



# International Commission on Microbiological Specifications for Foods (ICMSF)

*www.icmsf.org*

## Importance of sampling and testing for verification of food safety management system performance

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# Validation, Monitoring & Verification (CAC 2008)

## Validation

Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

## Monitoring

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

## Verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure is or has been operating as intended



# Microbiological testing: Limited value for Monitoring

- “...due to the time required for most microbiological analyses and the relative insensitivity of even the most stringent sampling plans, microbiological testing is of limited value for monitoring in quality and safety assurance programs.”
  - From ICMSF 201X *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, 2nd edition, Chapter 13



# Microbiological testing for Validation and Verification

- Despite limitations related to sensitivity and time to results, microbiological testing can play an important role in
  - validation and verification
  - of process control.



# Controlled Food Operations require...

## Validation considerations

1. Knowledge of the significant hazards
2. Knowledge of the factors that are necessary for control
3. Knowledge of the extent of variability and factors that influence variability
4. Establishing criteria for the factors that must be controlled

## Verification considerations

1. Establishing monitoring and **verification procedures**
2. Organizing and interpreting data
3. Using the data to measure change and improve control
4. Responding to the data
5. Learnings from Investigations



# Validation of Processing Equipment

Equipment validation can be performed by two means:

- Validation using surrogate microorganisms
- Validation of processing parameters in relation to established control measure



# Validation using surrogate microorganisms

- Ensure that surrogate behaves (minimum) like target microorganism at processing conditions
- Ensure that surrogate organisms do not introduce a risk
- Ensure that product characteristics are not changed despite of inoculation procedure
- Ensure to run equipment under most critical conditions
- Consider variability of method of detection



# Validation using surrogate microorganisms

## Advantages

- Direct reading of lethal step effectiveness (log-reductions achieved)
- Validation data based on inoculated material

## Disadvantages

- Requires microbiological laboratory / external services
- Heat resistance of the organism has to be confirmed for each trial
- Requires possibility to confine inoculated material
- Valid for the tested equipment only





# Validation of processing parameters

- Ensure that critical parameters established by scientific studies are applicable for the process
- Evaluate process variability with respect to critical parameters, e.g. unevenness of roasting
- In case of major differences review whole process with engineering & adapt parameters
- Ensure to run equipment under most critical conditions
- Ensure that critical parameters are being monitored in the product / material being processed
- Record / relate to material characteristics, e.g. ingoing temperature, moisture before / after processing
- Consider tolerance of measuring devices used at treatment conditions



# Validation of processing parameters

## Advantages

- No microbiological laboratory required
- Immediate result readings / discussions
- Easier to perform / repeat

## Disadvantages

- Validity depends on scientific basis used
- Equipment needs to be accessible for the validation equipment used



# Potential Verification Activities

- ❖ Calibration of equipment
- ❖ Review of records
- ❖ Targeted sampling and testing
- ❖ Visual inspection of equipment
- ❖ Environmental monitoring
- ❖ 2<sup>nd</sup> and 3<sup>rd</sup> party audits



