

# Behind the Certificate of Analysis: Risk Assessment in Pathogen Testing Methods

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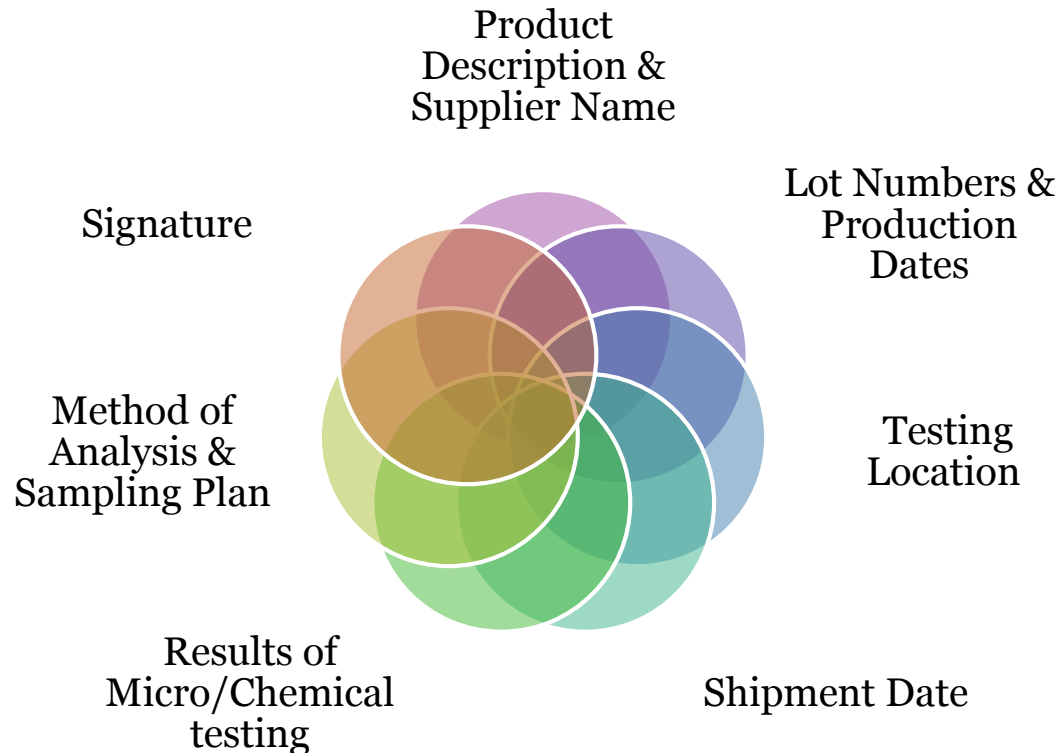


# Goals

- Review the purpose of a Certificate of Analysis (COA)
- Understand the critical impact the COA plays in ensuring Quality
- Understand why it is important to know the methodology behind COA results
- Recognize differences in methods of analysis

