Useful Testing in Food Safety Management
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Discussion Topics

- ICMSF Microorganisms in Foods 8 – overview
- Different tests serve different purposes
- Testing for maximum value

Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance

- Update previously recommended end-product testing criteria
- Add other useful tests for specific product types
- Include microbial food safety and quality

ICMSF Provides Advice
No official status

- ICMSF recommendations have no official status
- Official recommendations and standards are the province of:
  - Governments for national standards and regulations, e.g.
  - Intergovernmental agencies for international standards, e.g.

Book 8 Contents

- Part 1 – Principles
  - Utility of microbial testing for safety & quality
  - Validation of control measures
  - Verification of process control
  - Verification of environmental control
  - Corrective action to re-establish control
  - Microbial testing in customer-supplier relationships

- Part 2 – Product Categories
  - Meats
  - Poultry
  - Seafood
  - Fresh & past food
  - Vegetables
  - Fruits
  - Spices, dried soups, flavorings
  - Cereals
  - Nuts, oilseeds, dried legumes
  - Cocoa and confectionery
  - Oil-based foods
  - Sugar, syrups, honey
  - Beverages
  - Water
  - Dairy products
  - Eggs
  - Shelf stable, heat treated foods
  - Infants and young children
  - Formulated foods

Different Tests Serve Different Purposes

Some “work in progress” examples shared today.
Microbial Testing

"Microbial testing" means different things to different people:
- Reams of data
- Detective game to identify unknown or causative agent
- Presence/absence or qualitative reaction that's observed
- Quantitative measurement of the microbial status of a sample or lot

When & Where to Test

- When there is good evidence that:
  - There is a microbiological problem
    - Food safety or quality
    - Historical or current
  - Testing will help to control the problem

Target Organism Examples

ICMSF Hazard Categories

| Utility     | Spoilage, reduced shelf life, no health concern |
| Indicator   | Measure of GMP                                    |
| Moderate hazard | Not life threatening, short duration, self limiting, no sequelae |
| Serious hazard   | Incapacitating, usually not life threatening   |
| Severe hazard   | Life threatening, chronic sequelae, or long duration OR |

Key ICMSF Sampling Plan Terms

- n Number of sample units analyzed
- c Maximum number of sample units with unsatisfactory test results
- m Level that separates acceptable quality from marginally acceptable or unacceptable quality
- M Level above which is unsatisfactory or requires further investigation
ICMSF Suggested Sampling Plans for Lot Acceptance Testing

<table>
<thead>
<tr>
<th>Hazard Group</th>
<th>Likely Change Before Consumption</th>
<th>n</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility</td>
<td>Reduce</td>
<td>n5</td>
<td>c=3</td>
</tr>
<tr>
<td></td>
<td>Case 1</td>
<td>n5</td>
<td>c=2</td>
</tr>
<tr>
<td></td>
<td>Case 2</td>
<td>n5</td>
<td>c=1</td>
</tr>
<tr>
<td>Indicator</td>
<td>Case 3</td>
<td>n5</td>
<td>c=2</td>
</tr>
<tr>
<td></td>
<td>Case 4</td>
<td>n5</td>
<td>c=2</td>
</tr>
<tr>
<td></td>
<td>Case 5</td>
<td>n5</td>
<td>c=1</td>
</tr>
<tr>
<td>Moderate</td>
<td>Case 6</td>
<td>n5</td>
<td>c=2</td>
</tr>
<tr>
<td></td>
<td>Case 7</td>
<td>n5</td>
<td>c=1</td>
</tr>
<tr>
<td></td>
<td>Case 8</td>
<td>n5</td>
<td>c=1</td>
</tr>
<tr>
<td></td>
<td>Case 9</td>
<td>n10</td>
<td>c=1</td>
</tr>
<tr>
<td>Severe</td>
<td>Case 10</td>
<td>n5</td>
<td>c=0</td>
</tr>
<tr>
<td></td>
<td>Case 11</td>
<td>n10</td>
<td>c=0</td>
</tr>
<tr>
<td></td>
<td>Case 12</td>
<td>n20</td>
<td>c=0</td>
</tr>
<tr>
<td></td>
<td>Case 13</td>
<td>n15</td>
<td>c=0</td>
</tr>
<tr>
<td></td>
<td>Case 14</td>
<td>n30</td>
<td>c=0</td>
</tr>
<tr>
<td></td>
<td>Case 15</td>
<td>n60</td>
<td>c=0</td>
</tr>
</tbody>
</table>

Sample Size Influence on Probability of Acceptance

- n = 15
- n = 30
- n = 60

Useful Microbial Testing

- Identification of contamination sources
- Environmental monitoring to identify potential pathogen harborage sites
- Utility and indicator organisms to verify effective controls & trends
  - Effective processing
  - Effective control of post process contamination
- Investigation sampling for problem solving