# Targeted Sampling/Testing

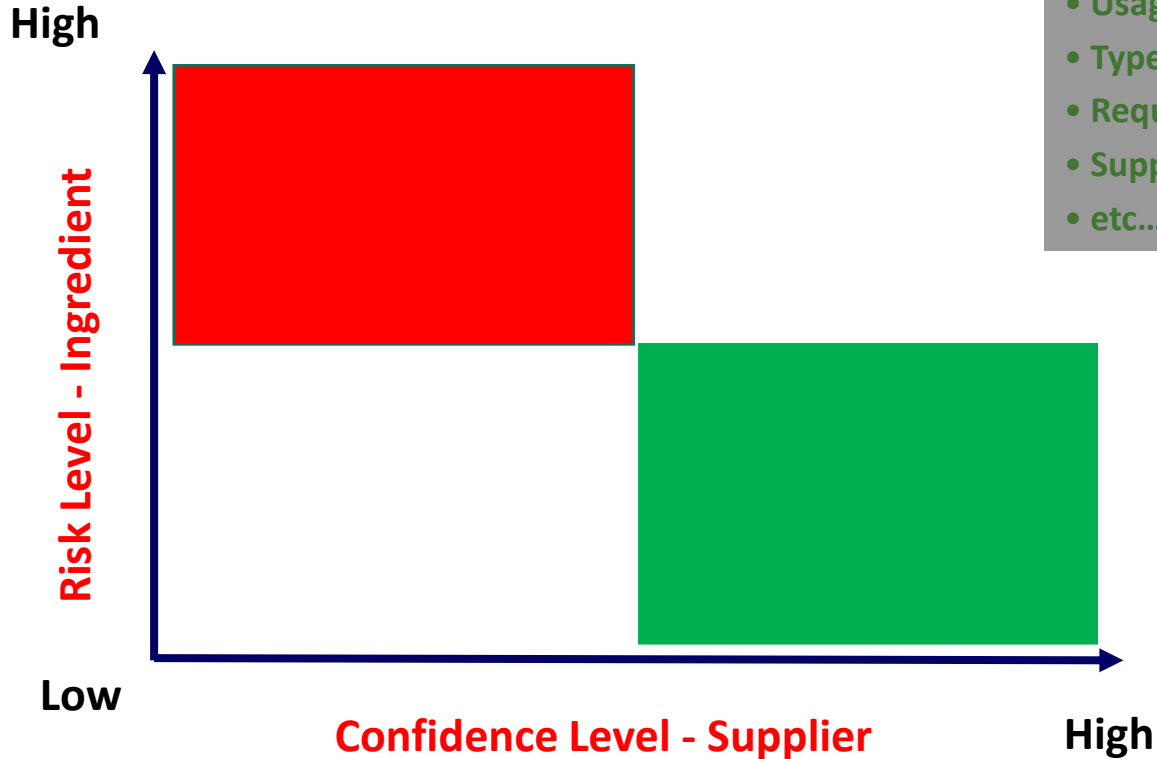
## - Verification For Process Control

For process control, periodic verification may include targeted sampling and microbiological testing of:

- ❖ **Ingredients**
- ❖ **In-process materials**
- ❖ **Finished products**



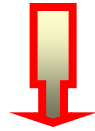
# Microbiological Testing - Ingredients



- Historical data
- Usage and further processing
- Type of finished product
- Requirements
- Supplier audits
- etc....

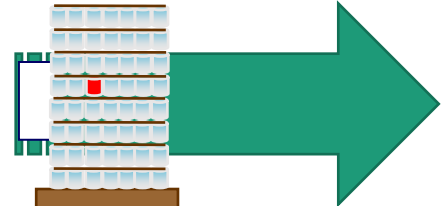
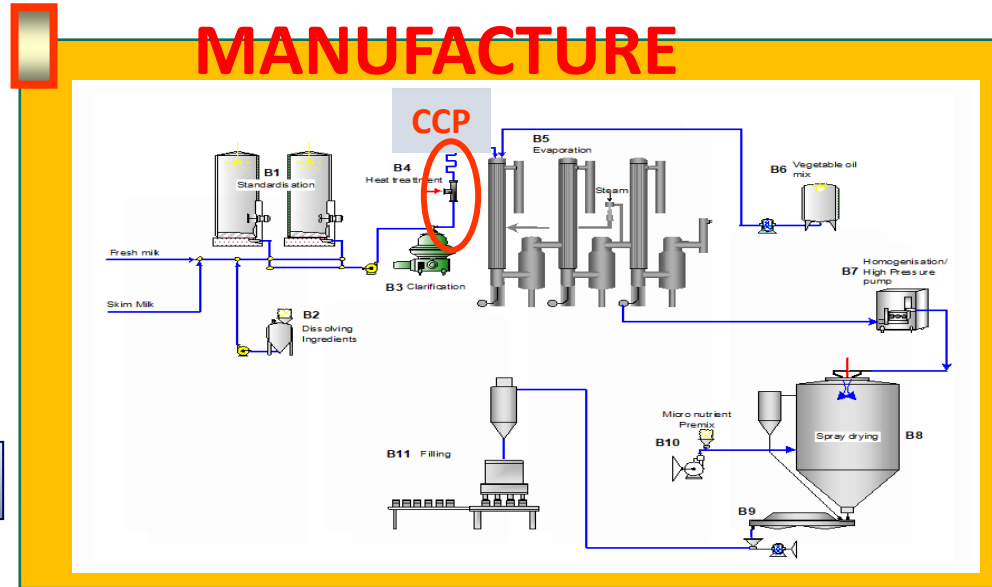


