GMP guidelines for food and beverage manufacturing.

## THE BIO-TOXIN ATTACK SIMULATION

Even without the threat of a bio-toxin terrorist attack, unintended breakdowns in the food supply-chain have caused considerable damage to the USA public's health. The Center for Disease Control (CDC) recently made the following announcement that was published by a respected newspaper:

"The Centers for Disease Control and Prevention estimate that our food supply now **sickens 76 million** Americans every year, putting more than **300,000 of them in the hospital, and killing 5,000"**

The paper then quoted a retired government official and introduced the topic of bio-terrorism:

"When Tommy Thompson retired from the Department of Health and Human Services in 2004, he said something chilling at his farewell news conference: 'For the life of me, I cannot understand why the terrorists have not attacked our food supply, because it is so easy to do.'"

The FDA has taken this threat seriously, and has gone beyond enforcement of the Bioterrorism Act. It has funded development of software simulation tools to model the consequences of an attack with different food types, bio-toxins, and geographies, and used known and specific distribution networks for each geography. This modeling tool was developed in cooperation with a major university/food safety center, the FDA and thought leaders in the food and beverage manufacturing community. During the year 2006, it was demonstrated in dozens of food safety forums.

The bottom-line, the operational discipline required to keep the food supply-chain safe is not optional; it is a moral obligation and a legal one. The good news is that this discipline can be leveraged into world-class inventory management. There is a reward for being good!

**BIOTERRORISM ACT OVERVIEW**

The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which was signed into law June 12, 2002. The Bioterrorism Act is divided into five titles:

1 Title I -- National Preparedness for Bioterrorism and Other Public Health Emergencies
2 Title II -- Enhancing Controls on Dangerous Biological Agents and Toxins
**3 Title III -- Protecting Safety and Security of Food and Drug Supply**
4 Title IV -- Drinking Water Security and Safety
5 Title V -- Additional Provisions

The FDA is responsible for carrying out certain provisions of the Bioterrorism Act, particularly Title III, Subtitle A (Protection of Food Supply) and Subtitle B (Protection of Drug Supply).

There are eight main requirements in Title III, Subtitle A:

1 SECURITY STRATEGY (301)
2 FOOD ADULTERATION (302)
3 DETENTION (303)
4 REGISTRATION (305)
**5 RECORDS MAINTENANCE (306)**
6 PRIOR NOTICE (307)
7 MARKING (308)

Records maintenance (306) is the requirement that if adhered to with discipline, including the implied requirements will lay down the foundation for excellent inventory management.

**RECORD KEEPING (LOT-TRACE) COMPLIANCE OVERVIEW**

The FDA was tasked to implement the Records Maintenance requirement, that is define specifically what was required and by whom. Their directive quickly evolved and identified the records that must be established and maintained by non-transporters of food. Non-transporters means those that manufacturer any ingredient or final food product. The specific guidance reads:

1. Identify the immediate non-transporter previous sources…of all foods received. Persons who manufacture, process or pack food also **must include lot or code number** or other identifier if the information exists.

2. Identify the immediate non-transporter subsequent recipients of all foods released. Persons who manufacture, process or pack food also **must include lot or code number** or other identifier if the information exists. The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

2. Netting it out, a Lot-Trace number must exist for every raw material, intermediate (sub-assembly) received, stored, issued and consumed into another lot. A lot number must also be assigned to every lot that creates an en-item. In practice, the statement "if the information exists" is not acceptable.

Since the lot-trace records must be recorded, and the purpose is to know what to recall if a batch/lot of food is known or suspected of being contaminated, the record availability requirements must be established. The FDA's directive on record availability is as follows:

"**Not to exceed 24 hours** from time of receipt of the official request. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food"

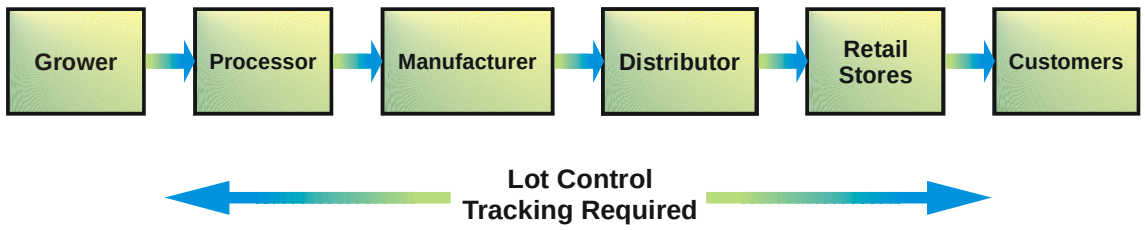
Again, the letter of the law and the expectation depart.

