



Process Management & Process Control Indicators

“The Journey to a State of Control”

NAMI NORTH AMERICAN
MEAT INSTITUTE



Operational Definitions

Verification Site Investigation

- Triggered by a Verification Program positive (Product, Z1, Z2 or Z3)
 - Verification program by definition measures the effectiveness of the plant's Sanitation Process Control System or the Environmental Control Program
- Example:
 - Food Safety has been compromised by a product positive
 - Food Safety may be potentially compromised by a Z1 Ls positive
 - Investigation following a Z2 or Z3 Ls Verification Site positive

Verification Site Investigation is conducted in response to a positive finding that calls into question the effectiveness of the control system

Operational Definitions

Process Control Site Investigation

- Food Safety has not been compromised
 - Examples:
 - Samples taken to find a new growth niche
 - Samples taken to find a new transfer vector / pathway
 - Samples taken to establish or qualify a hurdle or barrier system
 - Samples taken to establish a monitoring procedure or process
 - Samples taken to assess or characterize risk of a control procedure, part of facility or process change

Operational Definitions

Process Control Site Investigation

- Food Safety has not been compromised
 - Examples:
 - Can be triggered by a Z2, Z3 or Z4 indicator site positive.
 - These indicator sites are strategically located in close proximity to a known growth niche, barrier or hurdle. Movement of the organism from the indicator site through a verification site or area would be required before violation of food safety.
 - These indicator sites over time measure the strength of the barrier or hurdle or the effectiveness of the management of growth niches

Operational Definitions

Process Control Site Investigation

- Food Safety has not been compromised
 - Examples:
 - Seek and Destroy Investigation on a new piece of equipment to develop sanitation methods and identify potential areas of risk
 - Seek and Destroy Investigation on a piece of equipment that has been in operation without any linked Verification site positives. The purpose of this investigation is to measure effectiveness of sanitation methods below the normal level of disassembly.
 - Investigative sampling to identify optimal locations for placement of indicator sites in either Z3 or Z4
 - Measurement of risk in Z4 area

Validation Elements

Scope

- Program
- After Product Positive
- Z1 or Contact Surface Positive
- Z2 or Z3 **Verification** Positive

Program Validation

Approaches to Environmental Control Program Validation

- Data from Verification Monitoring results accumulated over time does not meet the technical criteria for validation.
- The scope of validation should cover Z4 to Z1 and Product.
- The effectiveness of hurdles and barriers to entry must be measured in the validation test design
- Harborage sites from equipment, facility as well as transient items must be included in the scope of the validation test design
- The validation test design should be composed of an intensified sampling process for a short period of time

Program Validation

Approaches to Environmental Control Program Validation

- Once validated Environmental Control Programs should be reassessed at least annually.
- Reassessment includes noting process changes since the last reassessment and intensified sampling over a short period of time.
 - If there have been no significant process changes then reassessment should occur.
 - Think of this as the verification of the validation process
- If there have been significant process changes then the Environmental Control Program should be revalidated.

Validation

Product Positive

- The root cause or harborage site itself (*Investigation to determine root cause is necessary*) and surfaces affected by the growth niche need to be measured negative for 3 consecutive samples.
- This includes Product confirmation.
- Definition:
 - Three Consecutive Samples
 - Once the operation starts up after corrective and or preventive action has been taken the first validation sample (s) is taken.
 - The second and third samples are taken after their preceding validation sample results are obtained. In many situations this could be a 3 week process.
- Program validation is recommended with in 6 months of a product positive

Validation

Contact Surface (Zone 1) Positive

- The harborage site and transfer pathway surfaces affected by the growth niche need to be measured negative for 3 consecutive samples.
- This includes the Contact Surface site from the Verification Program that was positive.
- Definition:
 - Three Consecutive Samples
 - Once the operation starts up after corrective and or preventive action has been taken the first validation sample is taken.
 - The second and third samples are taken after their preceding validation sample results are obtained. In many situations this this could be a 3 week process.
- Preventive Action resulting in process redesign need to be validated

Validation

Zone 2 or 3 Positive

- The transfer point and source harborage site and transfer pathway surfaces affected by the growth niche need to be measured negative for 3 consecutive samples.
- This includes the site from the Verification Program that was positive.
- Definition:
 - Three Consecutive Samples
 - Once the operation starts up after corrective and or preventive action has been taken the first validation sample is taken.
 - The second and third samples are taken after their preceding validation sample results are obtained. In many situations this is a 3 week process.
- Preventive Action resulting in process redesign need to be validated