# Microbiological Testing – In-Process Material/FP



In processing testing

Product / Semi-finished product  
Line – Food contact surfaces including residues  
Environment – Points close to/remote from line



Criteria,  
Guidelines,  
Specifications

Specifications



# Process Control Verification—Examples – ICMSF BK 8

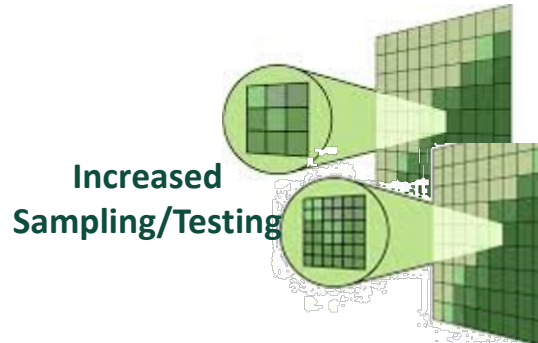
| Relative importance |                           | Useful testing   |        |                            |   |    |                 |
|---------------------|---------------------------|--|--------|----------------------------|---|----|-----------------|
| End product         | High                      | Testing for Enterobacteriaceae is recommended to verify process control  |        |                            |   |    |                 |
|                     |                           | Microorganism  | Method | Sampling plan & limits/g   |   |    |                 |
|                     |                           |  |        | Case                       | n | c  | m               |
|                     | <i>Enterobacteriaceae</i> | ISO 21528-2  | 2      | 5                          | 2 | 10 | 10 <sup>2</sup> |
|                     | Low                       | Testing for pathogens is not recommended during normal operation when GHP and HACCP are effective as confirmed by above tests. When above testing or process deviations indicate a possible safety issue, testing for Salmonella is recommended. |        |                            |   |    |                 |
|                     |                           | Microorganism  | Method | Sampling plan & limits/25g |   |    |                 |
| Case                |                           |  |        | n                          | c | m  | M               |
| <i>Salmonella</i>   | ISO 6579                  | 11   | 10     | 0                          | 0 | -  |                 |

| Relative importance |      | Useful testing  |  |  |  |  |
|---------------------|------|---|--|--|--|--|
| In-process          | High | <p>* <b>ICMSF 2011. <i>Microorganism in Foods 8: Use of Data for Assessing Process Control and Product Acceptance.</i></b></p> <p>Test appropriate in product residues and in-line samples for <i>Salmonella</i>. Typical guidance levels: <i>Salmonella</i> – absent</p> |  |  |  |  |

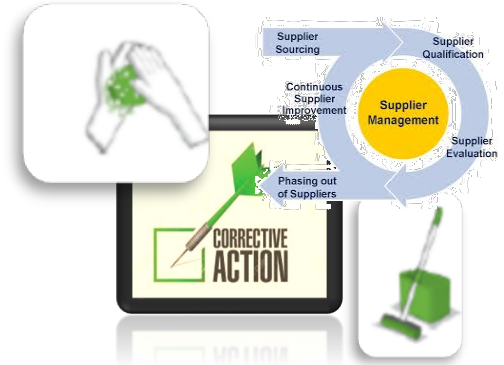


# Microbiological Testing: Environmental control verification...

- Used to VERIFY Hygiene, PRPs, GMP
- Indication of Process cross contamination
- Enables Factory to take actions in response to findings