If you are a contact manufacturer, the customer will demand all records within four – (4) hours! Remember the earlier statement - "Most of the companies in the food supply-chain are small to medium size companies who operate off of spreadsheets, ingenuity and hustle." With these conditions, a rapid response can be difficult.

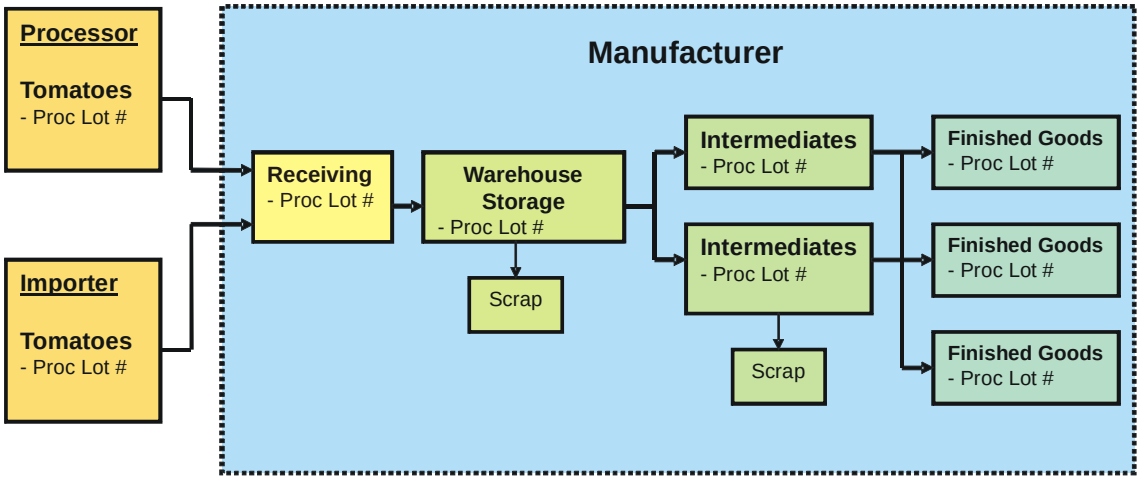
The next question is when did this requirement become enforceable? The FDA chose to use company size, specifically employee count, to time phase the enforcement over a three to four-year (3-4) year period. The enforcement started in December 2005 and concluded in December 2006. Today, if the workforce is equivalent to one full time employee, the manufacturer must be compliant.

## WHERE LOT-TRACING IS REQUIRED IN THE SUPPLY-CHAIN

The adage a picture is worth a thousand words applies here. The diagrams depict where lot tracing is required in the supply-chain:



A view inside the factory:




As the reader can see Lot-Trace requirement, are everywhere.

## IMPLIED REQUIREMENTS

If a lot recall is required and lives are at risk, is it not reasonable to conclude that the Lot-Trace records must be accurate? When the recall button is pushed not only is the concern public safety, but also a lot of money will be spent withdrawing the tainted products and dealing with the legal consequences of those injured. An accurate Lot-Trace record is really the sum of many different accurate transactions and supporting records. A list of those supporting the accurate Lot-Trace record:

1. ACCURATE RECIPES
2. DEFINED PROCEDURES & PROCESSES
3. RECEIVING DATA IS ACCURATE & RECORDED
4. DEFINED QUARANTINE OR HOLD AREAS
5. ORGANIZED RECEIVING & WAREHOUSE STORAGE AREAS
6. ACCURATE RECORDING OF MATERIALS USED IN PRODUCTION OR SCRAPPED
7. ACCURATE RECORDING OF FINISHED PRODUCTION
8. **ACCURATE INVENTORY RECORDS**

The most common constraint to achieving record accuracy for the small food and beverage manufacturer is the way information is recorded. The use of Cardex masquerading as spreadsheets is common and is the culprit. Disconnected data, by its very nature will inevitably lead to inaccurate information. The illustration used by many is silos or “islands of information.” Throughout the food manufacturing industry there are “deluxe” information silos.







DELUXE COLLECTION OF (INFORMATION) SILOS

HOW ACCURATE DO THE RECORDS HAVE TO BE?