PROCESS CONTROL

Pillars of Microbiological Process Control Technology

1. Eliminate the organism from Exposed Product Area
2. Control transfer of the organism
3. Deploy Process Management Techniques



Eliminate the Organism From the Exposed Product Area

Development of Interventions

- Each piece of equipment needs an intervention (*a process that is capable of eliminating the organism from the most likely point of contamination to the deepest most difficult to remove location*).

Eliminate the Organism

Requirements for effective control Listeria spp. in a plant:

1. Process Control Investigation coupled with corrective and preventive action must lead to locating the growth niches.
2. Process control must be data-driven; data will be derived from Indicator site monitoring, qualification and investigative work.
3. Product and contact surface sampling results coupled with validation results will validate the effectiveness of the program.

Prevent Movement of the Organism

Control of Transfer Vectors

- Distinct Hygienic Zones are established in the facility
- Physical separation of raw from RTE
 - Personnel & material flows are controlled to reduce hazards:
- Water accumulation is controlled inside the facility
- Sanitation GMP's
- Operational GMP's are designed and executed to establish control and to prevent cross contamination

Process Management

Listeria Equation

**Controlled
Traffic
Patterns** + **GMP's** + **Sanitary
Design
Equip &
Building** + **Clean Dry
Uncracked
Floors** + **Effective
Sanitation
Procedures**

**= Listeria
Control**

Aggressive Sampling

- A focused effort **not directed towards** process verification sites such as
 - Product and
 - Product Contact Surfaces
 - High traffic floor flow patterns
- **But directed to** indicator sites such as development of interventions and measurement of the effectiveness of hurdles.

