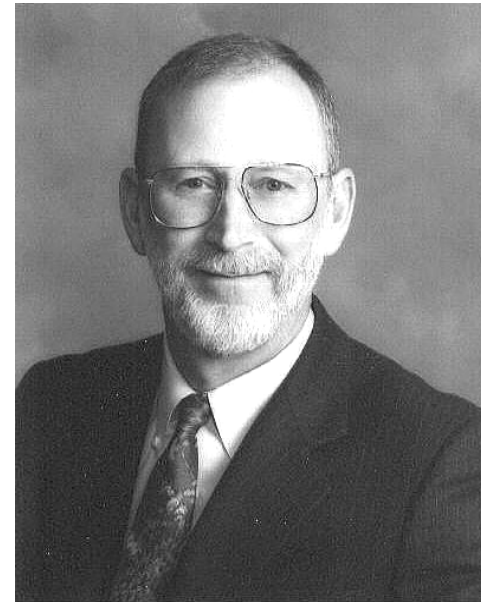


**IS OUR FOOD SUPPLY SAFE?
REGULATORY COMPLIANCE IN FOOD & BEVERAGE
MANUFACTURING**

**PRESTON W BLEVINS
CFPIM, CIRM
BATCHMASTER**



**VENTURA COUNTY PROFESSIONAL DEVELOPMENT
MEETING**

DISCUSSION OUTLINE

- **Why I developed this presentation**
- **The food & beverage manufacturing industry in the USA – an overview**
- **The bio-toxin attack simulation**
- **Food Engineering magazine:**
 - **Top ten critical issues**
- **Regulatory compliance buzzword bingo:**
 - **The Bioterrorism Act**
 - **HACCP**



DISCUSSION OUTLINE

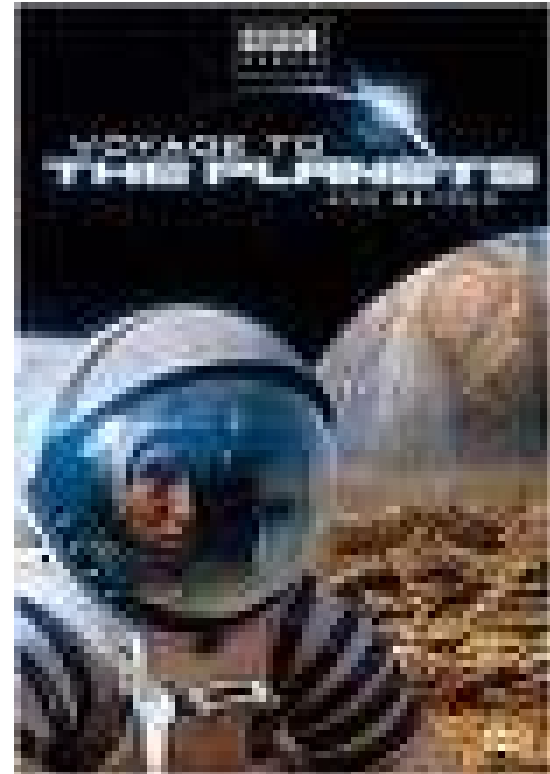
TWO FOR ONE THINKING

- **The Bioterrorism Act – record keeping**
- **Leveraging the FDA record keeping requirement – advanced inventory planning**
- **Leveraging HACCP to improve factory operations**
- **The benefits**
- **Conclusion - video**



WHY I DEVELOPED THIS PRESENTATION

- **Joined a company that serves recipe/formula based manufacturing – new experience**
- **Discovery - regulatory compliance impacts every vertical industry using this “style”**
- **Food & beverage industry – Bioterrorism Act**
- **Attended an IFT conference – bio-toxin attack simulation – Intimidating!**



THE FOOD AND BEVERAGE MANUFACTURING INDUSTRY IN THE USA – AN OVERVIEW

- **Diverse and approximately 400,000 (estimate FDA)**
- **Distinction made between manufacturing, distribution (transporter) and food service**
- **Many small companies**
- **Note: USA has acquired adventurous culinary tastes**
- **Relatively low cost of start-up operations**
- **Continued.....**

