

# **Microbiological Specifications for Foods: Developing Specifications and Testing Options for Out of Specification Results**

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## Setting micro specs for foods should be simple, right?

- There would be two options based on my micro test results:



# But in reality, it's kinda complicated

- Acceptance criteria
  - Acceptable for a production run?
  - Acceptable by your customer?
- Food safety/quality objectives
  - Food safety is non-negotiable (or is it?)
  - Quality attributes differ by customer and what they want to pay for
- Economic concerns
  - How many samples to take without “breaking the bank”
  - Is your customer willing to pay more for a higher number of samples
- Regulatory requirements
  - Supply chain verification activities
- What is a batch or lot?
  - Gets back to economic concerns again

# Agenda

- ICMSF sampling plans
- 2-class vs. 3-class plans: pros and cons
- Product category sampling plans and specifications
- Sampling plans: normal vs. problem resolution vs. OOS
- Out of Specification (OOS) – what it means for provider vs. customer
- Regulatory considerations
- COA's and COA verification
- Lot definition

# ICMSF Sampling Plans

- Microorganisms in Foods 7: Microbiological Testing in Food Safety Management (2002, Kluwer Academic/Plenum Publishers, New York, NY)
- Discusses:
  - Food Safety Objectives
  - Acceptance Criteria/Establishing Micro Criteria for Lot Acceptance
  - Concepts of Probability and Principles of Sampling
  - Sampling Plans
  - Selection of Cases for Sampling Plans
  - Tightened, Reduced, and Investigational Sampling
  - Using 2-Class Plans
  - Examples of specific food safety objectives for selected product categories

## 2-Class Sampling Plans

- Have single limits for each microorganism
- Typically test a single sample for the quantitative tests

Test	Limit	Individual or Composite?	Reporting Unit
Aerobic Plate Count	<1,000	I	Per gram
Coliform	<10	I	Per gram
Yeast	<100	I	Per gram
Mold	<100	I	Per gram
Salmonella	Negative	C	Per 375 grams (15x25g)

## 3-Class Sampling Plans

- Have little “m” and big “M” limits for each microorganism
- Have to minimally test 5 samples for the quantitative tests

Test	I/C	n	c	m	M	Reporting Unit
Aerobic Plate Count	I	5	2	1,000	10,000	Per gram
Coliform	I	5	2	10	100	Per gram
Yeast	I	5	2	100	1,000	Per gram
Mold	I	5	2	100	1,000	Per gram
Salmonella	C	15	0	0	0	Per 375 grams (15x25g)

## 2-class vs. 3-class

- 2-Class sampling plans
  - Simple pass or fail criteria
    - Sample is acceptable or unacceptable (2 classes)
    - Does not take into account sampling variability or microorganism distribution
    - Does not allow for test method variability
  - Typically used for qualitative or zero-tolerance pathogen testing
    - Need to know whether or not the pathogen is in the food
    - Probability of finding the pathogen depends on sampling and compositing schemes
  - Economically viable
    - Single sample per batch/lot is tested for quantitative results

## 2-class vs. 3-class

- 3-Class sampling plans
  - More accurate, but complex pass or fail criteria
    - Sample is acceptable, marginal, or unacceptable (3 classes)
    - Factors in sampling variability and the heterogeneous distribution of microorganisms in a sample
    - Can help take into account method variability
  - Not really applicable for qualitative or zero-tolerance pathogen testing
    - Rarely, if ever used for this
  - More expensive
    - More samples have to be taken and tested

## Provider vs. Customer Micro Specifications

- Provider will often use 2-class sampling plans for their in-house product specifications
  - They know their process capability
  - They have the history of product performance
- Customers more commonly ask for micro spec limits in 3-class plan format (with the exception of zero-tolerance pathogen testing)
  - Allows for provider to accommodate the variability in sampling and test methods
  - Limits can be set tighter because of this flexibility
  - Can negotiate to have provider test using 2-class, but agree to meeting 3-class limits, for cost savings

## Provider vs. Customer Micro Specifications – Onion Powder Example

- Setting actual number limits
  - Customer wants

Test	I/C	n	c	m	M	Reporting Unit
Aerobic Plate Count	I	5	2	10,000	100,000	Per gram
Coliform	I	5	2	10	100	Per gram
Yeast	I	5	2	100	1,000	Per gram
Mold	I	5	2	100	1,000	Per gram
Lactic Acid Bacteria	I	5	2	10,000	50,000	Per gram
Salmonella	C	15	0	0	0	Per 375 grams (15x25g)

# Provider vs. Customer Micro Specifications – Onion Powder Example

- Provider can provide (depending on cost)

Test	I/C	n	c	m	M	Reporting Unit
Aerobic Plate Count	I	5	2	1,000,000	10,0000	Per gram
Coliform	I	5	2	1,000	10,000	Per gram
Yeast	I	5	2	10,000	100,000	Per gram
Mold	I	5	2	10,000	100,000	Per gram
Lactic Acid Bacteria	I	5	2	100,000	500,000	Per gram
Salmonella	C	15	0	0	0	Per 375 grams (15x25g)