"Accurate" is the operative word in this discussion on the implied requirements. How accurate does the lot-trace information need to be? Two illustrations help us understand the level of accuracy needed. The first one is a Transatlantic shipping travel example, the parameters of the example:

- Port of departure – New York
- Cross the Atlantic Ocean
- Destination port – St. Peter Port, UK
- Two degree error during the journey

A two – (2) degree error does not seem unacceptable until the consequences are examined. This seemly small error had the ship arriving in Lle D Groix, France, one hundred and sixty-three – (163) miles off course!

Another example, in our day-to-day life individuals have been conditioned to think a ninety-(90) percent achievement is a top tier performance level. The reality suggests otherwise. The culprit is the compounded effect of data errors and the confusion that inaccuracy **imposes** on factory operations. If the following typical documents and transactions used in manufacturing are multiplied throughout the company:

1 90% RECIPE ACCURACY X
2 90% BILL-OF-MATERIAL ACCURACY X
3 90% WORK INSTRUCTION ACCURACY X
4 90% INVENTORY RECORD ACCURACY X
5 90% INVENTORY ISSUING ACCURACY X
6 90% FACTORY REPORTING ACCURACY X

The result is what is often referred to as the “confusion factor”, in this example it is fifty-three – (53) percent!

There are no established accuracy targets exclusive to the food and beverage industry, but there are ones established for discrete manufacturing that can serve as a guide:

- Recipes/Bills of Materials - 98%
- Inventory Record Accuracy - 98%
- Order Shipping Accuracy - 99% +

## HOW TO SATISFY THE IMPLIED REQUIREMENTS

Satisfying the implied requirements requires a multi-prong attack. The key elements are:

- BATCH-PROCESS ENTERPRISE RESOURCE PLANNING (ERP)
- ORGANIZE THE WORKPLACE - 5S & LEAN
- DATA SECURITY & VALIDATION
- COMPLIANCE INTEGRATED INTO WORK ACTIVITIES
- VISIBILITY INTO THE WAREHOUSE AND FACTORY OPERATIONS

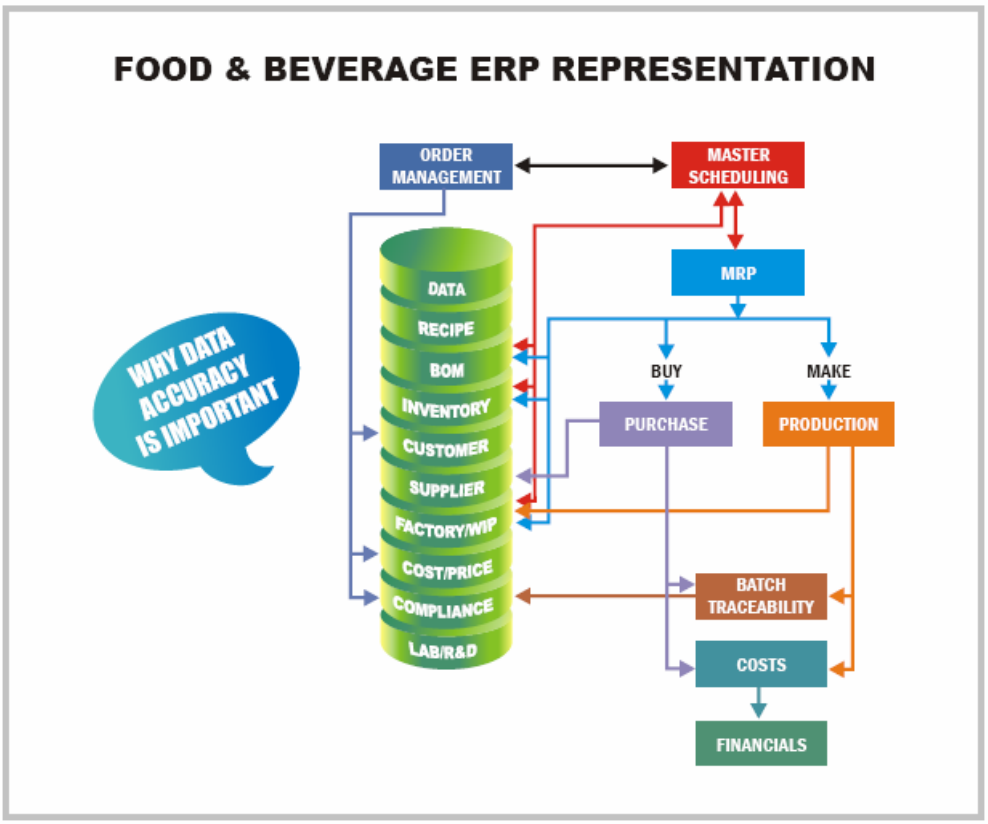
BATCH-PROCESS ENTERPRISE RESOURCE PLANNING (ERP)

Since the root cause of data inaccuracy is often a collection of disconnected informal and legacy systems, the most straightforward strategy is to replace them with a single integrated database and one consistent method of transacting. Batch-Process ERP satisfies that requirement. ERP is generally thought of as a planning and scheduling system, but its contribution to achieving data accuracy is the boundaries it creates based on best business practices. It integrates information flows and enables consistency. With good data quality ERP can now effectively plan and control inventory and factory operations.