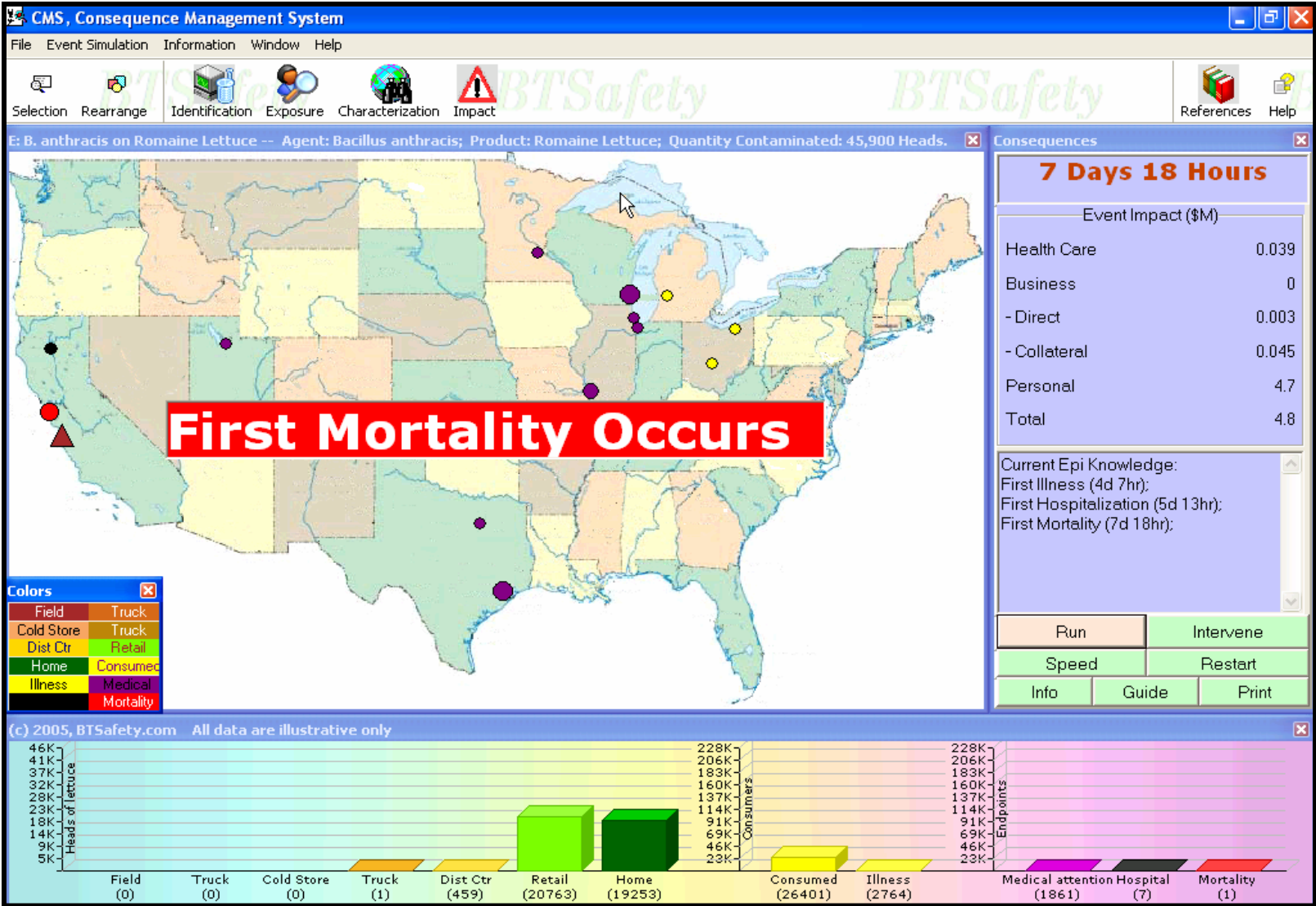


THE FOOD AND BEVERAGE MANUFACTURING INDUSTRY IN THE USA – AN OVERVIEW

- **Contract manufacturing**
- **Laggardism (new word)**
- **Bioterrorism Act & HACCP**
- **FDA/USDA oversight**
- **Escalating requirements – allergen management, Kosher, Organic**
- **Small companies – unsophisticated controls**
 - **Cardex disguised as spreadsheets**



BIOTERRORISM BIO-TOXIN ATTACK SIMULATION



COURTESY: BT SAFETY

THE MOST CRITICAL ISSUES THE FOOD & BEVERAGE MANUFACTURING EXECUTIVE MUST DEAL WITH

FOOD ENGINEERING'S TOP TEN ISSUES:

1. Food Safety
2. Automation
3. Skilled Labor
4. Product Traceability
5. Systems integration



THE MOST CRITICAL ISSUES THE FOOD & BEVERAGE MANUFACTURING EXECUTIVE MUST DEAL WITH

FOOD ENGINEERING'S TOP TEN ISSUES:

6. Maintenance improvements
7. Supply-chain integration
8. Increased capacity
9. Employee Training
10. Improved changeover



DISCUSSION OUTLINE

- √ Why I developed this presentation
- √ The food & beverage manufacturing industry in the USA – an overview
- √ The bio-toxin attack simulation
- √ Food Engineering magazine: Top ten critical issues
 - **Regulatory compliance buzzword bingo:**
 - **The Bioterrorism Act**
 - **HACCP**



REGULATORY COMPLIANCE BUZZ WORD BINGO

- **Bioterrorism Act**
- **HACCP**
- **Material Requirements Planning (MRP)**
- **Value Stream Mapping**