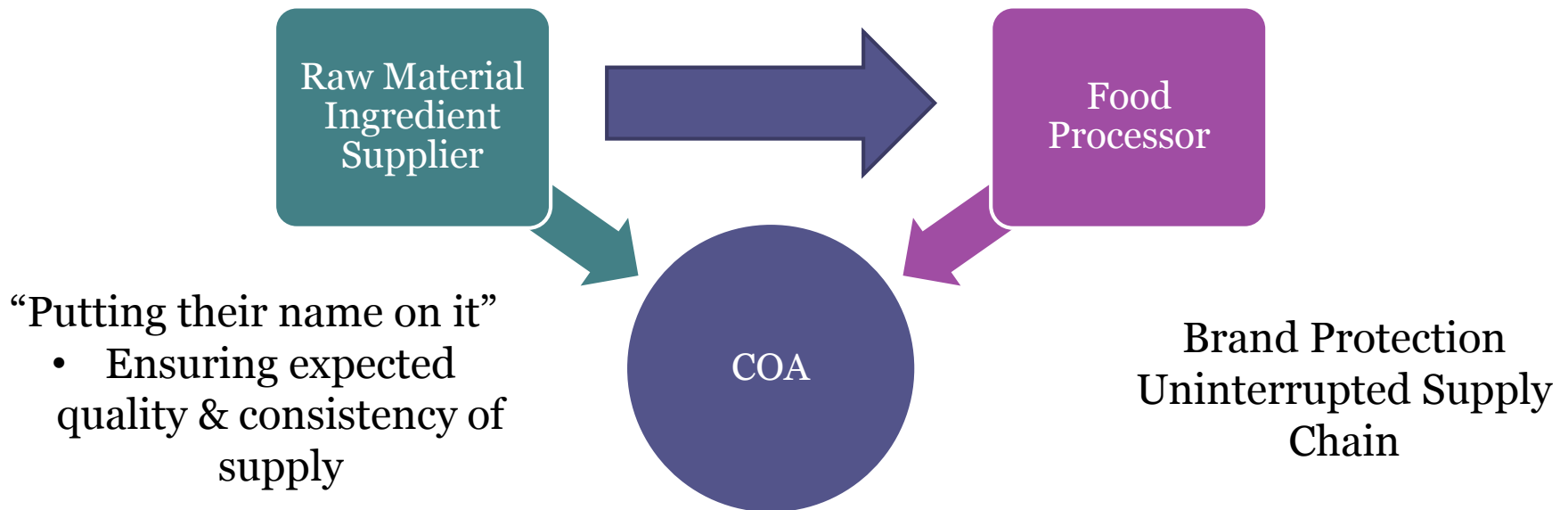
# Certificates of Analysis (COA)

Developed to address the analytical parameters for specific foods, lots or shipments



# Certificate of Analysis (COA)

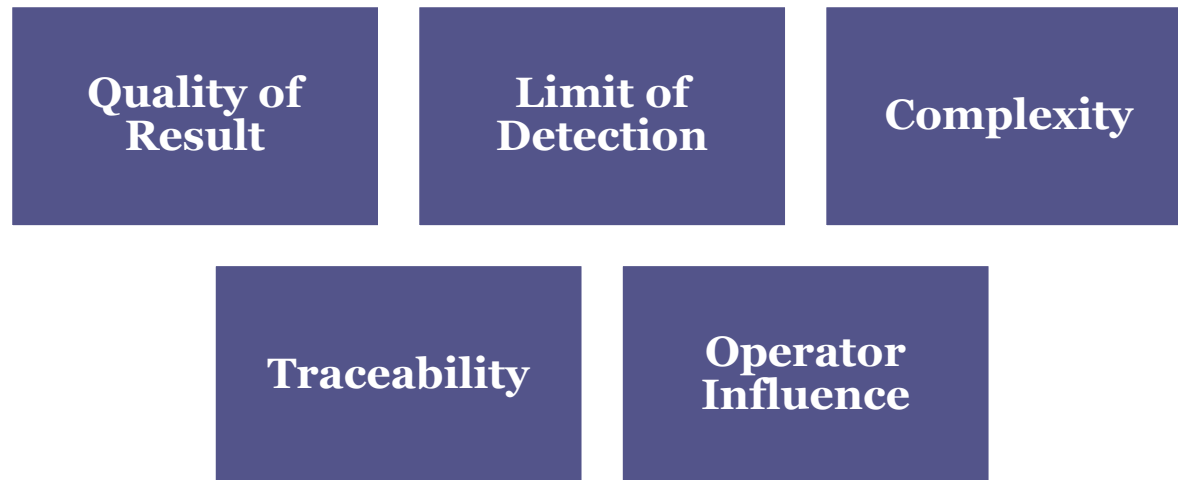
Pivotal Role in Quality Assurance & Supply Chain Fidelity



# COA: Method of Analysis & Results

Not All Methods of Analysis Are the Same.

Differences can be seen in all of the following important elements:



Method Differences Can Introduce Process and System Risk.