There are differences between traditional and Batch-Process ERP. A few of the differences:

- An intelligent lot tracing scheme
- Multiple unit of measure conversations
- The Item Master has more attributes in it that define physical, nutritional and special handling
- The ability to calculate the interaction between ingredients, nutritional values and costs
- The need to effectively manage regulatory compliance and quality assurance data
- Support of Good Manufacturing Practices (GMP)
- The information needed for every item inventoried; the lot number, expiration date and associated Certificate of Analysis (COA)
- Controlled segregation of inventory; standard, allergenic, organic, and Kosher
- The information needs for batching on the factory floor
- Support of food safety procedures such as Hazard Analysis Critical Control Point (HACCP)
- A dynamically created lot-trace tree to support a potential lot recall

The illustration below depicts a food and beverage variant of ERP:




ORGANIZE THE WORKPLACE - 5S & LEAN

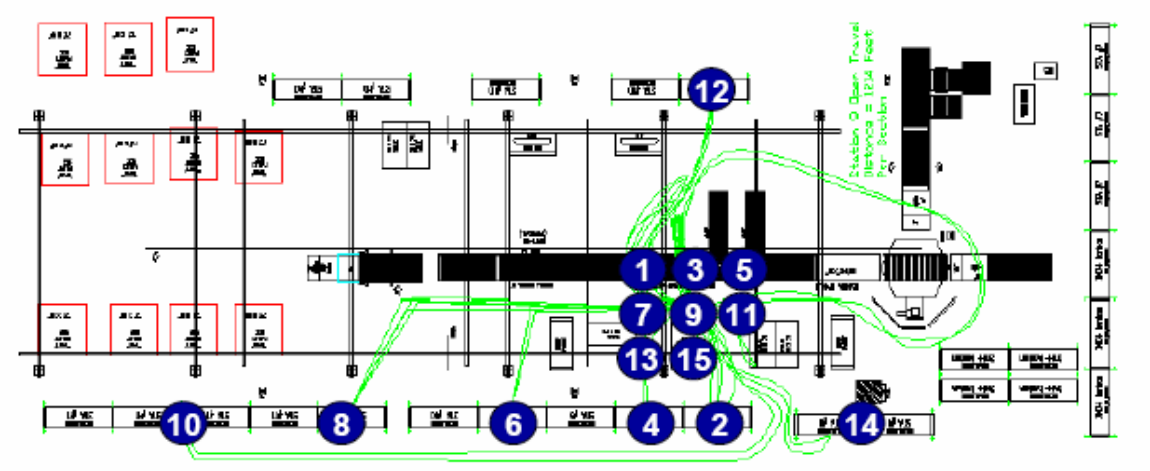
The Lean movement and the techniques associated with it have attracted a large following. Lean is an exceptional set of tools for organizing the workplace, eliminating waste, improving velocity through the enterprise and creating an environment for minimizing data errors.

With the goal of compiling accurate lot-trace records the four areas that require immediate examination are shipping and receiving, quality assurance, quarantine storage, and the warehouse. The goal is eliminate convoluted chaotic work areas that foster mistakes and data errors. Three tools are effective in achieving an orderly work area:

- 5S
- Spaghetti diagramming
- Value Stream Mapping

5S is the Japanese concept for House Keeping. The 5S stands for Sort, Straighten, Shine, Standardize, and Sustain. Less is more in 5S, remove anything not needed and used infrequently. Try to apply Poka-Yoke thinking, mistake proofing everything that remains and used to perform work.

Spaghetti diagramming helps visualize the movement of products and people performing work. A convoluted diagram identifies the need for that work area or process to be redesigned. Spaghetti diagramming is widely accepted in many industries and disciplines. In the example diagram below the green lines depict movement:




Value Stream Mapping (VSM) and spaghetti diagramming are often used in conjunction with each other. The object of utilizing VSM is to eliminate wasted time and handling associated with the issuing, receiving and storage of inventory.