REGULATORY COMPLIANCE BUZZ WORD BINGO



SECURITY STRATEGY (301)

FOOD ADULTERATION (302)

DETENTION (303)

REGISTRATION (305)

RECORDS MAINTENANCE (306)

PRIOR NOTICE (307)

MARKING (308)

THE BIOTERRORISM ACT 2002

- 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 President Bush signed into law June 12, 2002.
- Complete Text: [HTML](#); [PDF](#)
- The Bioterrorism Act is divided into five titles:
- [Introduction](#)
- [Title I](#) -- National Preparedness for Bioterrorism and Other Public Health Emergencies
- [Title II](#) -- Enhancing Controls on Dangerous Biological Agents and Toxins
- [Title III](#) -- Protecting Safety and Security of Food and Drug Supply
- [Title IV](#) -- Drinking Water Security and Safety
- [Title V](#) -- Additional Provisions
- 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).

REGULATORY BUZZWORD BINGO: HACCP

HAZARD ANALYSIS AND CRITICAL CONTROL POINT

ANALYZE

IDENTIFY

PREVENTIVE MEASURES

PROCEDURES TO
MONITOR

CORRECTIVE ACTIONS

VERIFY

DOCUMENT

U.S. Food and Drug Administration

The Food and Drug Administration has adopted a food safety program developed nearly 30 years ago for astronauts and is applying it to seafood and juice. The agency intends to eventually use it for much of the U.S. food supply.

One of the most important challenges is the increasing number of new food pathogens.

Advantages:

- Focuses on identifying and preventing hazards
- Is based on sound science
- Permits more efficient and effective government oversight
- Places responsibility on the producer
- Helps food companies compete more effectively in the world market
- Reduces barriers to international trade.

Buzzword Bingo:

Material Requirements Planning (MRP)

A set of techniques

Recipe & BOM, inventory, demand

Time phased

Recommendations

What, when & why

Proven

Material Requirements Planning (MRP) – A set of techniques that uses bill of material data, inventory data, and the master production schedule to calculate requirements for materials. It makes recommendations to release replenishment orders for material. Further, because it is time-phased, it makes recommendations to reschedule open orders when due dates and need dates are not in phase. Time-phased MRP begins with the items listed on the MPS and determines:

(1) the quantity of all components and materials required to fabricate those items and (2) the date that the components and materials are required.

Time-phased MRP is accomplished by exploding the bill of material, adjusting for inventory quantities on hand or on order, and offsetting the net requirements by the appropriate lead times.

Source: APICS Dictionary, Eleventh Edition

BUZZWORD BINGO: LEAN MANUFACTURING/PRODUCTION

Minimization
of resources
used

Eliminating
non-value-
added

A set of
principles and
practices

Reduce cost

Relentless
removal of
waste

Simplification

Lean production – A philosophy of production that emphasizes the minimization of the amount of all the resources (including time) used in the various activities of the enterprise. It involves identifying and eliminating non-value-adding activities in design, production, supply-chain management, and dealing with customers. Lean producers employ teams of multiskilled workers at all levels of the organization and use highly flexible, increasingly automated machines to produce volumes of products in potentially enormous variety. It contains a set of principles and practices to reduce cost through the relentless removal of waste and through the simplification of all manufacturing and support processes.

Source: APICS Dictionary, Eleventh Edition

BIOTERRORISM ACT – RECORD KEEPING

- **Examine the FDA final directive**
- **Implied requirements**
- **Why an approximation is not adequate**
- **95% data accuracy dilemma**
- **The role of integrated data flow & real-time validation**



IT DOESN'T HAVE TO BE THIS WAY

BIOTERRORISM ACT – RECORD KEEPING: THE FINAL FDA DIRECTIVE

The records that must be established and maintained by non-transporters of food

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.

What are the record availability requirements?

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



<http://www.cfsan.fda.gov/~dms/fsbtac23.htm>

When is compliance with the recordkeeping regulation required?

All businesses... must comply...

- 500 - XXX number of employees - 12/09/05
- 11 - 499 number of employees - 06/09/06
- 1 - 010 number of employees - 12/09/06

IMPLIED REQUIREMENTS



IMPLIED REQUIREMENTS

- **Accurate recipes and Bill of Materials**
- **Organized receiving and warehouse storage areas**
- **Receiving data recording**
- **Defined quarantine or hold areas**
- **Data integrity and inventory record accuracy**



ATOMIC CLOCK

IMPLIED REQUIREMENTS

- **Accurate recording of materials used in production or scrapped**
- **Accurate recording of finished production**
- **Tracking of finished products to customer shipping locations**
- **Rapid access to critical regulatory data**



