What I will talk about..

- Finished Product Testing Alone Has Limitations
- Validation & verification - Role of Microbiological testing
- Microbiological testing for process control & environmental control verification
- Considerations for microorganisms to be tested for and methods to be used

Products dictate Stringency and Limits
**Microbiological Testing in Nestlé**

**What we test for...**
- Salmonella spp.
- Listeria monocytogenes
- Shigellae species
- Yersiniae spp.
- Enterococci
- Total Plate Count
- Enterobacteriaceae
- Yeasts & moulds

**Why we test...**
- Verification
- Validation

**The Food Chain Can be Long, Complex and many testing points**
- Primary production
- Intermediate processing
- Ingredient Reception (manufacturer)
- Environmental control
- Product release (process control)
- Border control/Authority/Compliance

**Food Safety requires: FSMS/HACCP/GAP/GMP/GHP**

Assurance of food safety cannot be based on finished product testing.

Assurance of food safety moves more and more from finished product testing to a proactive food safety management system.

**Limitations of End product testing**

- 0.1% contaminated
  - 10 samples
  - ~1% probability of detection
  - ~9% probability of detection

- 10% contaminated
  - 10 samples
  - ~35% probability of acceptance of a defective lot
Limitations of End product testing

End product testing has statistical limitations based on:

- The percentage of product that is contaminated
- The amount of product sampled (n and analytical unit)
- The distribution of contamination throughout the food

Therefore, it is impossible to detect every contaminant in a finished product even by taking a large number of samples.


Validation, Monitoring & Verification (CAC 2008)

Validation

Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Monitoring

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is or has been operating as intended.

Verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure is or has been operating as intended.

Microbiological testing: Limited value for Monitoring

“...due to the time required for most microbiological analyses and the relative insensitivity of even the most stringent sampling plans, microbiological testing is of limited value for monitoring in quality and safety assurance programs.”

– From ICMSF 201X Microorganisms in Foods 7: Microbiological Testing in Food Safety Management, 2nd edition, Chapter 13

Microbiological testing for Validation and Verification

Despite limitations related to sensitivity and time to results, microbiological testing can play an important role in validation and verification of process control.
Controlled Food Operations require...

1. Knowledge of the significant hazards
2. Knowledge of the factors that are necessary for control
3. Knowledge of the extent of variability and factors that influence variability
4. Establishing criteria for the factors that must be controlled
5. Establishing monitoring and verification procedures
6. Organizing and interpreting data
7. Using the data to measure change and improve control
8. Responding to the data
9. Learnings from Investigations

Potential Verification Activities

- Calibration of equipment
- Review of records
- Targeted sampling and testing
- Visual inspection of equipment
- Environmental monitoring
- 2\textsuperscript{nd} and 3\textsuperscript{rd} party audits

Targeted Sampling/Testing - Verification For Process Control

For process control, periodic verification may include targeted sampling and microbiological testing of:

- Ingredients
- In-process materials
- Finished products

Microbiological Testing - Ingredients

- Historical data
- Usage and further processing
- Type of finished product
- Requirements
- Supplier audits
- etc...
**Microbiological Testing - In-Process Material/FP**

In processing testing

MANUFACTURE

Specifications

Criteria, Guidelines, Specifications

**Process Control Verification-Examples - ICMSF BK 8**

<table>
<thead>
<tr>
<th>Relative importance</th>
<th>Useful testing</th>
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</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Testing for Enterobacteriaceae is recommended to verify process control</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>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, testing for Salmonella is recommended.</td>
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</table>

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Method</th>
<th>Case</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
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<td>Enterobacteriaceae</td>
<td>ISO 21528-2</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>10</td>
<td>10^6</td>
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<tr>
<td>Salmonella</td>
<td>ISO 6579</td>
<td>11</td>
<td>10</td>
<td>0</td>
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</table>

**Microbiological Testing: Environmental control verification...**

- Used to VERIFY Hygiene, PRPs, GMP
- Indication of Process cross contamination
- Enables Factory to take actions in response to findings

**Key Aspects of EM programme...**

**Where to Sample...**

- **Zone 1**
  - Product contact surfaces
  - E.g., conveyors, tables, racks, vats and tanks, utensils, pumps, valves, slicers, driers, freezers, filling and packaging machines

- **Zone 2**
  - Non-product contact surfaces in close proximity to product
  - E.g., exterior of equipment, refrigeration units, close floors

- **Zone 3**
  - Non-product contact surfaces more distant from product but in processing area
  - E.g., forklifts, floors and walls, telephones, drains

- **Zone 4**
  - Outside processing area
  - E.g., locker rooms, cafeteria, hallways
Key Aspects of Env Control Testing...

- What Microorganisms to sample for...

**Pathogen(s)**
- Salmonella
- Cronobacter sakazaki

**Hygiene Indicator(s)**
- Enterobacteriaceae
- L. monocytogenes
- Listeria spp.

**Pathogen(s)**
- Salmonella
- Others?
- Cronobacter sakazaki

**Hygiene Indicator(s)**
- Enterobacteriaceae
- EB
- L. monocytogenes
- Listeria spp.

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Key Aspects of EM programme...

- Data (EM) Management, Trend Spotting & Response

- Organise the Data
- Frequently Review
- Look for Trends
- Share
- React

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Trend Analysis from Microbiological Testing

**Testing Methods Are Not Always Perfect....**

- Sensitivity and Specificity are key parameters
- Use of ‘Official Methods’
- Proper Validation of Alternatives
- Proper assessment of Method Performance - proficiency Testing
- Accreditation of method performing Laboratories
### Key Messages....

- Microbiological testing Occurs at numerous points in the food Chain
- Finished product testing alone does not Assure food Safety
- Microbiological testing plays a key role in Verification and Validation
- Verification Testing for Process Control Across Lots for Ingredients, semi-finished & finished product is industry practice
- Environmental control (Microbiology) Testing is a key parameter in industry Food Safety Management System
- Method Selection, application and performance - an element not to be ignored!

### Thank you for Listening...