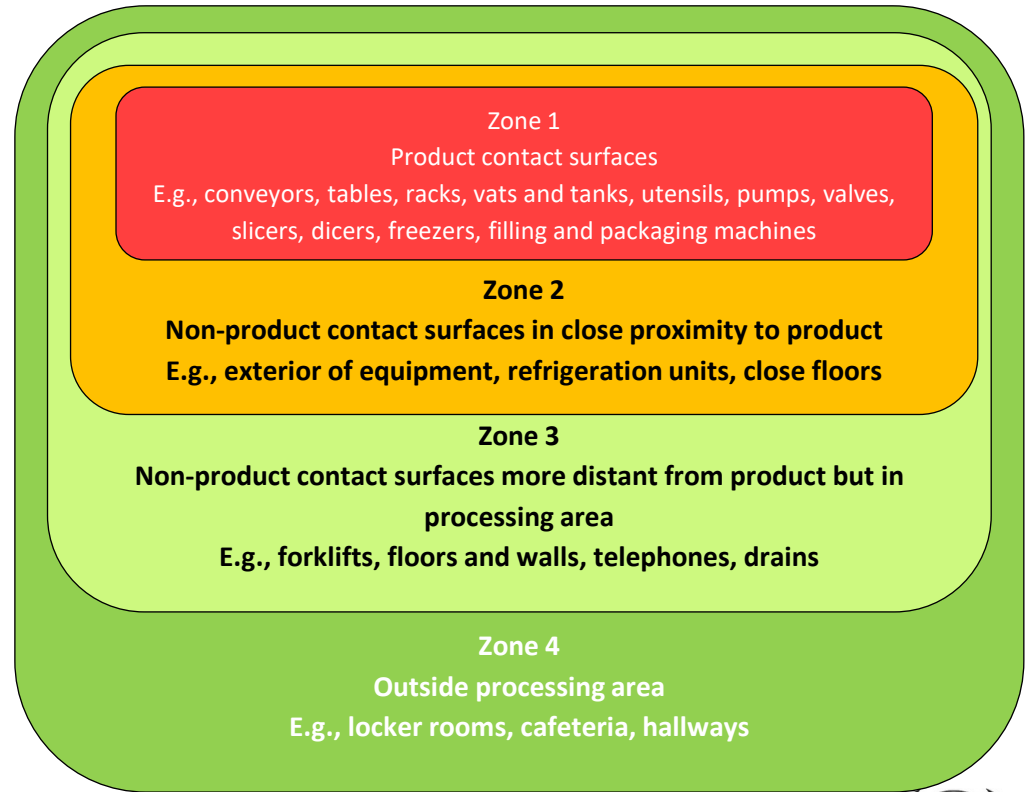
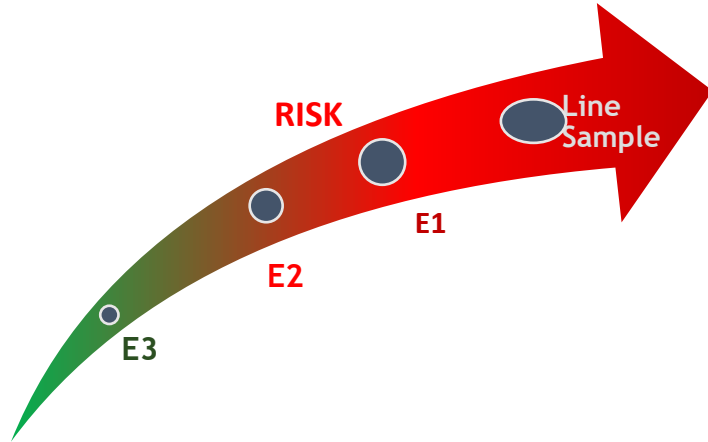
Water Ingress  
Growth Niches,  
Equipment Dismantling,  
Raw material Specs





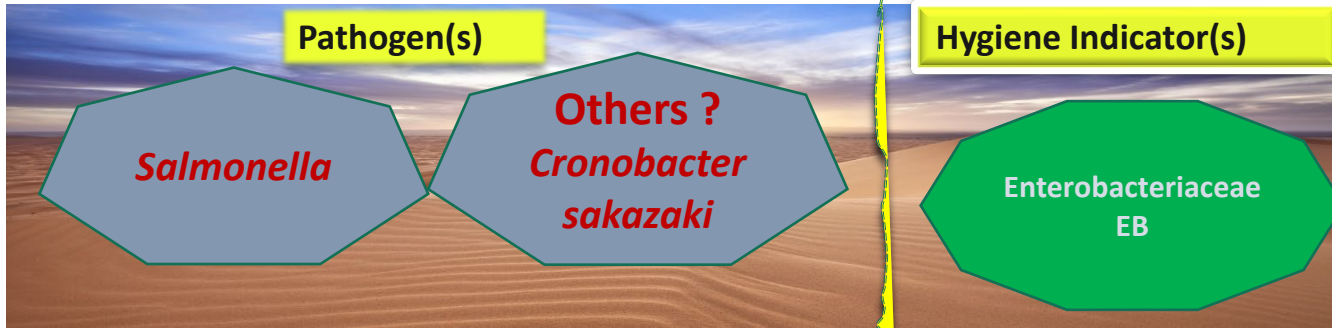
# Key Aspects of EM programme...