WHY AN APPROXIMATION IS NOT ADEQUATE

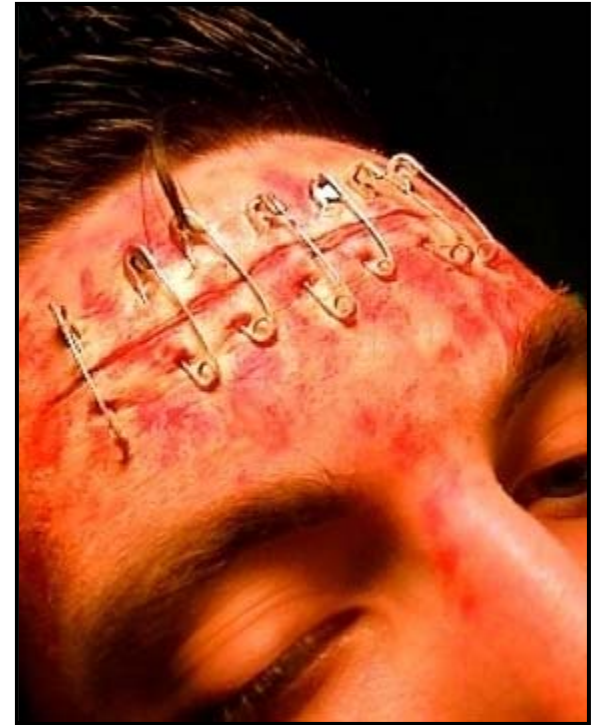
- **Port of departure -**
- **Cross the Atlantic Ocean**
- **Destination port -**
- **Two degree error during the journey**
- **Two degree's = this much**
- **Actual arrive point error =**



WHY AN APPROXIMATION IS NOT ADEQUATE

“He was scheduled for a removal of a minor skin cancer on his cheek. I was only off by six inches, I’ll get it right the next time, mistakes happen”

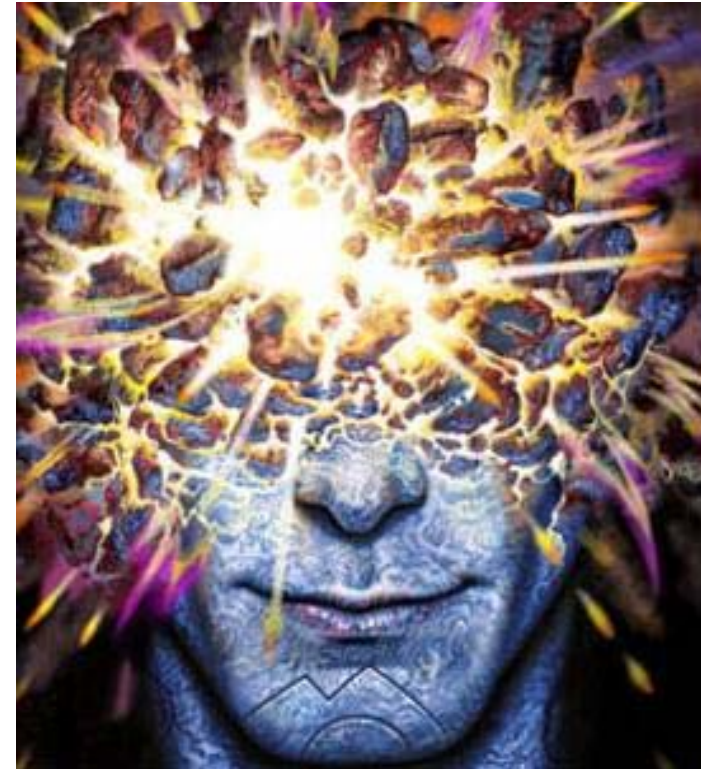
The surgeon



THE 95% DATA ACCURACY DILEMMA

95% SOUNDS GOOD UNTIL YOU CONSIDER THE “AMPLIFICATION EFFECT”

- **95% Recipe accuracy X**
- **95% Bill-of-Material accuracy X**
- **95% Work instruction accuracy X**
- **95% Inventory record accuracy X**
- **95% Inventory issuing accuracy X**
- **95% Factory reporting accuracy X**



= THE CONFUSION FACTOR

THE ROLE OF INTEGRATED DATA FLOW & REAL TIME INTEGRATION

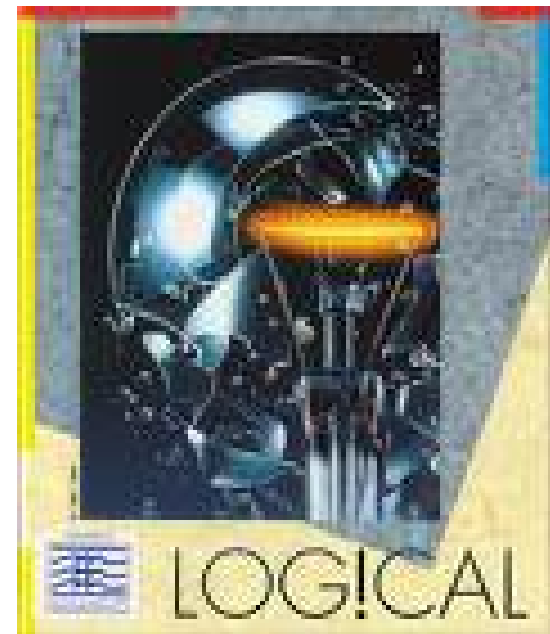


DELUXE COLLECTION OF (INFORMATION) SILOS

THE ROLE OF INTEGRATED DATA FLOW & REAL TIME INTEGRATION

Benefits

- **One source for data**
- **Real time data validation**
- **User accessibility**
- **Allows for query and reporting**
- **Provides basis for performance measurements**