OR

Test	I/C	n	c	m	M	Reporting Unit
Aerobic Plate Count	I	5	2	100,000	1,000,000	Per gram
Coliform	I	5	2	100	1,000	Per gram
Yeast	I	5	2	1,000	10,000	Per gram
Mold	I	5	2	1,000	10,000	Per gram
Lactic Acid Bacteria	I	5	2	50,000	100,000	Per gram
Salmonella	C	15	0	0	0	Per 375 grams (15x25g)

# Micro specifications for different product categories

- Dependent on the processing of the product
- RTE products that have been processed (pasteurized, cooked, etc.)
  - APC, EB/coliforms, lactic bacteria, yeast, mold limits should be low
- RTE fermented/cultured products
  - No APC or lactic bacteria testing, but EB/coliforms, yeast, and mold should still be low
- RTE dried products (i.e. herbs, spices)
  - APC, Lactic acid bacteria, yeast, mold will be higher
  - EB/coliforms should still be relatively low
  - Customer needs drive spec limits, negotiations are common by price, could use lot selection
- RTE produce
  - Specifications for APC, etc. are less common
- Frozen products
  - RTE frozen - typically set the same as for RTE counterparts
  - Frozen partially processed – more negotiable, depends on customer needs
- Raw products
  - Rare to have micro spec limits – one exception is Grade A raw milk

## Sampling to determine normal production capability (for quantitative tests)

- Typically use a 2-class sampling plan
  - Can have a preset limit based on previous history
  - Or, can have a “disaster check” limit
    - When running new products with no known history
- Multiple samples are taken throughout the day or lot (tightened sampling)
  - Can use these to determine probability of having a single sample with an out of specification result
- Data is used to set or determine running limits
- After limits are finalized, can scale back number of samples taken throughout the day (reduced sampling)

# Sampling for OOS

- If provider has agreed to micro specification limits in 3-class plan format, but only tests according to a 2-class scheme:
  - Can go back and test additional samples to meet the 3-class limits if the single sample is between “m” and “M”
  - There is a limit to this however, as provider should not test unlimited samples in order to find 5 “good ones”
- This is the most economically feasible, while still guaranteeing the food quality objectives for both parties
- If material is still out of specification, then provider should move to investigational mode

# What does OOS Mean? For the provider

- A particular sample from production does not meet the specification limits set for it
  - Spec limits represent normal production (including process capability)
- Product may or may not go on hold for further testing and investigation
  - Additional samples can be tested to determine if the result was an outlier, or caused by sampling error
  - If the cause is known or can be easily determined, product may still be acceptable and may still meet customer's limits
  - If cause is unknown, further testing should be conducted to determine source of higher numbers

## What does OOS mean? For the customer

- A particular sample from the provider does not meet the customer's quality standards for the product
  - Could cause quality defects in customer's finished products
  - Could cause defects further down the supply chain to the customer's customers
  - May not be getting the quality they paid for
- Product may or may not be returned to provider
  - Customer may choose to do additional sampling to determine if result was an outlier
  - Customer may choose to use product, but add in additional process controls to eliminate the concern
    - Often done if the material is rare or difficult to procure, or if customer is on a tight timeline
- Negotiations with provider can be conducted to mitigate the customer's additional costs

# Sampling during investigations

- Often involves product that has already been released to market
  - Report of an issue from the field
  - Customer complaint
  - Unexpected spoilage issue
- Used to determine the cause of a particular problem or out of specification result
- Help to decide what to do with a product
  - Determining if entire lot is unacceptable, or if can still release some portions of the lot
- Help to prevent the problem for recurring
  - Determine source of problem (personnel, environment, raw material)

# Sampling during investigations

- Micro specification limits during investigation
  - Product and raw material micro limits should remain the same as current specification limits
  - Sampling schemes should move to tightened
  - Raw materials not routinely tested, or where a COA is relied upon, should be tested per the specification sampling scheme (typically 3-class)
    - ▣ All lots of the raw material should be tested

# Regulatory considerations for micro specifications

- PMO Grade A standards
  - Specific micro limits set for Grade A products
- USDA HACCP
  - Validation of Critical Control Points
- Seafood HACCP and Juice HACCP
  - Validation of Critical Control Points
- Preventive Controls for Human Food, Animal Food, Produce Safety (FSMA)
  - Validation of Process Controls
  - Supply Chain Verification

## COAs and COA Verification

- For food safety, COAs can be used as a verification activity for a material where the supplier applies the pathogen control
- COAs can also be used for verifying the microbial load coming in on raw ingredients, to assure the effectiveness of the process controls being used for microorganism reduction
- Information on COAs coming from suppliers should be periodically verified by testing additional samples from the same lot of material at another laboratory
  - New suppliers – tightened sampling (i.e. first 10 lots received)
  - Established suppliers – reduced sampling (i.e. quarterly)

## Lot definition

- Often thought of as one day's production = one lot
- What about 5-day runs?
- What about dried products with 3-4 week runs?
- If a producer makes 3 hours of another customer's product, then switches to 4 hours of making your product, what happens when the other customer's product is out of specification?

**Thank you**