## ■ Where to Sample...



# Key Aspects of Env Control Testing..

## ■ What Microorganisms to sample for...

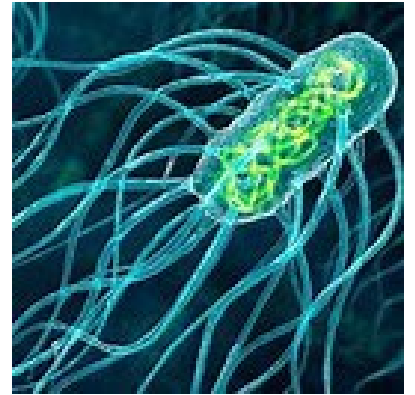


# Sampling and Testing

Which parameters should be tested ?

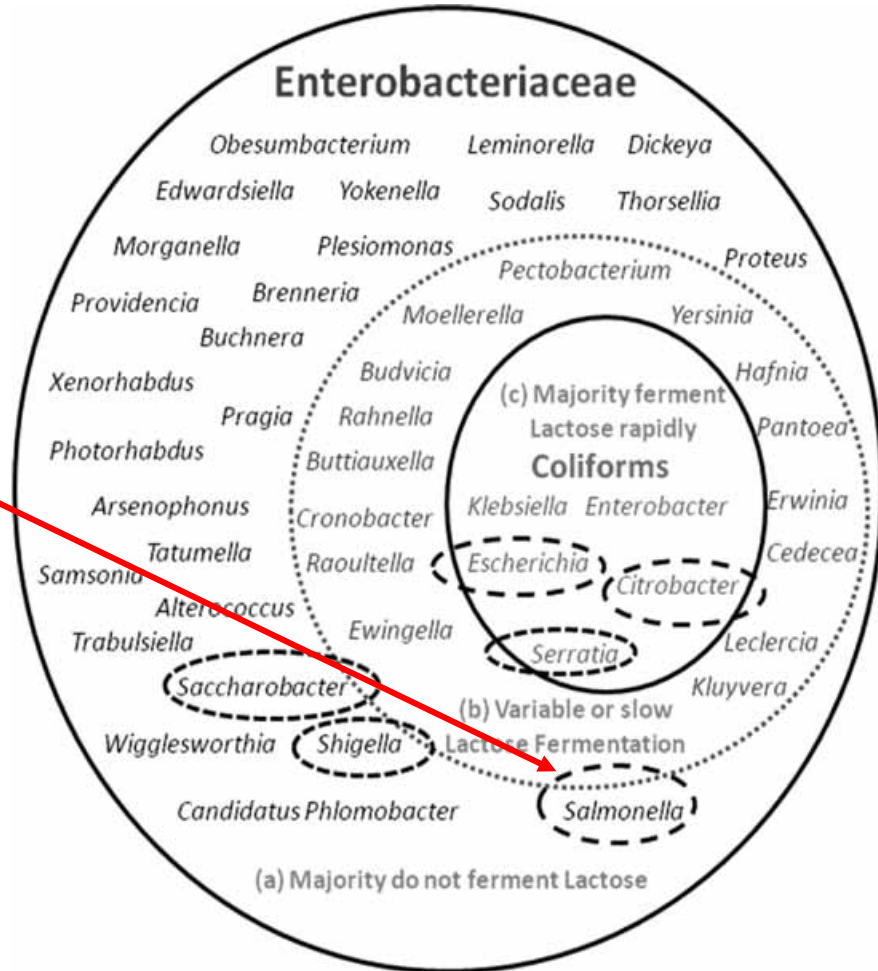
☞ *Salmonella*

☞ *Enterobacteriaceae*

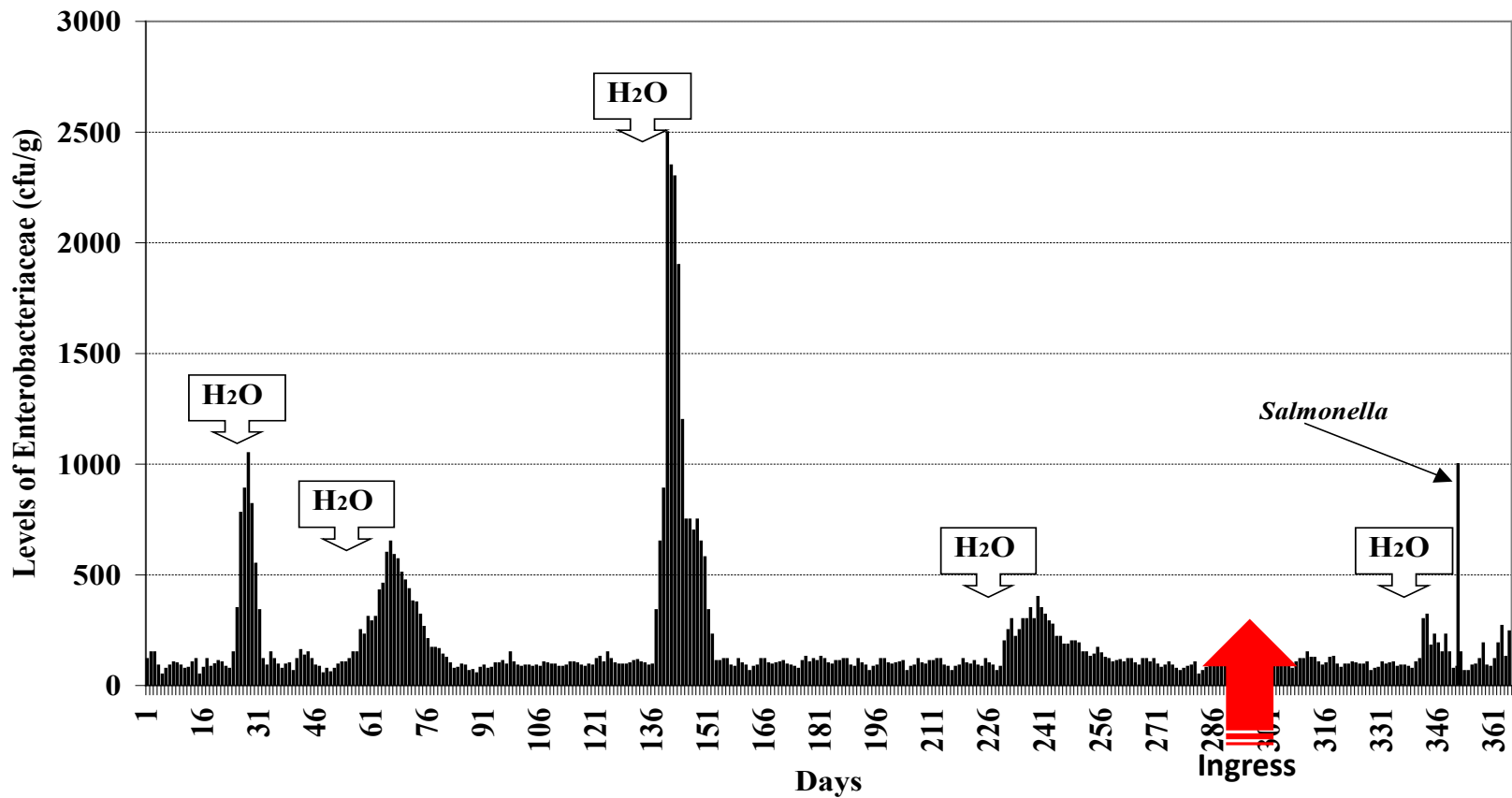


# Sampling and Testing

*Salmonella* is a member of the Enterobacteriaceae



# Enterobacteriaceae as Hygiene Indicator



Cordier, 2007



# *Enterobacteriaceae* as a Hygiene Indicator

*Enterobacteriaceae* ≠ *Salmonella*

*i.e. if you don't find Enterobacteriaceae, does not mean  
Salmonella is not present*

