



BAKINGTECH 2018

SUSTAINABILITY-SUCCESS THROUGH PEOPLE

PRODUCTS AND PRODUCTIVITY

The Impact of FSMA On Bakery Design & Construction

Mike Pierce & Jeff Dearduff

INTRODUCTION

Design and Construction of food plants, bakeries included, has went through many transitions through the years.

- *From wood and brick floors at the turn of the century to the polished, hardened or epoxy finished floors of today.....*
- *From the brick and steel frame building of the past to the precast tilt wall and IMP buildings of today.....*
- *From the process layouts that were built on multiple floors to the large format single floor layouts of today.....*

Now we have more transitions to work through, driven by

**FDA FOOD SAFETY
MODERNIZATION ACT**



BAKINGTECH 2018
SUSTAINABILITY-SUCCESS THROUGH PEOPLE
PRODUCTS AND PRODUCTIVITY

Refresher: What is FSMA?

The **FOOD SAFETY MODERNIZATION ACT** (FSMA) was signed into law by President Obama on January 4, 2011.

It aims to ensure the U.S. food supply is safe by shifting the *focus of federal regulators* from RESPONDING to **contamination** to PREVENTING it.

Ref: FDA Website



And.....

About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention.

The **FOOD SAFETY MODERNIZATION ACT (FSMA)** is *transforming the nation's food safety system* by shifting the focus from RESPONDING to **foodborne illness** to PREVENTING it.