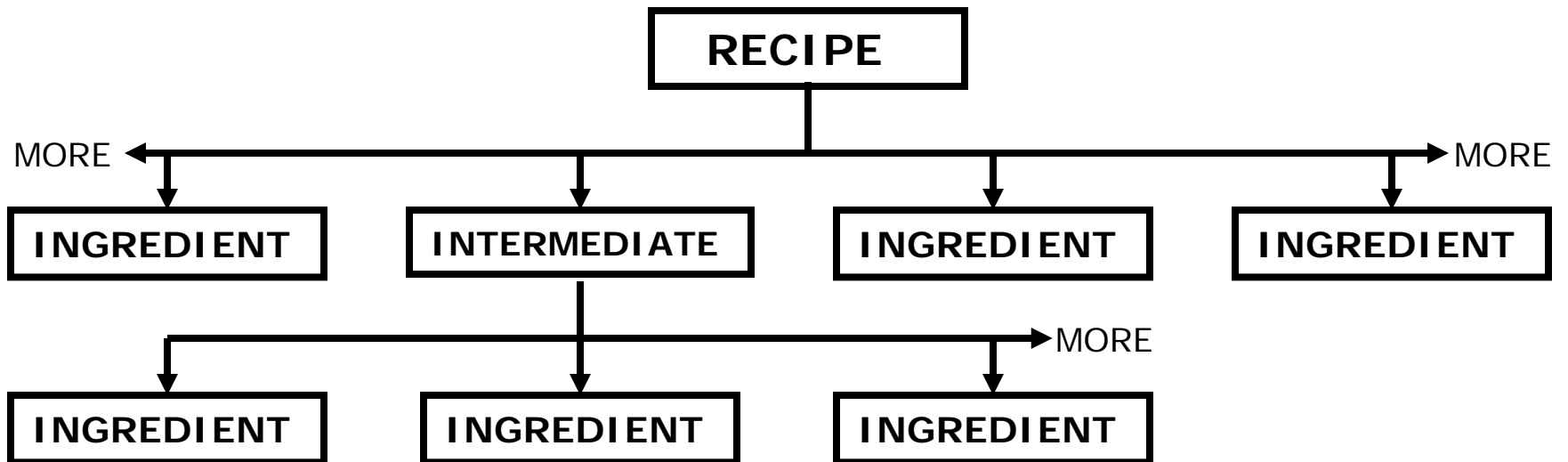
LEVERAGING THE RECORD KEEPING REQUIREMENT - ADVANCED INVENTORY PLANNING

- **Material Requirements Planning (MRP) – old faithful**
- **Requires high levels of data accuracy - just like FDA record keeping**
- **Proven**
- **Existing implementation & usage know-how**
- **Excellent ROI**



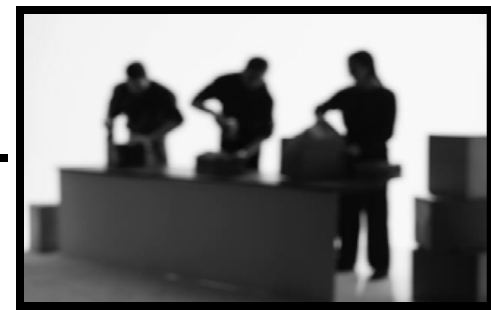
MATERIAL REQUIREMENTS PLANNING (MRP)

SIMPLIFIED EXAMPLE



IMAGINE MANY BACKLOGGED ORDERS

MATERIAL REQUIREMENTS PLANNING (MRP)