*But*

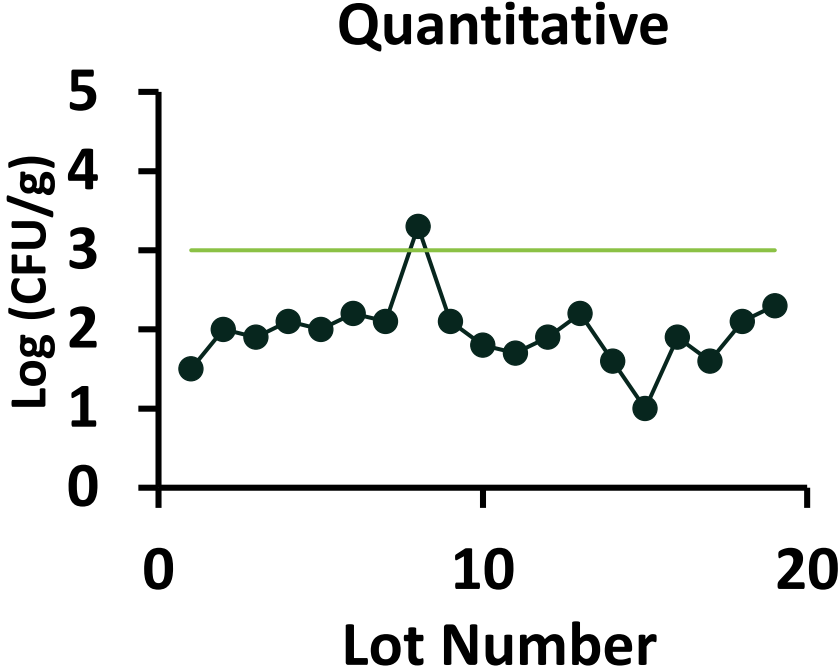
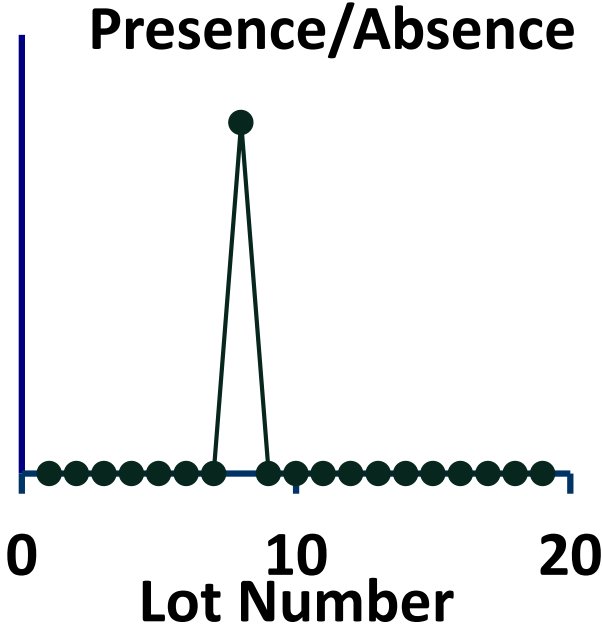
*If you do find Enterobacteriaceae, then it is more likely  
that Salmonella may be present*

**Rapid, Quantitative and Cheap**

**' Reactive' and " Operational "**



# Test Method Influences Information

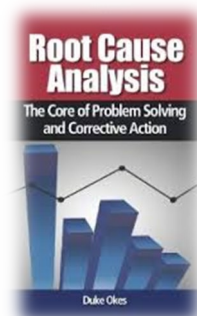
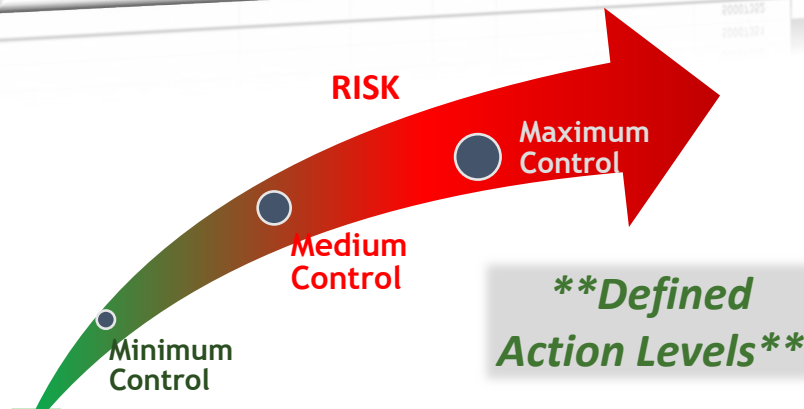