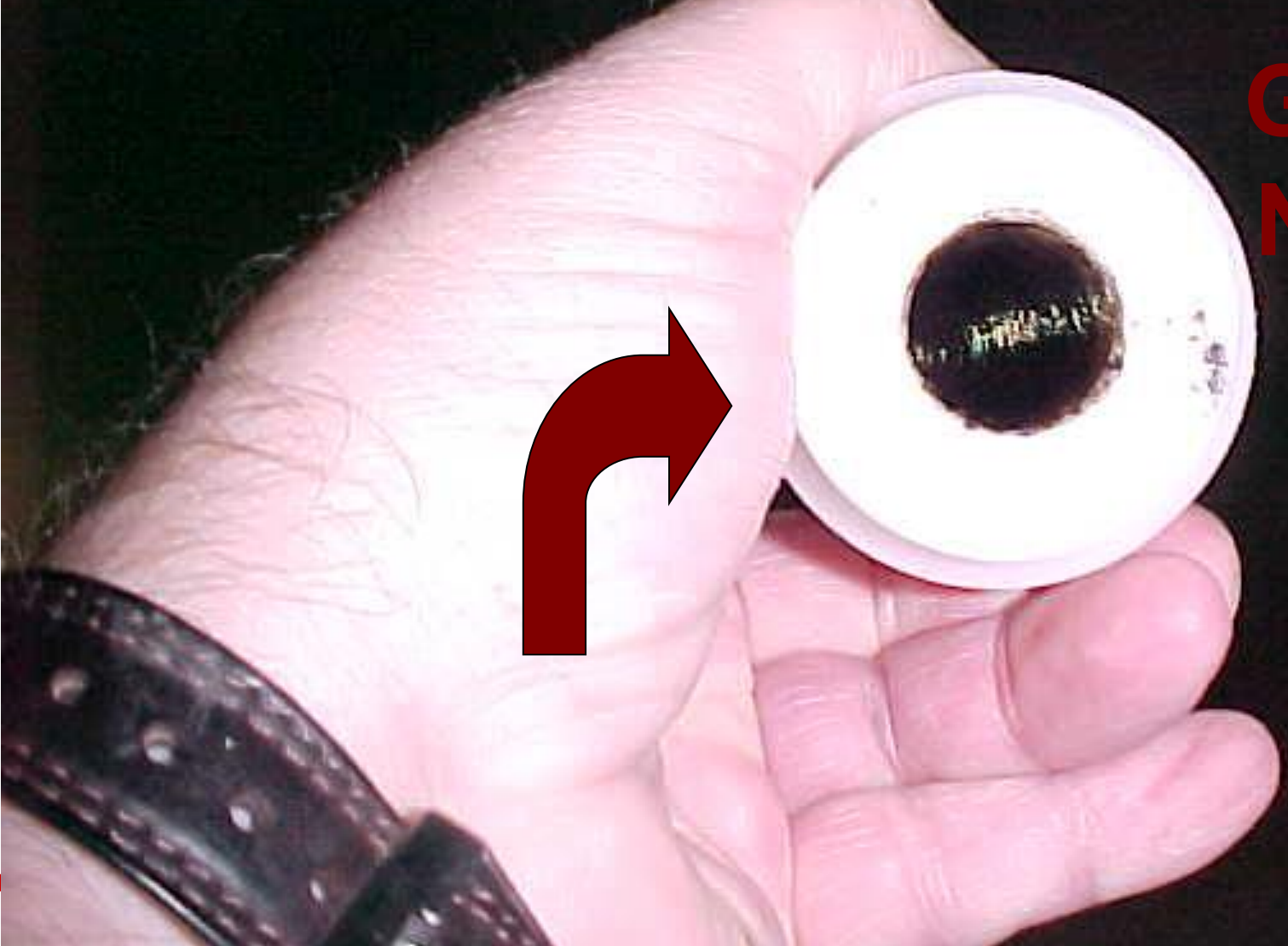
GROWTH NICHES

Locations harboring the organism after the routine sanitation process for that area has been completed.

**The Rinsing Process creates
Unintended Consequences**



Hollow roller with solid stainless steel shaft in center
(almost press fit).
When center shaft removed organic matter is
evident.



**Growth
Niches**

GROWTH NICHES

“Pets”

“The gift that keeps giving”

Must either be designed out of the system or managed as a part of the process.

- Design Examples
 - Equipment is redesigned to eliminate or seal hollow areas
- Minimize with process control techniques
 - The potential to support growth still exists within the machine, part or area

AMI Equipment Design Task Force

Resident - Persistence

Verification of Persistence within food plants

- PFGE
- MLST
- WGS

THE EVOLUTION OF THE S&D PROCESS

Doubtful to Internalized

Maturity Model for Ls Control

Sampling Results

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
Sampling Results	Contact Surface and Product positives	Expanded and regular sampling of contact surfaces and environmental sites. Intermittent positives on contact surfaces. Routine positives on environmental sites	Early preventive phase positive results dominated by indicator sites such as post rinse. In final phase of preventive, only rare Contact Surface positives. No Product Positives. Investigative facility based positives dominate RTE	No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives

FOOD SAFETY BY DESIGN



Maturity Model for Ls Control

Methods Deployed & Growth Niche Management

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
Process Control Investigations	None to Minimal	None to Minimal	Potential Growth niches mapped. Some scheduled intervention practices in place. Managing “Critical Factors” of the Sanitation process. Engaged in Equipment and Facility redesign.	Aggressive early warning sampling in place. Intervention practices in place with all RTE equipment. Focus on zone 4 and facilities. Advanced phases of both Equipment and Facility redesign.
New Equipment and Process Changes	Little to no change in Verification monitoring of Product, Z1, Z2, & Z3	NFCI testing after installation	Formal NFCI Qualification Process	Formal NFCI Qualification Process
Reaction to Indicator Site Ls+	None	None	Intensified sampling and / or intervention	Intensified sampling and / or intervention
Post Rinse Indicator Sites	None	None	Line Equipment	Line Equipment & Facility
Reaction To VER Positive	Investigate positive site and surroundings. Focused sanitation efforts on positive area. Verified with 3 negatives in a row	Found a growth niche. Cleaned and Sanitized. Did some process redesign and some heat treatment. Verified with 3 negatives in a row.	Applied intervention to harborage site and/or redesigned equipment to eliminate	Applied intervention to harborage site and/or redesigned equipment to eliminate