Ref: FDA Website



BAKINGTECH 2018
SUSTAINABILITY-SUCCESS THROUGH PEOPLE
PRODUCTS AND PRODUCTIVITY

Foundational Rules

Rules and Related Programs

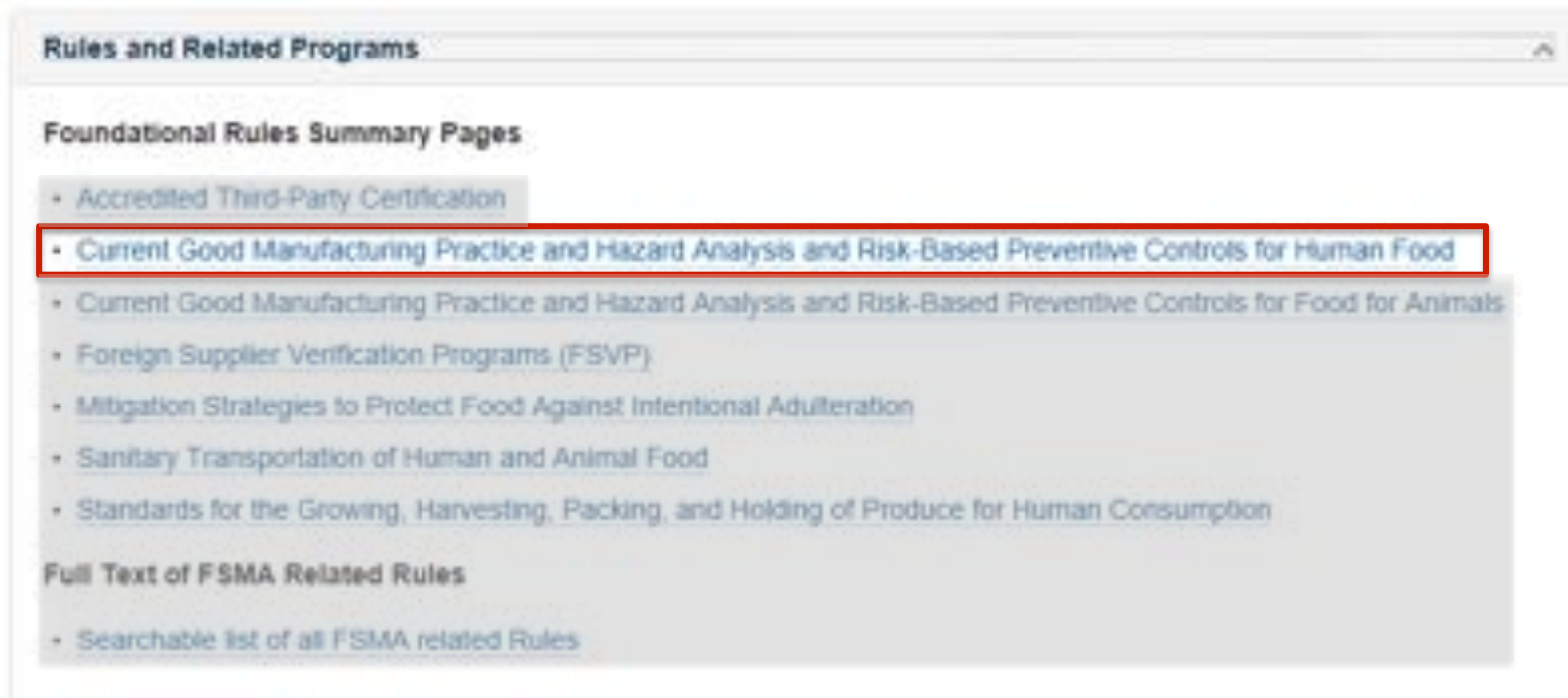
Foundational Rules Summary Pages

- [Accredited Third-Party Certification](#)
- [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
- [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals](#)
- [Foreign Supplier Verification Programs \(FSVP\)](#)
- [Mitigation Strategies to Protect Food Against Intentional Adulteration](#)
- [Sanitary Transportation of Human and Animal Food](#)
- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)

Full Text of FSMA Related Rules

- [Searchable list of all FSMA related Rules](#)

Foundational Rules



Rules and Related Programs

Foundational Rules Summary Pages

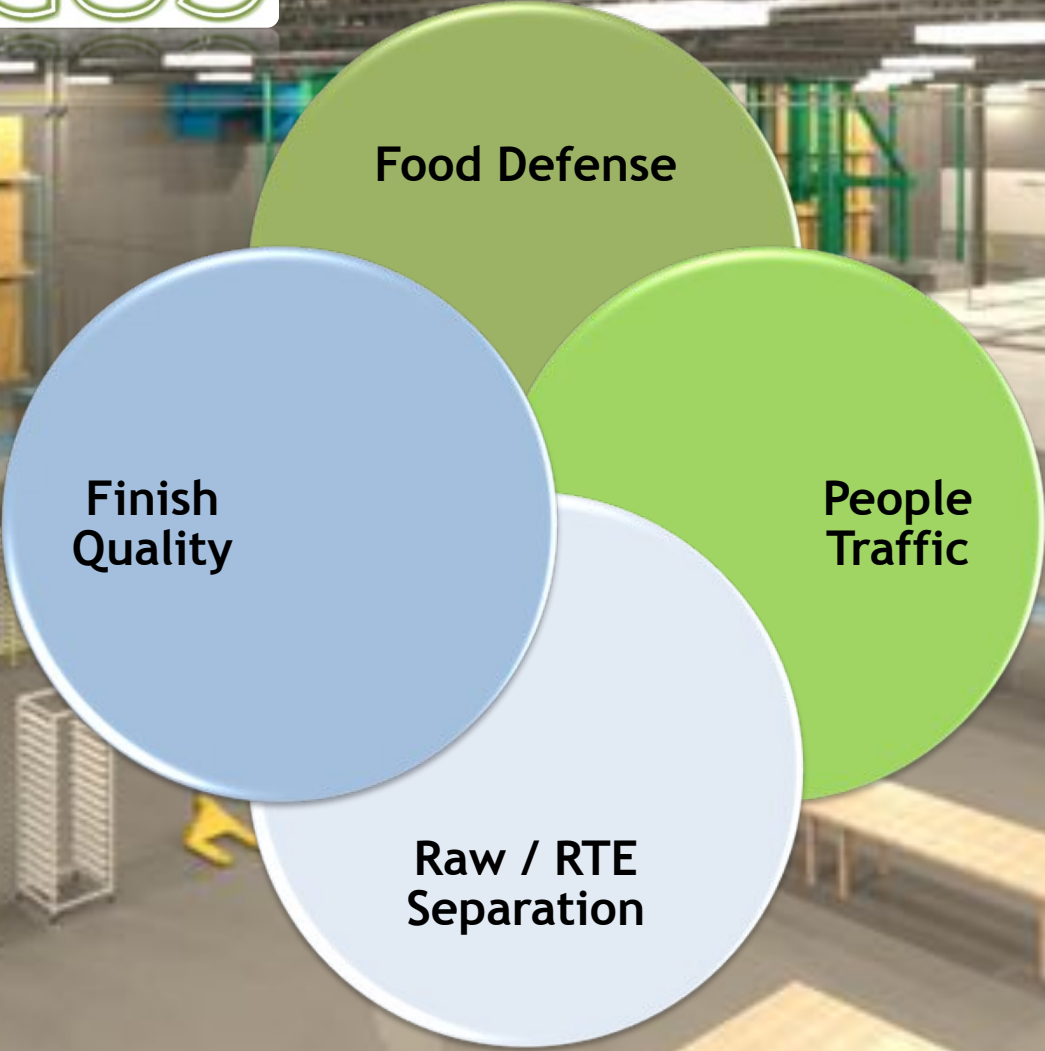
- Accredited Third-Party Certification
- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
- Foreign Supplier Verification Programs (FSVP)
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Sanitary Transportation of Human and Animal Food
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Full Text of FSMA Related Rules