# Key Aspects of EM programme...

## ■ Data (EM) Management, Trend Spotting & Response

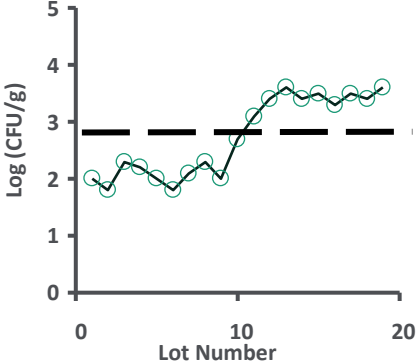
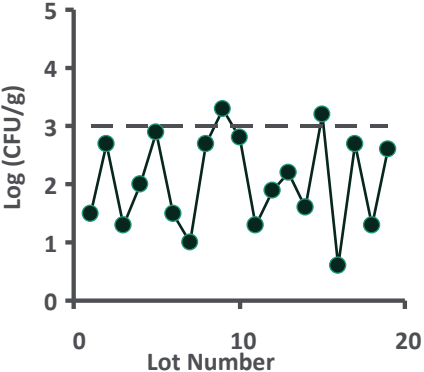
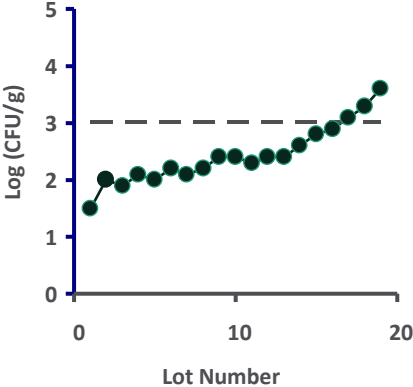
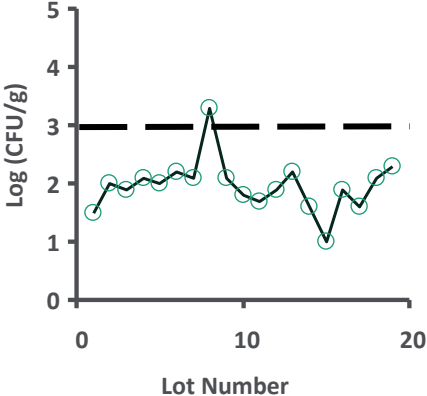
| Sampling point description           | Priority rating | Parameter | Method    | Frequency     | Tool           | Number   | January | February | March | April | May | June |
|--------------------------------------|-----------------|-----------|-----------|---------------|----------------|----------|---------|----------|-------|-------|-----|------|
| <b>Routine sampling points</b>       |                 |           |           |               |                |          |         |          |       |       |     |      |
| Filling head 1                       | E1              | EB        | LI-00.757 | Weekly        | Scraper        | 50007356 | █       | █        | █     | █     | █   | █    |
| Filling head 2                       | E1              | EB        | LI-00.757 | Weekly        | Spoon          | 50007345 | █       | █        | █     | █     | █   | █    |
| Filling head 3                       | E1              | EB        | LI-00.757 | Weekly        | Moistened wipe | 50007346 | █       | █        | █     | █     | █   | █    |
| outside conveyor belt                | E2              | EB        | LI-00.757 | Twice a month | Moistened wipe | 50007347 | █       | █        | █     | █     | █   | █    |
| Floor                                | E2              | EB        | LI-00.757 | Twice a month | Spatula        | 50007348 | █       | █        | █     | █     | █   | █    |
| <b>Investigative sampling points</b> |                 |           |           |               |                |          |         |          |       |       |     |      |
|                                      |                 |           |           |               |                | 50007349 |         |          |       |       |     |      |
|                                      |                 |           |           |               |                | 50007350 |         |          |       |       |     |      |
|                                      |                 |           |           |               |                | 50007351 |         |          |       |       |     |      |
|                                      |                 |           |           |               |                | 50007352 |         |          |       |       |     |      |

- ❖ Organise the Data
- ❖ Frequently Review
- ❖ Look for Trends
- ❖ Share
- ❖ React





# Trend Analysis from Microbiological Testing



# Testing methods are not always perfect....

- Sensitivity and Specificity are key parameters
- Use of 'Official Methods'
- Proper Validation of Alternatives
- Proper assessment of Method Performance - proficiency Testing
- Accreditation of method performing Laboratories



# Key Messages....

- **Microbiological testing occurs at numerous points in the food chain**
- **Finished product testing alone does not assure food safety**
- **Microbiological testing plays a key role in Verification and Validation**
- **Verification testing for process control across lots for ingredients, semi-finished & finished product is industry practice**
- **Environmental control (microbiological) testing is a key parameter in industry Food Safety Management System**
- **Method selection, application and performance – an element not to be ignored!**

