The "moving window"

A new approach to food safety

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When is product testing for microbial content useful?

When information of content is needed and not otherwise available

- Foods of unknown/dubious quality or history
- Documentation for a claimed safety status

When routine testing is a useful tool for the verification of:

- the design of the food safety control system
- the daily operation of the food safety control system

Focus on the acceptability of the batch

Focus on the acceptability of the system
METHODS FOR THE VERIFICATION OF CONTROL SYSTEMS

• Review and evaluation of the records and documents

• Measurements and evaluation activities to ensure that a PRP or process is operating within defined parameters

• Internal and external audits

• On-site inspections

• (End-)product sampling and testing
Approach to testing

• The performance of a HACCP system depends on the effectiveness of PRPs & the degree of commitment

• Testing in a processing plant is carried out at various locations:
  • Incoming materials
  • Along the process
  • Processing environments
  • End of manufacture
  • Durability assessment

• Any testing procedure is normally governed by an MC
## MICROBIOLOGICAL CRITERIA (MC)

<table>
<thead>
<tr>
<th>Organism</th>
<th>( n )</th>
<th>( c )</th>
<th>( m )</th>
<th>( M )</th>
</tr>
</thead>
<tbody>
<tr>
<td>L. monocytogenes</td>
<td>5</td>
<td>0</td>
<td>100 cfu/g</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0</td>
<td>Absent in 25g</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0</td>
<td>100 cfu/g</td>
<td>-</td>
</tr>
<tr>
<td>E. coli</td>
<td>5</td>
<td>2</td>
<td>100 cfu/g</td>
<td>1,000 cfu/g</td>
</tr>
<tr>
<td>Coagulase positive Staphylococci</td>
<td>5</td>
<td>2</td>
<td>100 cfu/g</td>
<td>1,000 cfu/g</td>
</tr>
<tr>
<td>Staphylococcal enterotoxin</td>
<td>5</td>
<td>0</td>
<td>Absent in 25g</td>
<td>-</td>
</tr>
</tbody>
</table>
THE ”N/C/m/M” SYSTEM

- Developed prior to the HACCP era
  ICMSF Book 2 (first ed. 1970)
- Designed for lot-by-lot testing
  Used to sort between acceptable and non-acceptable food lots/batches
  (the 15 ICMSF cases)
- Not designed for today's primary application:

  Verification of the ongoing performance of HACCP based systems
# LOT-BY-LOT TESTING

Possibility of not detecting a contaminated lot

<table>
<thead>
<tr>
<th>Sample size</th>
<th>1% contaminated</th>
<th>5% contaminated</th>
<th>10% contaminated</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>0.95</td>
<td>0.77</td>
<td>0.59</td>
</tr>
<tr>
<td>10</td>
<td>0.90</td>
<td>0.60</td>
<td>0.35</td>
</tr>
<tr>
<td>15</td>
<td>0.86</td>
<td>0.46</td>
<td>0.21</td>
</tr>
<tr>
<td>20</td>
<td>0.82</td>
<td>0.36</td>
<td>0.12</td>
</tr>
<tr>
<td>30</td>
<td>0.74</td>
<td>0.21</td>
<td>0.04</td>
</tr>
<tr>
<td>40</td>
<td>0.67</td>
<td>0.13</td>
<td>0.01</td>
</tr>
<tr>
<td>50</td>
<td>0.61</td>
<td>0.08</td>
<td>0.01</td>
</tr>
</tbody>
</table>
LOT-BY-LOT TESTING

No. of samples required to find defect lots

No. of samples

300 samples required to guarantee that no more than 1% of lots are defect
OBTAINING SAFE FOODS

• Safe food is obtained through preventive control, i.e.
  • Verified PRPs
  • Validated control measures
  • HACCP

• Lot-by-lot testing is not an effective tool to provide nor document safe foods

• Product testing can be useful to assist in verifying the continuous performance of the food safety control system
MOWING WINDOWS
A new approach for system verification

Codex Committee on Food Hygiene (CCFH)

CCFH working group on Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods

IDF AT on MC
Codex drafting team
Changed definition of MC

The old
A microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.

The new
A microbiological criterion is a risk management metric, which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for
A series of sampling occasions with a specified sampling frequency within a defined time frame

\[ \rightarrow = n \]
\[ \rightarrow = \text{e.g. one/week} \]
\[ \rightarrow = n \times \text{frequency} \]
A MOVING WINDOW

Test results

m

M

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

Test results
m
M

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

Test results

m

M

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

Test results

n=5; c=2; m=10,000; M=100,000
A MOVING WINDOW

n=5; c=2; m=10,000; M=100,000
Corrective action

**When?**

Last "n" results (n=5, 10 or 30):
- When "M" is exceeded (action on individual results)
- When "c" is exceeded within the sampling period

**What?**

Targeted actions based on review of data, source tracking & root cause analysis, e.g.:

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Design</th>
<th>Affected lot, if required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restore control of control measures</td>
<td>Revalidation</td>
<td>Rework</td>
</tr>
<tr>
<td>Improve monitoring</td>
<td>Improve PRPs</td>
<td>Containment &amp; recall</td>
</tr>
<tr>
<td>Change intended level of</td>
<td>Alternate use</td>
<td></td>
</tr>
</tbody>
</table>
Moving windows: Why?

- Shift in focus towards system performance
- Excellent as feed-in to trend analysis
- Cost-effectiveness
  - Generates more data and information from operations
  - Maximizes output of analytical sampling & testing
  - Reduces analytical costs in well performing HACCP based systems

“The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system.” (Codex Alimentarius 2013 - CAC/GL 21)
Moving windows: When?

Routine verification
- Daily
- Weekly
- Bi-weekly

Type of microbiological criteria
- 3-class \((n;c;m;M)\)
- 2-class \((n;c;m)\)

Well performing HACCP based systems
IS IT LEGALIZED IN EU?

EU Definition of MC*

Microbiological criterion means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

*) Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs

The new Codex definition

A microbiological criterion is a risk management metric, which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms at a specified point of the food chain.
Art 5.1
The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.

Art 5.3
The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

Art. 5.5
Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Interpretation:
→Art 5.1: Typically 1 monthly sampling (n=5)
→Art 5.5: Moving window as alternative sampling procedure (n=1 spread over time)
Not a new concept!

Reg 853/2004, Annex III, Section IX, Chapter III

• ≤ 100.000 per ml as rolling geometric average over a two-month period

• In case of non-compliance, the rolling geometric average over a two-month period shall be <100.000 per ml again, before the end of a 3 month period
Mean log count is >5 (≈100,000) first time

Deadline for resolving the problem
Deadline for resolving the problem

Moving window - bacterial counts

Mean log count is still >5 (≈100 000)
Deadline for resolving the problem

Mean log count is still $>5$ ($=100,000$)
Deadline for resolving the problem

Mean log count is still >5 (=100 000)
Mean log count is still >5 (=100 000)
Mean log count is now <5 (=100 000)

Deadline for resolving the problem

Problem resolved!
Thank you!