Considerations for Setting Specifications and Action Limits
Katherine M. J. Swanson, Retired Food Safety Professional

Managing Microbiological Testing as a Preventive Control Verification
October 24, 2019

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Katherine MJ Swanson, Ph.D.
October 24, 2019
Burr Ridge, IL

Institute for Food Safety and Health
Food Research Institute, UW-Madison

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


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

Considerations for Setting Specifications & Action Limits

EXAMPLE
Supplier Microbiology Specifications for White Sugar

Is Preventive Control Needed?

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Limit (max.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeast and Mould</td>
<td>20 cfu/10g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>10 cfu/10g</td>
</tr>
<tr>
<td>Salmonella (Sensitive population/ unheated)</td>
<td>Absent in 25g</td>
</tr>
<tr>
<td>Total plate count</td>
<td>100,000 cfu/10g</td>
</tr>
<tr>
<td>Thermophilic bacteria</td>
<td>150 cfu/10g</td>
</tr>
<tr>
<td>Flat sour spores</td>
<td>75 cfu/10g</td>
</tr>
<tr>
<td>Moderate Thermophilic bacteria</td>
<td>100 cfu/10g</td>
</tr>
<tr>
<td>Thermophilic anaerobes not producing H2S</td>
<td>5 cfu/10g</td>
</tr>
<tr>
<td>Thermophilic anaerobes producing H2S</td>
<td>5 cfu/10g</td>
</tr>
</tbody>
</table>

Considerations for Setting Specifications & Action Limits

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.

Process Example

Indicator or Pathogen?

Ingredients

Process 1

Packaging Line A

Process 2

Process 3

Packaging Line B

Considerations for Setting Specifications & Action Limits


Test Results for Packaging Line B

Presence/Absence Testing

Quantitative Testing

Trend Analysis

Can Inform Process Control

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Usefulness</th>
<th>Typical Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasteurized milk</td>
<td>Useful</td>
<td>&lt;10/g</td>
</tr>
<tr>
<td>Blanched vegetables</td>
<td>Useful, not always absent</td>
<td>&lt;ess/g</td>
</tr>
<tr>
<td>Fresh produce</td>
<td>Limited or no use</td>
<td>Naturally present</td>
</tr>
</tbody>
</table>

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 of Indicators – End Product

<table>
<thead>
<tr>
<th>Target Organism Examples</th>
<th>ICMSF Suggested Sampling Plans for Lot Acceptance Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility</td>
<td>Indicator</td>
</tr>
<tr>
<td>General contamination, reduced shelf life, incipient spoilage</td>
<td>Low, indirect hazard</td>
</tr>
<tr>
<td>Aerobic colony counts, yeast, mold, etc.</td>
<td>Direct, limited spread</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>Incapacitating, not usually life threatening, sequelae rare, moderate duration</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Life threatening or substantial chronic sequelae, or long duration</td>
</tr>
<tr>
<td>E. coli</td>
<td>C. botulinum toxin, E. coli O157:H7, L. monocytogenes (sensitive populations)</td>
</tr>
</tbody>
</table>

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####Product (relative importance) Indicator or Utility | Sampling Plan and Limits

<table>
<thead>
<tr>
<th>Frozen fruit</th>
<th>E. coli</th>
<th>Sampling Plan and Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry milk powder</td>
<td>Aerobic colony count</td>
<td>Sampling Plan and Limits</td>
</tr>
</tbody>
</table>

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#### Examples of Indicators – End Product

<table>
<thead>
<tr>
<th>Product (relative importance)</th>
<th>Indicator or Utility</th>
<th>Sampling Plan and Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen vegetables</td>
<td>E. coli</td>
<td>Sampling Plan and Limits</td>
</tr>
<tr>
<td>Fresh-cut RTE</td>
<td>E. coli</td>
<td>Sampling Plan and Limits</td>
</tr>
</tbody>
</table>

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#### Relative Importance | Test | Sampling Plan and Limits

<table>
<thead>
<tr>
<th>In-process</th>
<th>High</th>
<th>Enterobacteriaceae</th>
<th>Same as end product</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Enterobacteriaceae</td>
<td>Same as end product</td>
<td></td>
</tr>
</tbody>
</table>

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#### Example: Dry Milk Powder

<table>
<thead>
<tr>
<th>Product (relative importance)</th>
<th>Indicator or Utility</th>
<th>Sampling Plan and Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen fruit</td>
<td>E. coli</td>
<td>Sampling Plan and Limits</td>
</tr>
<tr>
<td>Dry milk powder (high)</td>
<td>Aerobic colony count</td>
<td>Sampling Plan and Limits</td>
</tr>
</tbody>
</table>

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#### Considerations for Setting Specifications & Action Limits

- Preventive Control Verification

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#### Commission Regulation (EC) No 2073/2005, of 15 November 2005, on microbiological criteria for foodstuffs


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#### Targets for Setting Specifications & Action Limits

- In-process limits
- End product limits

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#### Microorganism Examples

- Aerobic colony counts, yeast, mold, etc.
- Enterobacteriaceae
- Salmonella
- E. coli
- C. botulinum toxin
- L. monocytogenes

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#### Hazard Group | Likely Change Before Consumption | Hazard Group | Likely Change Before Consumption |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility</td>
<td>Reduce</td>
<td>No Change</td>
<td>Increase</td>
</tr>
<tr>
<td>Indicator</td>
<td>Case 1</td>
<td>Case 2</td>
<td>Case 3</td>
</tr>
<tr>
<td>Moderate</td>
<td>n=5</td>
<td>n=10</td>
<td>n=15</td>
</tr>
<tr>
<td>Serious</td>
<td>n=5</td>
<td>n=10</td>
<td>n=15</td>
</tr>
<tr>
<td>Severe</td>
<td>n=5</td>
<td>n=10</td>
<td>n=15</td>
</tr>
</tbody>
</table>

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#### Process Control and Product Acceptance

- NOTE: Method omitted to for clarity

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#### Considerations for Setting Specifications & Action Limits

- High Importance
- Medium Importance
- Low Importance

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#### Sampling Plan and Limits

- n = # of samples
- c = # allowed
- M = Maximum number of samples that may test positive

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#### Exclusions

- Salmonella
- E. coli
- Enterobacteriaceae

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#### Considerations for Setting Specifications & ActionLimits

- General contamination, reduced shelf life, incipient spoilage
- Aerobic colony counts, yeast, mold, etc.
- Enterobacteriaceae
- Salmonella
- E. coli
- C. botulinum toxin
- L. monocytogenes
- (sensitive populations)

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#### Examples

- Precut vegetables
- Fruit & Vegetable Juices
- Frozen Vegetables
- Frozen Fruit
- Dry Milk Powder
- Blanched Vegetables
- Precooked Rice

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#### Literature

- Considerations for Setting Specifications & Action Limits
- Microorganisms in Foods: Use of Data for Assessing Process Control and Product Acceptance
- In-process limits
- End product limits

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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?

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?

Resources

Guidance, Standards, Guidelines

- 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.

- 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


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


### Codex Alimentarius Commission

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

### Acknowledgements

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

[www.ICMSF.org](http://www.ICMSF.org)

### Questions?

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