A definition of VSM:

"Value stream mapping is a paper and pencil tool that helps you to see and understand the flow of material and information as a product or service makes its way through the value stream.

Value stream map (AKA end-to-end system map) takes into account not only the activity of the product, but the management and information systems that support the basic process. This is especially helpful when working to reduce cycle time, because you gain insight into the decision making flow in addition to the process flow. It is actually a Lean tool." - Source: iSixSigma

DATA SECURITY & VALIDATION

Data accuracy cannot be achieved without well thought out control of those who record activities and those who use information. Random and uncontrolled access will create unreliable and inaccurate data. A standard used in the pharmaceutical/life sciences industry provides the level of control needed, 21 CFR Part 11. This standard supports user ID and password protection, defined approvals, electronic signatures, and in some cases dual electronic signatures, as well as date and time stamping for every transaction including who did what.

COMPLIANCE INTEGRATED INTO WORK ACTIVITIES

A few obvious activities: the lot number must be integrated into every inventory movement, production reporting, quality assurance and shipping transactions. Using wireless bar-coding makes sense today because the costs are minimal and the

reduction in administrative workload is significantly reduced as are the errors in data input, the less needed to be inputted into ERP, the less errors would be generated.

Most food and beverage companies have a Hazard Analysis Critical Control Point (HACCP) plan. If the company processes poultry, seafood, un-pasteurized juices a HACCP plan is mandatory. Most companies that are not obligated to a mandatory plan will put a voluntary plan in place; particularly those that are contract manufacturers. How to analysis processes and the behavior of the food in a process step is well defined by the FDA. In many companies today, the HACCP plan is separate from the business systems. This is unacceptable. Once the plan is developed, the scheduled tasks to support the plan and the associated data inputs should be managed by the Batch-Process ERP system.

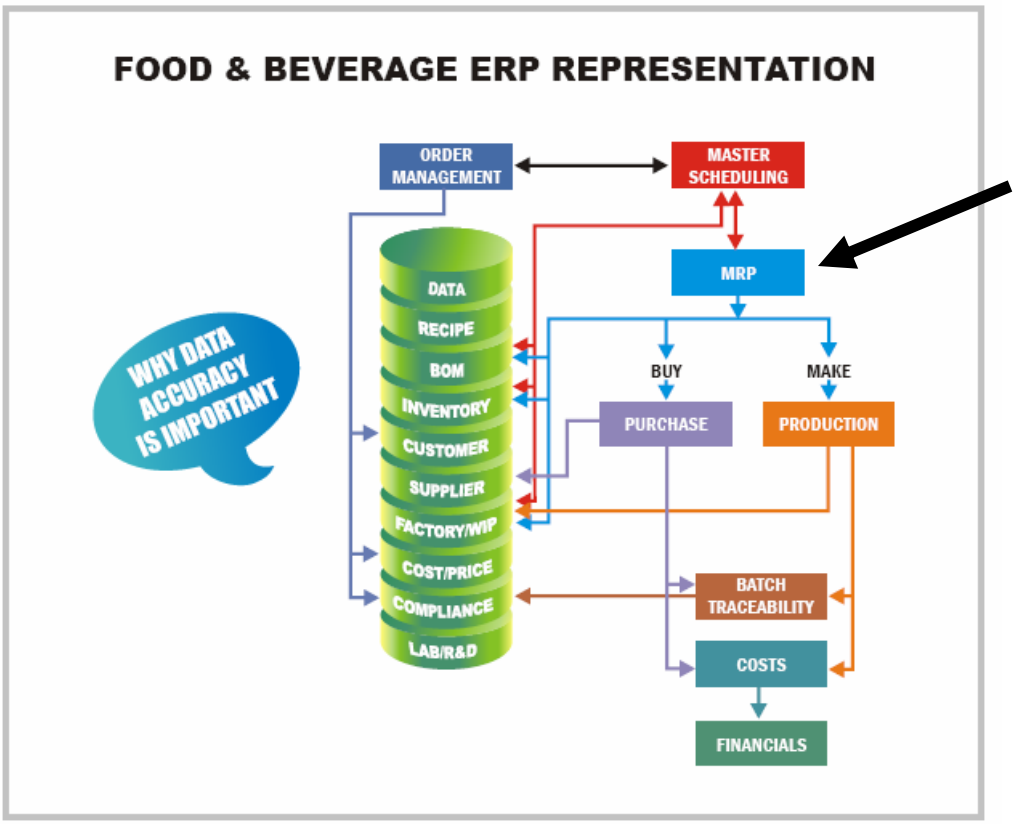
An FDA recommendation for those companies deploying HACCP is that Good Manufacturing Practices (cGMP/GMP) be put in place first. GMP defines the "what", not the "how", that is the function of Standard Operating Procedures (SOP). The SOP defines how a task must be executed in support of the applicable GMP requirement. It has multiple purposes; food safety, the minimizing of errors and the consistency in performing tasks. In many companies today, the SOP library is stored separately from those who perform the tasks. Companies ISO 9001-2000 certified often follow this approach. Restated, companies often have the SOP library in a "black binder sitting on a shelf". With the transaction completeness of ERP and the latest generation of Information Technology, the SOP should embedded at the point of work and instruction given in the most appropriate form; be that written, graphical, audio or video. Exploiting the latest technology and putting the SOP at the point of work also is a form of employee training. In addition, there is nothing wrong with repetition for emphasis!