Process Example

Result Format Influences Information Provided

<table>
<thead>
<tr>
<th>Presence/Absence</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Log (CFU/g)</td>
<td>Log (CFU/g)</td>
</tr>
</tbody>
</table>

Log (CFU/g)
Trend Analysis Can Inform Process Control

ICMSF Book 8 Testing Considered
- Primary production
- Ingredients
- In-process
- Processing environment
- Shelf life
- End product

Primary production
Included for some product types
- Included when production conditions have a major influence on the microbial quality or safety
  - Fruits, vegetables, spices, meat, poultry, and fish products
- Examples of samples to consider
  - Irrigation water, fertilizer, feed, and other on-farm practices

Ingredient Testing
- May be useful for some applications and not others, e.g. cocoa powder:
  - Used in chocolate, no heat treatment
  - Used in ice cream mix that is subsequently pasteurized
- Questions considered:
  - Is control at the ingredient step necessary for safety or quality?
  - Is testing necessary to verify the acceptability of the ingredient?

In-Process Testing
- Use to verify a kill step or predict potential re-contamination
- Examples
  - Intermediate product, line residues, tailings, wash water
  - Typically indicators with quantitative results
- Questions considered:
  - Does the process need to be controlled to prevent increase, ensure decrease, maintain current level, or prevent spread of a microbial concern?
  - Is testing needed to verify a) the process is functioning as intended or b) contamination is not occurring in the process?
  - Are there locations in the process where accumulated product residue may provide a representative or “worst case” sample that predicts the safety or quality of the final product?

Processing Environment Testing
- Use to verify that the environment is under appropriate hygienic control
- Examples
  - Swabs or sponges for sampling sites on equipment or in the environment
  - Rapid testing to verify cleaning & sanitation adequacy
- Benefits:
  - Identify harborage sites that can contaminate end product
  - Frequently, earlier detection of issues than end product testing
- Questions considered:
  - Does the environment need to be controlled to prevent contamination of the product with a microbial concern?
  - Will testing be beneficial to verify control of the microbial concern in the environment?
Shelf Life Testing

- Discussed only if microbial activity is relevant to the commodity
- Purpose – verify adequacy of microbial stability for the product life cycle
- Benefits – may predict issue before they experience in the market place
- Questions considered:
  - Is shelf life limited by a microbiological safety or quality concern?
  - Is shelf-life testing feasible?

End Product Testing

- Purpose:
  - Demonstrate successful application of controls or assess the microbiological status of a lot when no other information exists to assess its status.
  - Relative importance of end product testing is lower than that for in-process or environmental testing for many product categories.
  - Alternative sampling plans may be appropriate, for example:
  - Reducing the number of samples for on-going surveillance activity
  - Increasing the number of 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?

Preliminary Example:
Dried Cereal Products

<table>
<thead>
<tr>
<th>Critical Ingredients</th>
<th>Relative importance</th>
<th>Useful testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for mycotoxins if confidence in raw grains is low. Test nuts, cocoa, and other sensitive ingredients with no subsequent kill step for Salmonella if confidence in supplier is low.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In-process

<table>
<thead>
<tr>
<th>In-process</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test appropriate product residues and in-line samples for Salmonella. Typical guidance levels: Salmonella – absent.</td>
<td></td>
</tr>
</tbody>
</table>

Processing environment

<table>
<thead>
<tr>
<th>Processing environment</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for Salmonella and Enterobacteriaceae in the processing environment. Typical guidance levels: Enterobacteriaceae – 100-1000 cfu/g Salmonella – absent.</td>
<td></td>
</tr>
</tbody>
</table>

Shelf-life

<table>
<thead>
<tr>
<th>Shelf-life</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

End product

<table>
<thead>
<tr>
<th>End product</th>
<th>Relative importance</th>
<th>Useful testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Testing for Enterobacteriaceae is recommended to verify process control. Analytical method Microorganism Product ISO 21528 - Enterobacteriaceae Dried cereal</td>
<td></td>
</tr>
</tbody>
</table>

Low

| Low | Testing for pathogens is not recommended during normal operation when GMP and HACCP are effective as confirmed by above tests. When above testing or process deviations indicate a possible safety issue, test for Salmonella. |

Microbial Sampling Summary

- Testing safety “into” products usually does not work because of sampling probability
- Testing is recommended to generate meaningful data
  - Impact quality or safety
- Focus on process control preferred
  - Environmental monitoring
  - Selected sampling tailored to the line to verify control

International Commission on Microbiological Specifications for Foods (ICMSF)

The ICMSF recommendations in this presentation are not final.

The work is still under development and subject to internal and external peer review.