FOOD SAFETY BY DESIGN

AWARENESS ENLIGHTENMENT PREVENTATIVE PREDICTIVE

Maturity Model for Ls Control Sanitation Processes

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
Sanitation Methods	Measure clean with visual at preop. MSS based on Sanitation Mgr. judgement and local regulatory direction	Measure clean with visual at preop. MSS based on Sanitation Mgr. judgement and local regulatory direction. Some deep periodic cleaning.	Measure clean with APC. ATP used to train sanitors. Defined periodic deep cleaning on complex equipment. Routine scheduled heat interventions on complex equipment.	Measure clean with APC. ATP used to train sanitors. Periodic deep cleaning and interventions on complex equipment based on indicator site data.
COP	N/a	N/a	All small parts & subassemblies removed during disassembly. Maintenance & operator tools pasteurized daily	All small parts & subassemblies removed during disassembly. Maintenance & operator tools pasteurized daily

FOOD SAFETY BY DESIGN

AWARENESS ENLIGHTENMENT PREVENTATIVE PREDICTIVE

Maturity Model for Ls Control of Transfer Into RTE and within RTE

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
GMP's	Design and layout require strict GMP compliance. GMP's measured subjectively	GMP's measured subjectively. Good GMP compliance	Design and layout enable high risk GMP compliance issues.	Design, layout and process simplification from a personnel perspective reduces GMP compliance issues
Floor management	Wet floors	Partially wet floors with hurdles at most Z4 entries and room transfer points	<p>Dry floors. Hurdles in place at all Z4 entries. Floor sanitizer used to minimize transfer.</p> <p>Wet Floors with physical and chemical hurdles at controlled entry into RTE. Doorway foamers at points of transfer. Floor sanitizer applied liberally.</p>	<p>Dry floors. Hurdles in place at all Z4 entries. Floor sanitizer used to minimize transfer.</p> <p>Wet Floors with physical and chemical hurdles at controlled entry into RTE. Doorway foamers at points of transfer. Floor sanitizer applied liberally.</p>

FOOD SAFETY BY DESIGN

AWARENESS ENLIGHTENMENT PREVENTATIVE PREDICTIVE

Maturity Model for Ls Control

Investigation & Control

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
Investigation Tools	For Cause investigation (FCI)	FCI	FCI & Process Control Sampling With more Process Control Sampling	Rare FCI, Routine Process Control Sampling
Indicator Sites	None	None	Associated with known growth niches	Associated with known growth niches, Z4 & Z4-Z3 hurdles
Post Rinse Indicator Sites	None	None	Line Equipment	Line Equipment & Facility
Verification	Three in a row negatives after VER Ls+	Three negatives in a row after VER Ls+	Three negatives in a row after VER Ls+. Data Analysis and trending of area over time. Indicator site sampling deployed	Three negatives in a row after VER Ls+. Data Analysis and trending of area over time. Indicator site sampling deployed



SAMPLING TOOLS FOR THE JOURNEY

The Foundation of a Preventive and Predictive Environmental Pathogen Control Program



A solid **Foundation** enables **Preventive Control**

“

“THE GOAL OF THE FOOD SAFETY PROFESSIONAL SHOULD BE TO CREATE A FOOD SAFETY CULTURE NOT A FOOD SAFETY PROGRAM

”

- Frank Yiannas

Control by Effect Measures vs Preventive Practices

The Food Safety Culture Equation

“Values” + “Why” + Preventive Practices → Strong Food Safety Culture

“For Cause” as well as “Not For Cause” Investigational Sampling and Indicator Site Monitoring *define* and *measure* Preventive Practices