Critical to Understand What is Behind the “Pass” on a COA Pathogen Result

# Using Six Sigma to Identify Method Differences and Risk

## Failure Modes and Effects Analysis (FMEA)

- Risk Analysis
- Objectives:
  - Identify potential failure modes for a process or product.
  - Assess the risk of each failure mode.
  - Reduce or eliminate failures and risk of failure.
- The FMEA was introduced in the food industry in 1959.
  - Identification of critical control points for preparation of food for manned space flight.

# Applications in Food Industry

The FMEA used alone and in conjunction with HACCP or HARPC has become increasingly important in the food industry.

Examples:

- Manufacture and shipping of cookie dough
- Snack Industry: Corn Curl Processing
- Chocolate producing industry
- Industrial processing of Salmon
- Processing of pastry products
- Production of Turkish Delight

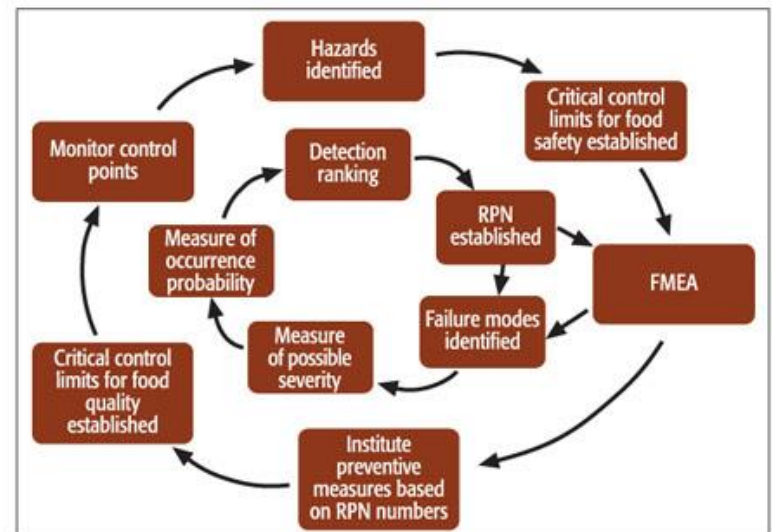


Figure 5: Combined HACCP and FMEA Flowchart 2A

# Failure Modes and Effects Analysis (FMEA)

- Methodology
  - Identify product or process to be studied
  - Agree on standard rating scales
    - Severity of failure when it does occur
    - Frequency of occurrence of failure
    - Ability to Detect the failure
  - Identify and rate all failure modes
  - Calculate risk priority number (RPN)
    - $F \times S \times D = RPN$



# FMEA Interpretation

- RPN – High RPN = high risk of hazard, error or consumer injury
- Trends in high RPN
  - Steps requiring human interaction commonly increase risk.
    - Example output:  
Cookie Dough FMEA case study<sup>2A</sup>

Potential failure mode	RPN
Human errors in scaling, mixing and packing	280
Temperature problems in storage and freezers	165
Poor quality ingredient received	54
Worn or damaged machines	42
Incorrect machine settings	24
Metal detector malfunction	18
Poor loading	16
Poor driving	16
Storage with noxious items	10

*Table 3: Realignment of RPNs into Groups*

# FMEA Application for Food Industry

Example for one line on the FMEA for the Cookie Dough Process

- Process Stage = Frozen cookie shipping
- Failure Mode = Frozen transport too warm
- Effect = Bacterial contamination
- Severity = 5
- Cause = Poor transportation
- Frequency of occurrence = 2
- Detection = 4
- RPN = 40

# FMEA Application to Test Methodology in the Food Testing Laboratory

- Study Purpose: Identify all potential process failures to quantify risk and error potential of common pathogen testing methods
- Methodology:
  - Expert elicitation, product inserts, and user guides
  - Numeric value assigned for severity, frequency and detection of each failure mode
  - RPN calculation
    - **Lower RPN = lower error potential**
- FMEA analyzed molecular and immunoassay testing methods for *Listeria spp.*, *Salmonella enterica* and *E. Coli*.
  - Roka Bioscience Atlas, DuPont BAX, Bio Rad iQ-Check, BioControl Assurance GDS and bioMérieux VIDAS

