

Considerations for Setting Specifications & Action Limits

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October 24, 2019 Burr Ridge, IL

Presented in the
Institute for Food Safety & Health
Food Research Institute Symposium
on
Managing Microbiological Testing as a
Preventive Control Verification

Discussion Topics

- Terminology
 - Standards, Guidelines, Specifications
- Approaches
 - Specification anatomy
 - Setting specifications
- Resources

Considerations for Setting Specifications & Action Limits

Terminology: Acceptance criteria categories*

- **Standard**
 - A **mandatory** criterion that is part of a law or ordinance
- **Guideline**
 - An **advisory** criterion issued by government, industry association or food producer to indicate what might be expected when best practices are applied
- **Specification**
 - Part of a purchasing agreement between a buyer and supplier of a food
 - Can be mandatory or advisory according to use

* ICMSEF, 2018. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management, 2nd edition, pg 107

Considerations for Setting Specifications & Action Limits

Specification Conundrum & Preventive Controls

- Most specifications cover much more than food safety requirements!
 - Suitability for a particular use
 - Adherence to GMP
 - Food safety
 - Quality is a major focus
- Some ingredients may be used in multiple products with different risk profiles.
 - Relevant specifications may vary

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EXAMPLE

Supplier Microbiology Specifications for White Sugar

Is Preventive Control Needed?

Microorganisms	Limit (max.)
Yeast and Mould	20 cfu/10g
Coliforms	10 cfu/10g
Salmonella Sensitive population/unheated?	Absent in 25g
Total plate count	100,000 cfu/10g
Thermophilic bacteria	150 cfu/10g
Flat sour spores	75 cfu/10g
Moderate Thermophilic bacteria	100 cfu/10g
Thermophilic anaerobes not producing H ₂ S	5 cfu/10g
Thermophilic anaerobes producing H ₂ S	5 cfu/10g

Canned product spoilage

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Approaches

- Anatomy of a specification
- Indicator or pathogen
- Setting specifications

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Anatomy of a Specification

- The target
 - Indicator or pathogen
 - Desired outcome is actionable information for verification and process improvement
- The method
 - Must be scientifically valid
- The sample
 - The number and type of sample; size of analytical units for presence/absence tests
- The frequency
 - Daily, weekly, monthly, event triggered
- The action
 - Rejection, process adjustment, recall, etc.

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Process Example

Indicator or Pathogen?

From ICMSF (2018) Microorganisms in Foods 7: Microbiological Testing in Food Safety Management

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Test Results for Packaging Line B

Presence/Absence Testing

Quantitative Testing

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Trend Analysis Can Inform Process Control

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Limitations of Indicators

- Relationship between a pathogen and an indicator is influenced by product and process → **NOT universal**
- May indicate conditions that allow presence of pathogens

Coliforms as Indicators		
Product	Usefulness	Typical Levels
Pasteurized milk	Useful	<10/g
Blanched vegetables	Useful, but not always absent	<100/g
Fresh produce	Limited or no use	Naturally present

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Considerations for Setting Specifications

- Do standards or guidelines exist?
 - Regulatory standards such as the pasteurized milk ordinance
 - Trade association guidelines
 - International standards
 - Other resources

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Examples
n = # of samples
c = # allowed positive

Commission Regulation (EC) No 2073/2005, of 15 November 2005, on microbiological criteria for foodstuffs
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02005R2073-20140601>

Food type	Organism	n	c	m	M	Limit	Reference method	Stage where criterion applies
Precut fruits & vegetables RTE	<i>Salmonella</i>	5	0	-	-	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
	<i>E. coli</i>	5	2	100	1000	/g	ISO 16649-1 or 2	

Action in case of unsatisfactory results:

- Salmonella* in marketplace – recall
- E. coli* in manufacturing process – improvements in production hygiene, selection of raw materials

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Examples of Indicators – End Product

Product (relative importance)	Indicator or Utility	Sampling Plan and Limits			
		n	c	m	M
Frozen vegetables, blanched (medium)	Aerobic colony count	5	2	10,000/g	100,000/g
	Enterobacteriaceae	5	2	10/g	100/g
Fresh-cut RTE vegetables (medium)	<i>E. coli</i>	5	2	<10/g	-
	<i>E. coli</i>	5	1	10/g	100/g

From ICMSF (2011) *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*
NOTE: Method omitted to for clarity

Examples of Indicators – End Product

Product (relative importance)	Indicator or Utility	Sampling Plan and Limits			
		n	c	m	M
Frozen fruit (low)	<i>E. coli</i>	5	2	10/g	100/g
Dry milk powder (high)	Aerobic colony count	5	2	10,000/g	100,000/g
	Enterobacteriaceae	5	2	<3/g	9.8/g