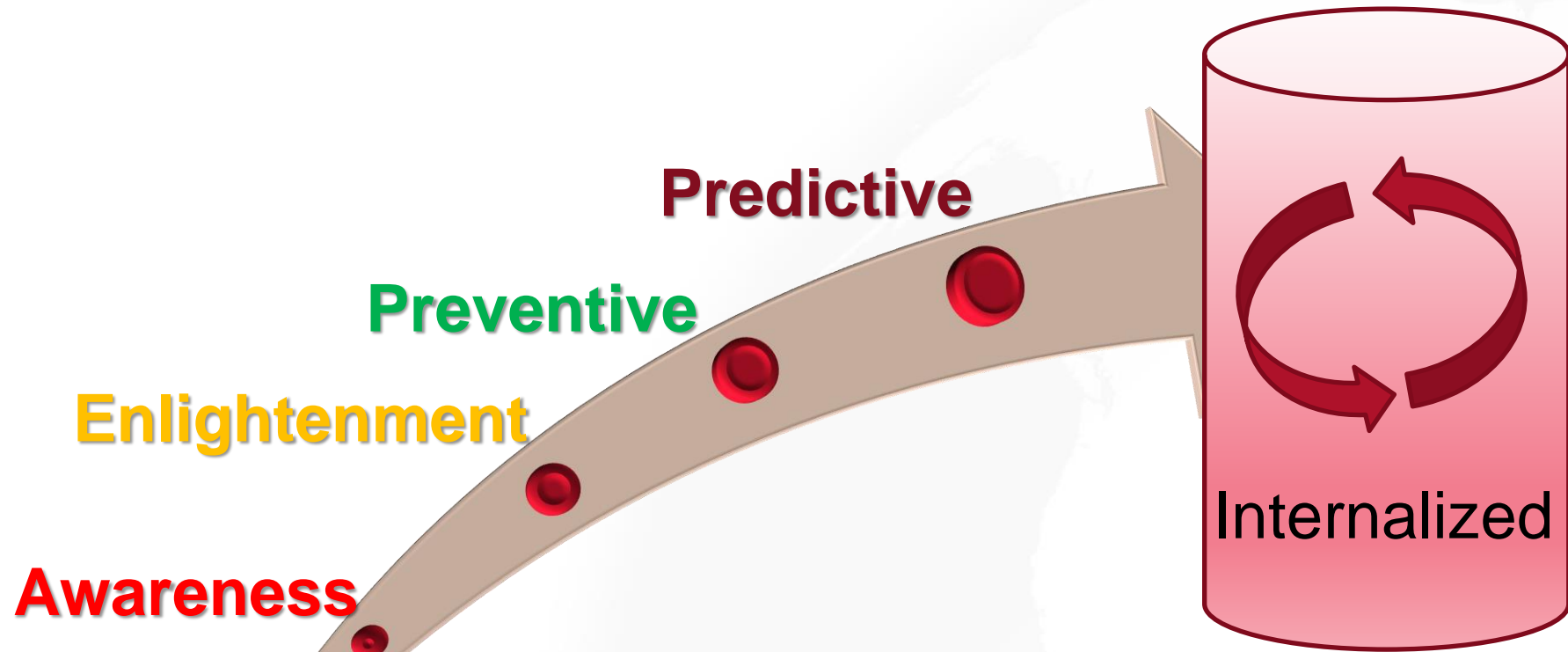
Person(s) Responsible for Food Safety

TEAM

The involvement of a multidiscipline team or group to take corrective action is a great benefit over a single person with limited scope.

- Engineer
- Microbiologist
- Sanitation
- Production operations
- Maintenance
- Food Safety or QA

The Food Safety Culture Journey



Credit to Lone Jespersen
Cultivate Food Safety

Environmental Monitoring and Preventive Practices

- Provides data for prevention of product contamination
- Must be a leading indicator, not a trailing indicator
- Foster preventive action vs “firefighting”
- Measures can be treated as a success as opposed to a system failure