# *Listeria spp.* test method study

Example for one line on the FMEA of a *Listeria spp.* test method:

- Process Step = Transfer enriched sample (5uL) into lysis tube.
- Failure Mode = Incorrect volume of sample transferred.
- Effect = Ineffective lysis resulting in indeterminate results
- Severity = 9
- Cause = Pipette out of calibration, inadequate training
- Occurrence (frequency) = 1
- Current Controls = Periodic pipette calibration
- Detection = 9
- RPN = 81

# Listeria Study Results

<i>Listeria</i> Failure Modes and Effects Analysis (FMEA)					
Manufacturer/Instrument/Protocol	Number of Process Steps	Number of Touches per "Sample"	Number of Defect Opportunities	RPN	
Roka Bioscience Atlas System Universal food and environmental	16	13	34	1,002	Lowest risk
DuPont BAX Standard Environmental and food	32	21	73	2,813	High risk
DuPont BAX 24E Frankfurters, spinach, shrimp, queso fresco cheese and stainless steel	33	21	75	3,047	Highest risk
Bio-Rad iQ-Check Easy Stainless steel, plastic, ceramic and sealed concrete	24	19	60	2,612	
BioControl Assurance GDS Deli meats, hot dogs, seafood, dairy products, produce and soft cheese, stainless steel, rubber, plastic and concrete	28	21	77	2,557	
bioMerieux VIDAS Universal food	23	18	51	2,063	
bioMerieux VIDAS Environmental	19	15	38	1,595	
bioMerieux VIDAS LSX Universal food	25	20	54	2,234	
bioMerieux VIDAS LSX Environmental	19	15	38	1,595	

# Summary of Lowest and Highest RPNs for all Studies

Manufacturer/Instrument/Protocol	Number of Process Steps	Number of Touches per "Sample"	Number of Defect Opportunities	RPN
<b>Listeria Failure Modes and Effects Analysis (FMEA)</b>				
<b>Roka Bioscience Atlas System</b> Universal food and environmental	16	13	34	1,002
<b>DuPont BAX 24E</b> Frankfurters, spinach, shrimp, queso fresco cheese and stainless steel	33	21	75	3,047
<b>Salmonella Failure Modes and Effects Analysis (FMEA)</b>				
<b>Roka Bioscience Atlas®</b> Universal food and environmental	16	13	34	1,002
<b>DuPont BAX Standard</b> Meat, poultry, fruit and vegetable products, dairy, chocolate/bakery products, animal feeds, pasta and environmental	34	22	77	2,964
<b>BioMerieux VIDAS</b> Universal full protocol	29	23	78	3,386
<b>E. Coli Failure Modes and Effects Analysis (FMEA)</b>				
<b>Roka Bioscience Atlas E. Coli 0157:H7 EG2 Detection Assay</b> Fresh raw high fat ground beef and romaine lettuce	16	13	34	1,002
<b>DuPont BAX 0157:H7</b> Ground beef and beef trim, spinach and lettuce	28	18	60	2,237
<b>DuPont BAX STEC Suite</b> Beef and beef trim	28	18	60	2,237

# Salmonella Study Results

## Salmonella Failure Modes and Effects Analysis (FMEA)

Manufacturer/Instrument/Protocol	Number of Process Steps	Number of Touches per "Sample"	Number of Defect Opportunities	RPN	
Roka Bioscience Atlas® Universal food and environmental	16	13	34	1,002	Lowest risk
DuPont BAX Standard Meat, poultry, fruit and vegetable products, dairy, chocolate/bakery products, animal feeds, pasta and environmental	34	High risk	22	77	2,964
Bio-Rad iQ-Check Easy I Eggs, raw chicken, raw beef, cantaloupe	24	19	62	2,662	
Bio-Rad – iQ-Check Standard I AFNOR approval only Food products, animal feed, environmental	25	21	65	2,737	
BioControl Assurance GDS Foods, ingredients, environmental	27	20	72	2,350	
BioMerieux VIDAS Universal full protocol	29	23	78	3,386	Highest risk
BioMerieux VIDAS Universal EASY protocol	23	19	53	2,225	