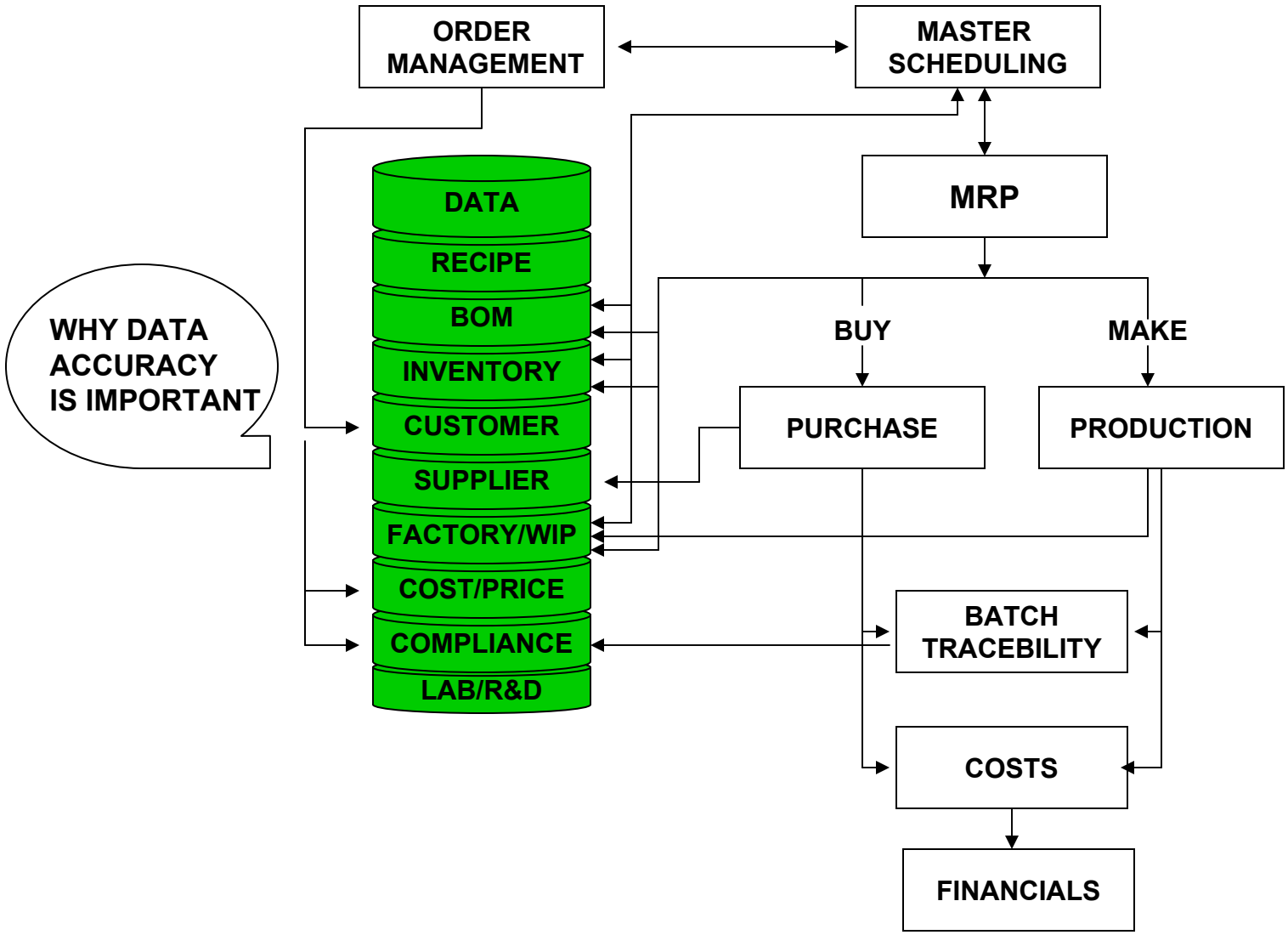
WHAT DO WE NEED

HOW MANY

WHEN DO WE NEED THEM

WHEN DO WE NEED TO START

CONCEPTUAL GENERIC ERP REPRESENTATION



DISCUSSION OUTLINE

TWO FOR ONE THINKING

- √ Why I developed this presentation
- √ The food & beverage manufacturing industry in the USA – an overview
- √ The bio-toxin attack simulation
- √ Food Engineering magazine:-
Top ten critical issues
- √ Regulatory compliance buzzword bingo:
 - The Bioterrorism Act
 - HACCP
- √ The Bioterrorism Act – record keeping
- √ Leveraging the record keeping requirement required by the FDA – advanced inventory planning
- **Leveraging HACCP to improve factory operations**
- **The benefits**
- **Conclusion - video**