- Searchable list of all FSMA related Rules

Today we will discuss the design elements related to GMP's and Hazard Prevention

INFOCUS



DESIGN & CONSTRUCTION

Food Defense

Key Points;

- **Site security**
- **Building security**
- **Bulk Ingredients protection**
- **Building access control**



Site Security

- **Perimeter Fencing**

- *Must be built in such a way that it is impenetrable, else it is decorative only*
- *Should have limited access points*
- *Must be monitored*



- **Traffic Control**

- *Freight haulers should be separate from employee and visitor car traffic*
- *Freight haulers should have to check in before entering the active part of the property*
- *Car parking should be by permit only and must be monitored*

- **Surveillance Cameras**

- *Must avoid blind spots when surveilling outside grounds*
- *Must be monitored and reviewed*

Building Security

- **Minimize Access**

- *Should be designed with 3 key access points;*
 - *Office and Visitor entry*
 - *Employee entry*
 - *Delivery / Trucking entry*
 - *All with proper signage and instruction*
 - *Access breaches must not be allowed*



- **Surveillance Cameras**

- *Should be aimed at EVERY access point and emergency exit*
- *Should also be aimed at EVERY critical processing point throughout the plant that can be accessed*
- *Must avoid blind spots*
- *Must be monitored and reviewed*

Bulk Ingredient Protection

- **What to Protect – Outdoor and Indoor**

- *Flour and Sugar Silos*
- *Oil Tanks*
- *Cream Yeast Tanks*
- *Water Supply*
- *Open ingredient vessels*
- *Raw Ingredient Warehousing*



- **Physical Barriers**

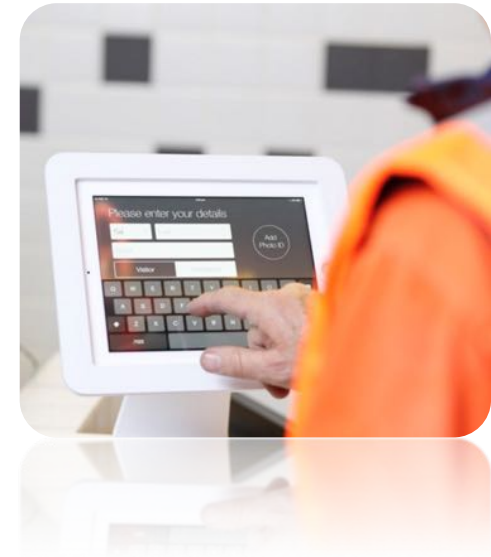
- *All access points, doors and ports must have locking devices with controlled access*
- *Multiple levels of security desired; fencing + locks + cameras*

- **Surveillance Cameras**

- *Should be aimed at EVERY bulk ingredient access point*
- *Must avoid blind spots*
- *Must be monitored and reviewed*

Building Access Control

- **Know Who is On Property**
 - *Stringent check in process for;*
 - *Office & Plant Visitors*
 - *Deliveries / Trucker check in*
 - *Employee check in*
 - ***CHECK OUT*** process for all!
- **Physical Controls**
 - *All entries must have some sort of monitored access;*
 - *Key Fob, Swipe Card, Biometrics*
- **Surveillance Cameras**
 - *Should be aimed at EVERY access point and emergency exit*
 - *Must avoid blind spots*
 - *Must be monitored and reviewed*