# E. Coli Study Results

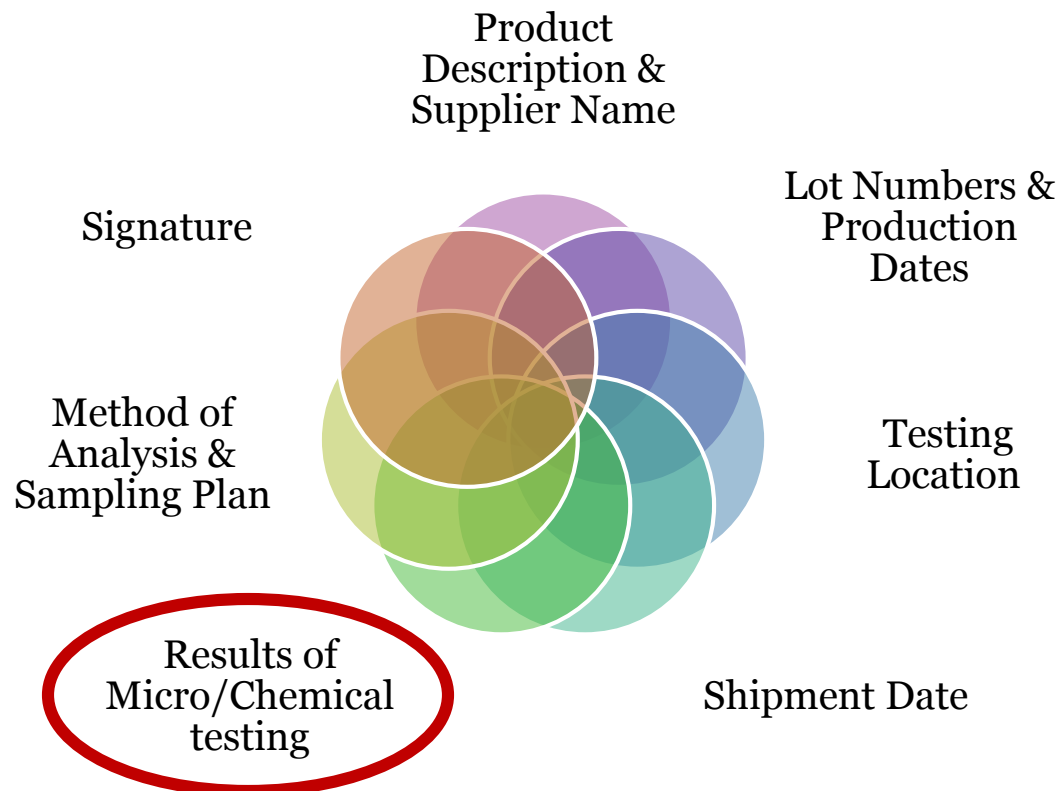
## *E. Coli* Failure Modes and Effects Analysis (FMEA)

Manufacturer/Instrument/Protocol	Number of Process Steps	Number of Touches per "Sample"	Number of Defect Opportunities	RPN	
Roka Bioscience Atlas E. Coli 0157:H7 EG2 Detection Assay Fresh raw high fat ground beef and romaine lettuce	16	13	34	1,002	Lowest risk
DuPont BAX 0157:H7 Ground beef and beef trim, spinach and lettuce	28	18	60	2,237	Highest risk
DuPont BAX STEC Suite Beef and beef trim	28	18	60	2,237	
BioControl Assurance GDS 0157:H7 Foods, ingredients and environmental samples	26	18	62	2,081	
BioControl Assurance GDS MPX Top 7 STEC Beef and fresh vegetables	27	20	66	2,114	



# Back to the COA

- What do you know about test methodologies in use?
- Could method complexity be increasing your risk?



# Questions?

*Thank  
you*

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