REGULATORY BUZZWORD BINGO: HACCP

HAZARD ANALYSIS AND CRITICAL CONTROL POINT

ANALYZE

IDENTIFY

PREVENTIVE MEASURES

PROCEDURES TO
MONITOR

CORRECTIVE ACTIONS

VERIFY

DOCUMENT

U.S. Food and Drug Administration

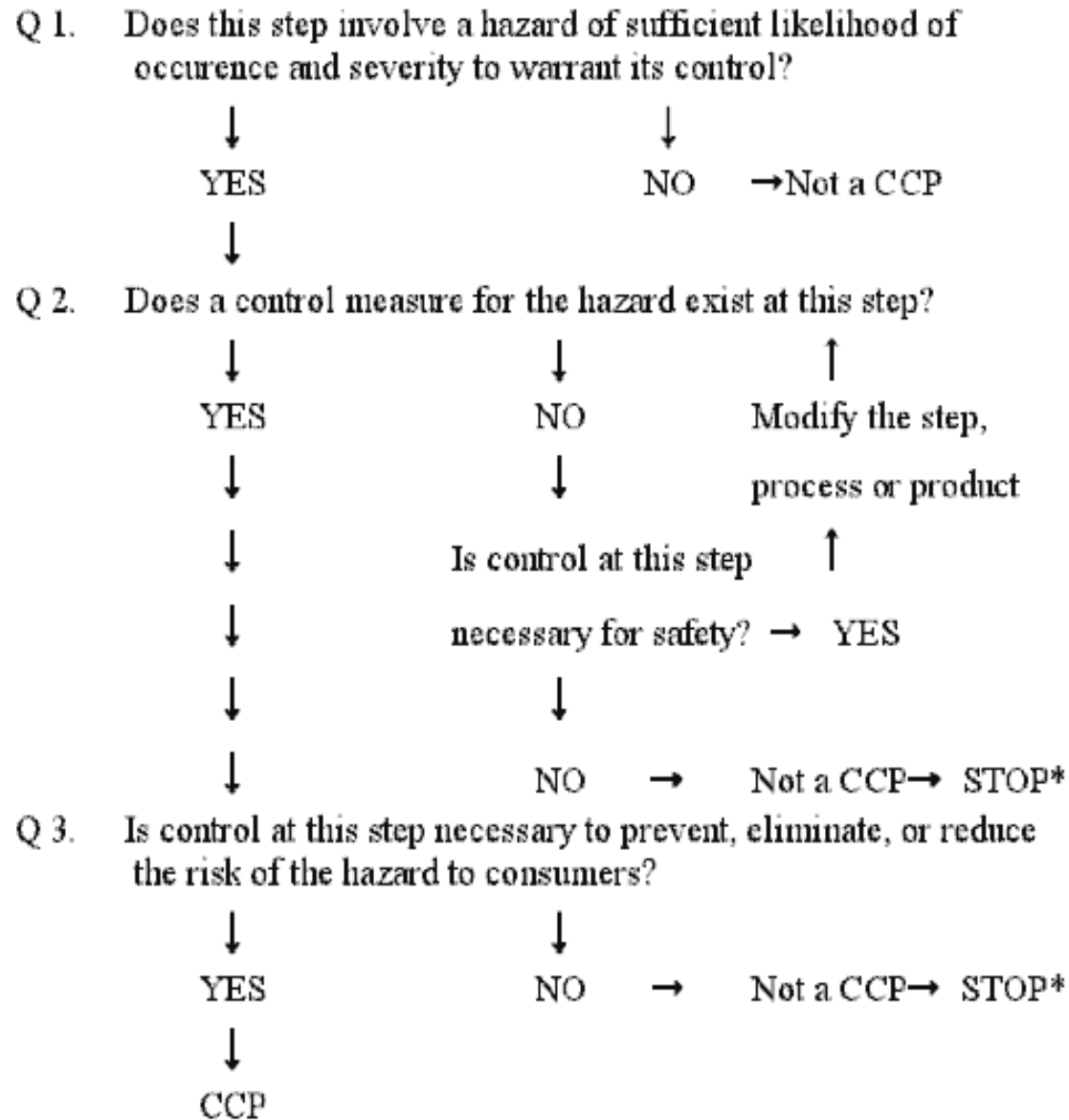
The Food and Drug Administration has adopted a food safety program developed nearly 30 years ago for astronauts and is applying it to seafood and juice. The agency intends to eventually use it for much of the U.S. food supply.

One of the most important challenges is the increasing number of new food pathogens.

Advantages:

- Focuses on identifying and preventing hazards
- Is based on sound science
- Permits more efficient and effective government oversight
- Places responsibility on the producer
- Helps food companies compete more effectively in the world market
- Reduces barriers to international trade.

HACCP - HAZARD ANALYSIS AND CRITICAL CONTROL POINT



SOURCE: FDA WEBSITE

LEVERAGING HACCP INTO OPERATIONAL IMPROVEMENTS

HACCP - CONCEPTUALLY SIMILAR BUT WITH A DIFFERENT PURPOSE TO:

- SOX (financial)
- ABC (priority)
- TOC (bottlenecks)
- Value Stream Mapping
 - Waste