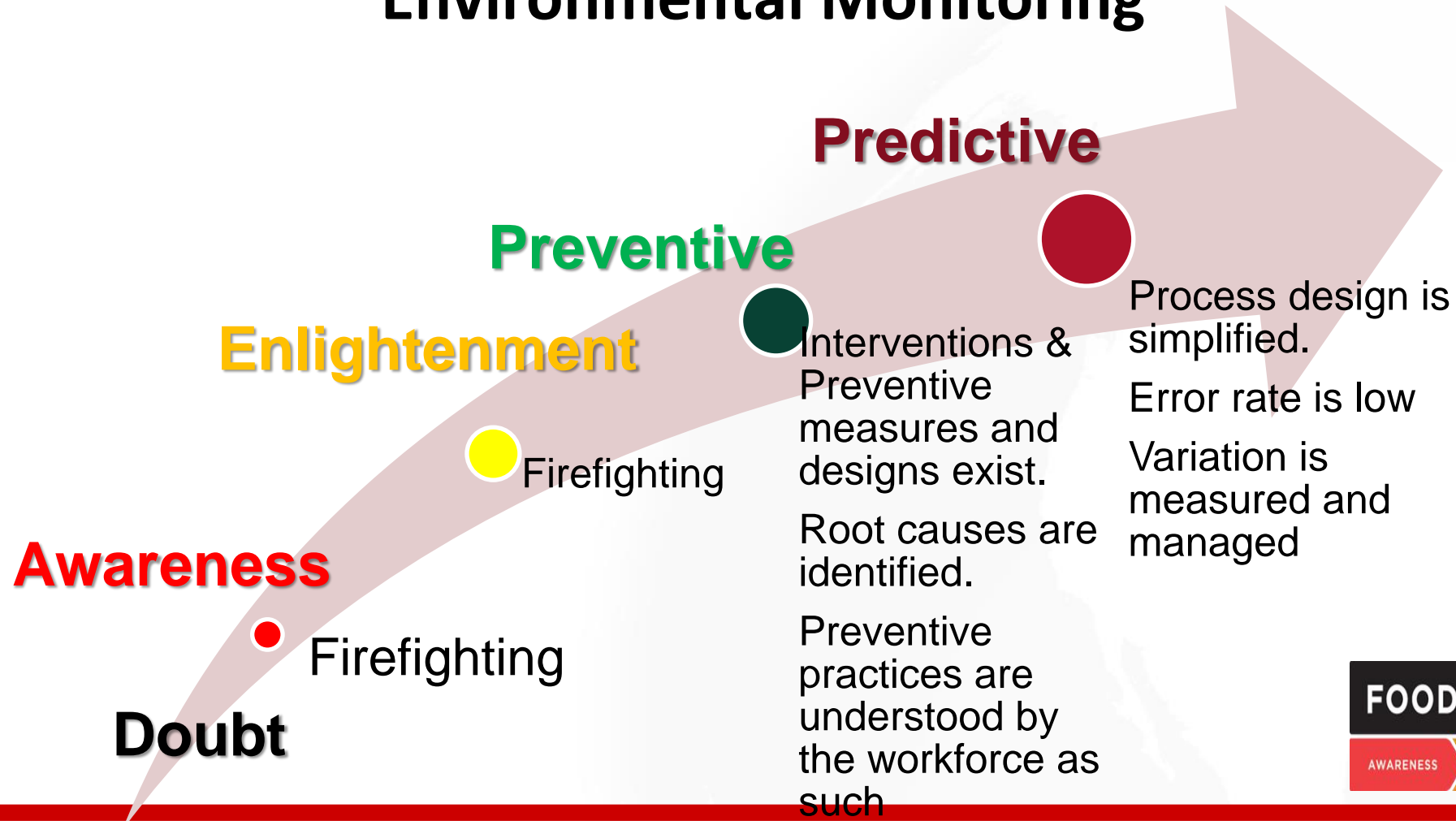
Cause & Effect

1. The punitive effect of “Verification Only” monitoring programs
 - a) Creates excessive firefighting
 - b) Fails to promote a “Preventive Mindset” and a strong Food Safety Culture
2. Aggressive sampling techniques such as Post Rinse and other Indicator type sampling can aid in discovering problems before contact surfaces or product are engaged.
3. Sampling Programs can be designed to create “success” when positives are found.
4. Data from Sampling Programs is used to measure the application of Preventive controls

“Nothing succeeds like success”