How Food Defense Impacts Design & Construction

- *Before FSMA to Now*



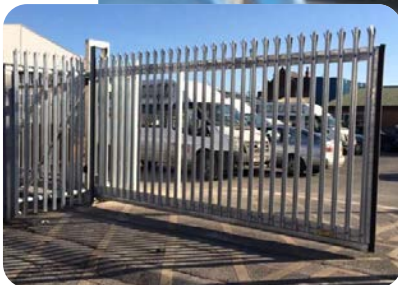
DELIVERIES



VISITOR
ENTRANCE

EMPLOYEE
ENTRANCE

**RESTRICTED
AREA**
ACCESS ONLY BY
**AUTHORIZED
PERSONNEL**



People Traffic

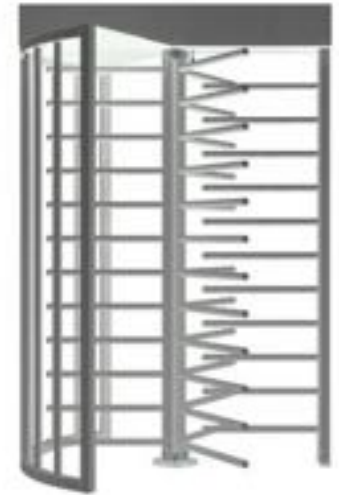
Key Points;

- **Flow through check in to plant floor**
- **Controlled walk paths**
- **Transition spaces**



Flow through check-in to plant floor

- **Permanent Employees**
 - *Enter controlled access point*
 - *Pass through clean laundry pick up area*
 - *Pass through lunch room*
 - *Pass through restrooms*
 - *Clock in to gain access to production floor*
- **Temporary Employees**
 - *Same as above PLUS assurance that the person is scheduled to work*
- **Visitors and contractors**
 - *Proper check in, gowning, GMP brief, accompaniment*
 - *Follow same rules as employees*



Controlled Walk Paths

- **Why is this important?**
 - *Keep people heading in the right direction*
 - *Keep opportunities for cross-contamination minimized*
 - *Keep employees in a safe zone from machinery and other traffic*
- **Methods**
 - *Taped or painted lines*
 - *Separate corridors*



Transition Spaces

- **What are they?**
 - *Dedicated spaces of transition to assure cross-contamination prevention between processes*
 - *Allows for re-gowning and hand washing when traveling from one area of process to another*
 - *Includes shoe washing and hairnet exchange*



How People Traffic Impacts Design & Construction

- Before FSMA to Now



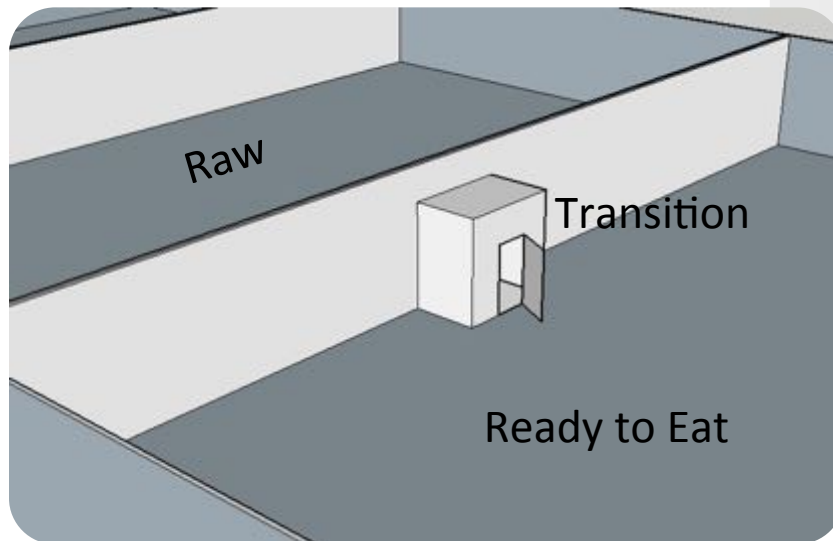
- *Travel paths utilize space that once could be for process therefore causing more space to be built in total*
- *Corridors are EXPENSIVE both in construction cost and in loss of space to processing*
- *Corridors are VALUABLE because they enable ready movement of people, materials and equipment before entering controlled space*
- *Travel times increase for employees leading to potential efficiency loss effect*