MIRROR IMAGE

BUZZ WORD BINGO: VALUE-STREAM MAPPING

Simple .. No
equipment
needed

See and
understand

Flow

Activity +
information

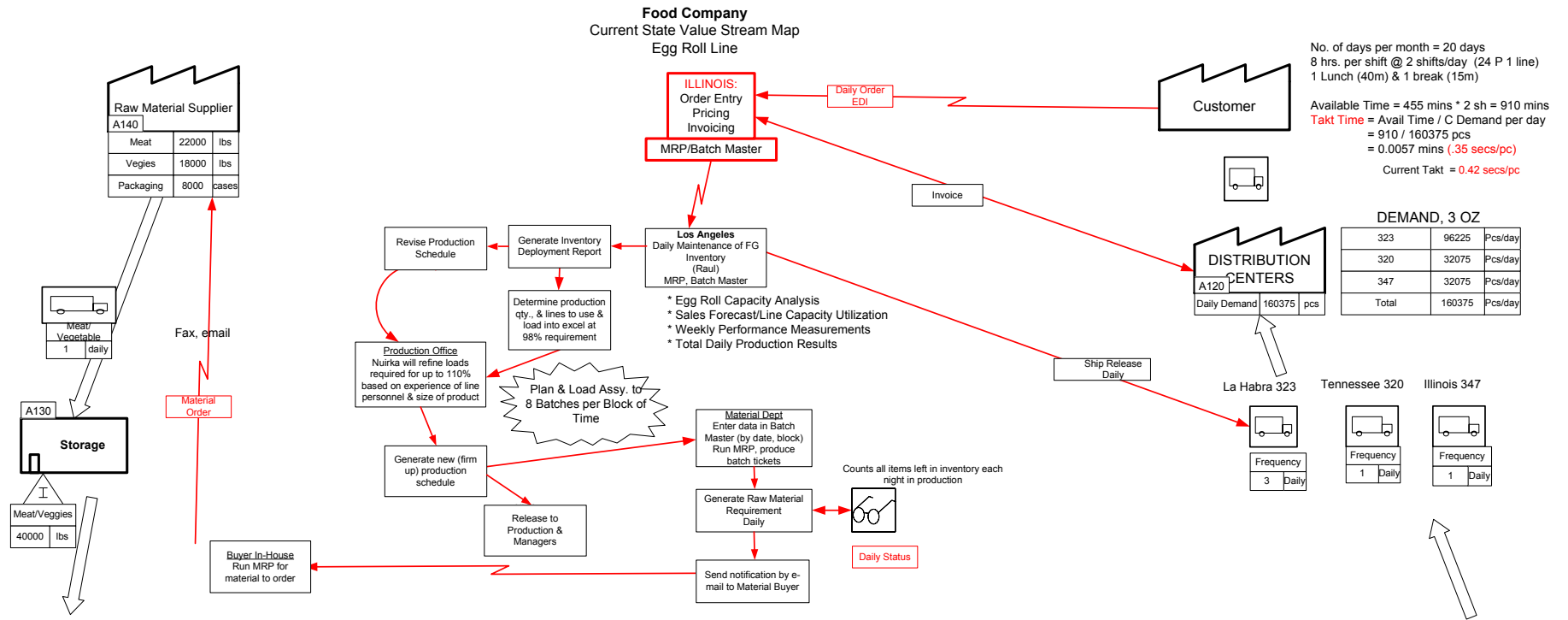
Eliminate
waste

Value Stream Mapping - 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

VALUE STREAM MAPPING



VALUE STREAM MAPPING BENEFITS

- **Helps you visualize more than the single-process level**
- **Links the material & information flows**
- **Provides a common language**
- **Provides a blueprint for implementation**
- **More useful than quantitative tools**
- **Ties together lean concepts & techniques**



THE BENEFITS OF ERP

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)

IF YOU HAVE ANY QUESTIONS OR RECOMMENDATIONS

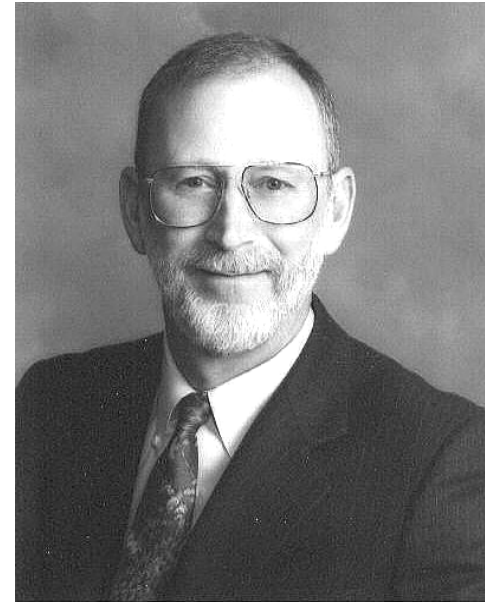
CONTACT ME AT:

**PRESTON W BLEVINS CFPIM,
CIRM**

E-MAIL:

pblevins@batchmaster.com

MOBILE: 949.813.5217



BATCHMASTER[®]
PROCESS MANUFACTURING ERP

IS OUR FOOD SUPPLY SAFE? REGULATORY COMPLIANCE IN FOOD & BEVERAGE MANUFACTURING

A SHORT VIDEO FOR
THOSE WITH A SENSE OF
HUMOR