VISIBILITY INTO THE WAREHOUSE AND FACTORY OPERATIONS

Many if not most small-to-medium sized food and beverage manufacturers, particularly those operating off of multiple disconnected spreadsheets, paper-based records and older computer systems have very poor visibility into the warehouse and factory operations. The modern computer-based Batch-Process ERP system has been designed to provide maximum visibility and controlled access into the enterprise through an extensive menu system with controlled privileges. An analogy of a building seems appropriate; controlled entrance through highly secured doors and visibility through many windows.

## LEVERAGING THE RESULTS INTO SIGNIFICANT INVENTORY REDUCTION

The theme of this paper is that food safety regulations and the disciplines needed for compliance can be leveraged into superior inventory management. ERP is the overall foundation for leveraging compliance, but the specific engine for inventory planning and control is that old faithful tool, Material Requirements Planning (MRP). It requires high levels of data accuracy to extract the full benefit from it, just like the high levels FDA record keeping demands. MRP is proven, there is extensive knowledge on how to implement it and use it effectively. It can produce an excellent ROI as a study by Clemson University has shown. The illustration below highlights MRP's role in the ERP framework:




The underlying calculating logic for MRP is known by APICS certified practitioners, but the majority of small-to-medium sized manufacturers do not. Therefore, it is hoped that they will read this paper and take the appropriate action.

The logic of MRP is designed to calculate time-phased requirements based on actual or a combination of actual and planned demand. Incoming demand can come from the Master Production Schedule or directly from customer orders. It is design to balance supply and demand. The information needed is:

- The demand item
- Its current inventory
- Current time-phased open commitments

- Its estimated lead time,
- Its recipe and Bill-of-Material
- Current inventory status of the ingredients needed
- The current time-phased commitments for each ingredient
- The lead time for each ingredient
- Time-phased work-in-progress orders for each ingredient
- Time-phased purchase orders for each ingredient

MRP takes all this data and calculates:

- What is needed
- How many
- When it should arrive in inventory
- When the replenishment activity should begin

THE REWARD

| METRIC | PRE-ERP | CURRENT ESTIMATE | FUTURE ESTIMATE |
|---|---|---|---|
| INVENTORY TURNOVER | 4.5 | 7.9 | 11.2 |
| LEAD-TIME (DAYS) | 55.6 | 41.7 | 31.8 |
| ON –TIME DELIVERY % | 73.9 | 88.6 | 94.6 |
| ORDER SPLITS % | 29 | 13.5 | 2.1 |
| NUMBER OF EXPEDITORS | 10.8 | 5.1 | 2.1 |

SOURCE: APICS JOURNAL (CLEMSON)

**THE AUTHOR**

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Preston's "hands-on", practitioner manufacturing industry experience spans twelve years. Positions held during that time include all positions associated with materials, manufacturing and plant management in a variety of manufacturing environments.

Following his manufacturing industry career, Preston has spent the last twenty-five years in the consulting and the manufacturing software industry. Preston has had extensive international experience. He lived on multi-year extended assignments in the UK, Sweden and Belgium. Preston also has had project oversight in Asia-Pacific and he currently collaborates with co-workers in India.

Preston's certifications by APICS include CFPIM, CIRM and CSCP. He has had extensive involvement with APICS and has held many key management offices. Preston has also participated in numerous special projects and study groups for the APICS National Board of Directors and headquarters staff.

Preston is also certified as a fellow by BPICS (now the Institute of Operational Management) and as an Organizational Engineer (Salton-MSU).