Alexandre Dumas

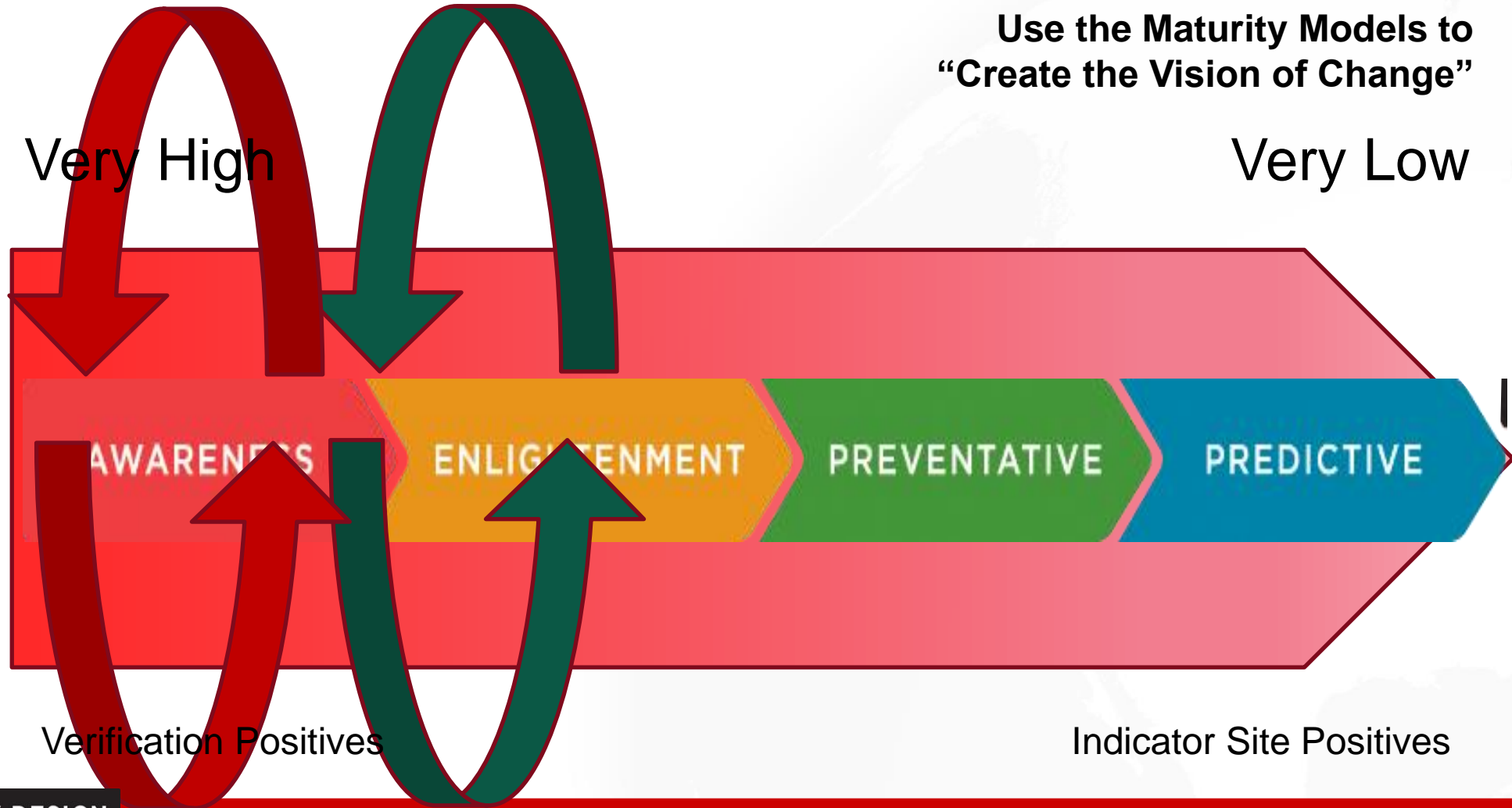
Visual Evidence of the Maturity Level of Organizational Process Thinking & Environmental Monitoring



Firefighting Intensity

Learn to Recognize Firefighting in your own Organization

Use the Maturity Models to
"Create the Vision of Change"



Indicator Sites

“tool used to eliminate firefighting”

Post rinse

- A broad indicator of control
- Sample large areas that collect “spatter”
- Composite sampling acceptable
- Improve sampling efficiency
- Positive results will direct investigation team to a line, pair of lines, or section on a line.

Summary of “Lessons Learned”

1. Growth niches can be identified and eliminated or managed.
2. Transfer points & pathways can be identified and their effect minimized with GMP practices
3. Sampling techniques such as post rinse sampling can aid in discovering problems before contact surfaces or product are engaged.
4. Sanitation Process Control “Critical Factors” can provide the basis for attaining and maintaining control of microbial contaminates in High-Risk RTE areas.

Summary of “Lessons Learned”

5. The regulatory environment is going to be very challenging due to DNA linkage and new requirements
6. We must continually build our consumers confidence in our Food Safety system
 - a) Food Safety incidents, Recalls, Bad Press in our Food Supply System is bad for all in the System
 - i. None of us benefit by another’s loss of control
7. We must share “Best Practices and Preventive Designs”

Questions?

- Thank You