From ICMSF (2011) *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*
NOTE: Method omitted to for clarity

Example: Dry Milk Powder

Relative Importance	Test	Sampling Plan and Limits
In-process	High Enterobacteriaceae	Same as end product
	High <i>Salmonella</i>	Absent in any samples
Processing environment	High Enterobacteriaceae	≤100 CFU/g or sample
	High <i>Salmonella</i>	Absent in any samples
End product		n c m M
	High Aerobic colony count	5 2 10 ⁴ /g 10 ⁵ /g
	High Enterobacteriaceae	5 2 <3/g 9.8/g
	Low* <i>Salmonella</i>	20 × 0 0 -

*unless other tests indicate a problem

From ICMSF (2011) *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*
NOTE: Method omitted to for clarity

ICMSF Hazard Categories

Target Organism Examples		
Utility	General contamination, reduced shelf-life, incipient spoilage	Aerobic colony counts, yeast, mold, etc.
Indicator	Low, indirect hazard	Enterobacteriaceae, generic <i>E. coli</i>
Moderate hazard	Direct, limited spread	<i>B. cereus</i> , <i>Campylobacter</i> , <i>C. perfringens</i> , <i>S. aureus</i> , <i>V. parahaemolyticus</i>
Serious hazard	Incapacitating, not usually life threatening; sequelae rare, moderate duration	<i>L. monocytogenes</i> , salmonellae, <i>Shigella</i> , <i>Yersinia</i>
Severe hazard	Life threatening or substantial chronic sequelae, or long duration	<i>C. botulinum</i> toxin, <i>E. coli</i> O157:H7, <i>L. monocytogenes</i> (sensitive populations)

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ICMSF Suggested Sampling Plans for Lot Acceptance Testing

Hazard Group	Likely Change Before Consumption		
	Reduce	No Change	Increase
Utility	Case 1 n=5, c=3	Case 2 n=5, c=2	Case 3 n=5, c=1
Indicator	Case 4 n=5, c=3	Case 5 n=5, c=2	Case 6 n=5, c=1
Moderate	Case 7 n=5, c=2	Case 8 n=5, c=1	Case 9 n=10, c=1
Severe	Case 10 n=5, c=0	Case 11 n=10, c=0	Case 12 n=20, c=0
	Case 13 n=15, c=0	Case 14 n=30, c=0	Case 15 n=60, c=0

Analytical unit = 25g

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Ingredient Testing

- May be useful for some applications and not others,
- Example - cocoa powder:
 - Used in chocolate, no heat treatment
 - ? Used in ice cream mix that is subsequently pasteurized
- Question
 - Is control at the ingredient step necessary?
 - Is testing necessary to verify acceptability?

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End Product Testing

- Demonstrate successful application of controls or assess the status of a lot when no other information exists.
- Alternative sampling plans may be appropriate, for example:
 - Fewer samples for on-going surveillance activity
 - More samples when investigating significant process deviations or outbreaks.
- Questions considered:
 - Is end product testing necessary to verify the overall manufacturing process?
 - Is end product testing relied upon for ensuring the safety or quality of the lot?

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Resources

Guidance, Standards, Guidelines

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FDA Guidance

- **Draft** Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
 - Stay tuned as more sections are added, which potentially could include testing guidance.

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Trade Association Examples

- American Spice Trade Association's *Clean, Safe, Spices Guidance Document*
- American Frozen Food Institute *Listeria Control Program*
- Grocery Manufacturers Association's *Control of Salmonella in Low-Moisture Foods Guidance Document*

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ICMSF. 2011. *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*, Springer

<ul style="list-style-type: none"> • Feeds & pet food • Vegetables & vegetable products • Fruits & fruit products • Spice, dry soups & Asian flavorings • Cereals & cereal products • Nuts, oilseeds, dried legumes & coffee • Cocoa, chocolate & confectionery 	<ul style="list-style-type: none"> • Oil & fat-based foods • Sugar, syrups & honey • Nonalcoholic beverages • Eggs & egg products • Milk & dairy products • Shelf-stable, heat-treated foods • Dry foods for infants & young children • Combination foods
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Commission Regulation (EC) No. 2073/2005, of 15 November 2005, on microbiological criteria for foodstuffs

- Food safety criteria
- Process hygiene criteria
- Rules for sampling and preparation of test samples

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02005R2073-20140601>

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Codex Alimentarius Commission

CAC/GL 21 – 1997 (last modified 2013)
Principles and guidelines for the establishment and application of microbiological criteria related to foods

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Acknowledgements

Thanks to the ICMSF members and consultants who contributed much to these concepts and my thought processes.

www.ICMSF.org



ICMSF 2018 Annual Meeting members and consultants, New Delhi, India

Questions?

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