Raw / RTE Separation

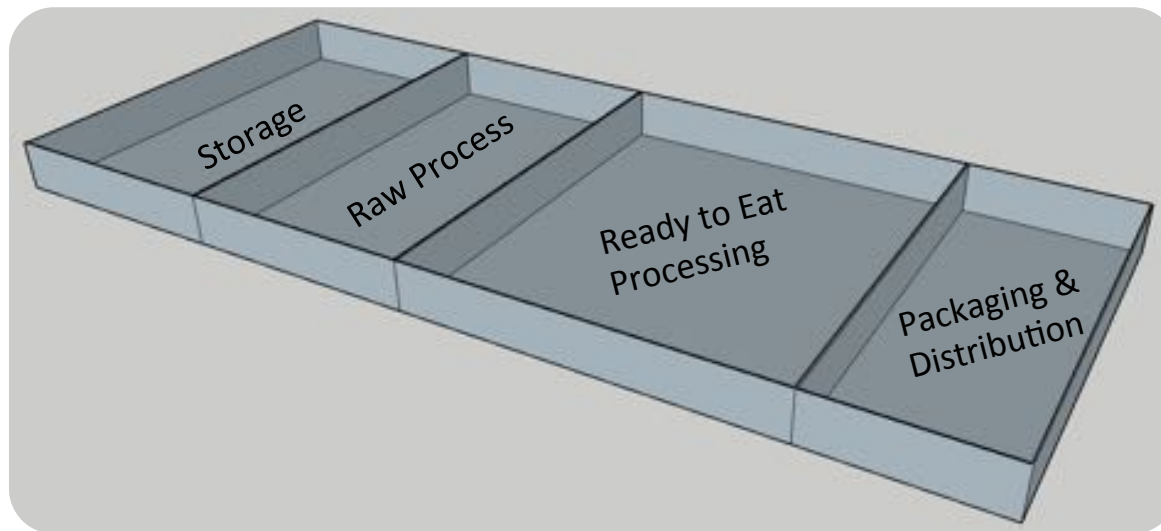
Key Points;

- Why separate
- How to separate



Why Separate?

- **Allergen and Cross-Contamination prevention**
 - *Best protection against bacteria transfer*
 - *Reduces opportunities for accidental activity*
 - *Reduces opportunities for malicious activity*
 - *Allows for cleaning in a raw area while finished product is processed in a Ready to Eat area*



How to Separate?

- **Methods of creating Separation**
 - *Dedicated area control, signage and marking*
 - *Least effective*
 - *Box-in-a-box structures using Insulated Metal Panels for walls and ceilings*
 - *MOST effective*
- **Other factors**
 - *Doors and door control*
 - *Transition spaces between processing points*
 - *Dedicated tools for maintenance and sanitation*
 - *Dedicated workers and supervisors for different process areas*



How Raw-RTE Separation Impacts Design & Construction

- *Before FSMA to Now*



- *Cost of construction increases as extra square footage is needed for walk paths and corridors*
- *Construction costs increase because of added walls, doors and transition areas and cleaning equipment*



Finish Quality

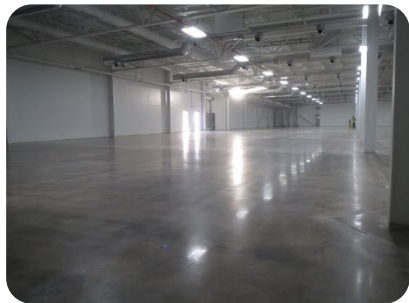
Key Points;

- Floors
- Drains
- Internal Walls & Ceilings



Floors

- Options
 - *Untreated concrete floors are yesterday's news*
 - *Polished concrete*
 - *Polished and hardened concrete*
 - *Polished, hardened and stained concrete*
 - *Epoxy coated concrete*
 - *Acid Brick floors*
 - *Stainless flooring in special areas*



Drains

- **Options**
 - *Standard cast iron drain heads are yesterday's news*
 - *Stainless drain heads*
 - *Stainless trench drains*
 - *Stainless slot drains*
- **Quality of the drain design is critical to sanitary performance**



Internal Walls & Ceilings

- Options
 - *Painted walls and ceilings are yesterday's news*
 - *Bare, but sealed concrete*
 - *Smooth finish Insulated Metal Panel*
 - *Epoxy coated walls*
 - *Stainless cladding wall sheets*



How Finish Quality Impacts Design & Construction

- *Before FSMA to Now*



- *Cost of construction increases as surface finishes are increased in quality for sanitary defense*



Conclusion

- There is nothing about food plant Design & Construction that leads to compliance with FSMA that cannot be done.
- The choice to fully comply or partially comply is always the decision of the owner and needs to be appropriately funded.
- The cost of full compliance is always going to be at a higher price point than partial, or zero compliance.
- When designing, the owner should provide guidance to the designer as to just how far towards compliance they want to go so that there are no surprises at the end.
- The designer needs to be prepared to walk the owner through the risks and rewards of all levels of sanitary design.



Q & A