ILSI Europe – IAFP webinar on the “Relevance of Microbial End-Product Testing in Food Safety Management”

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ILSI Europe – Vision

We build multi-stakeholder science-based solutions for a sustainable and healthier world.
ILSI Key principles

ILSI Europe is a science-driven organisation

Non-profit association

Tripartite nature / public-private partnership

Scientific discussions

Volunteering scientists

Public interest

No lobby

No marketing and pricing
Microbiological Food Safety Task Force: Goals and tools

**Ultimate goal** to investigate microbial issues in foods that are related to public health risks

- **Publishing guidelines** and working on an agreed terminology
- **Understanding** potential detection, control and management procedures
- **Reviewing and summarising** knowledge on pathogen behaviour and ecology and assessing their risk to consumers
- **Developing tools** to manage safety hazards and risks in food production systems

**Potential tools:**
- Peer-reviewed publications
- Workshops
- Webinars
- European projects
Microbiological Food Safety
Task Force: Topics and Activities

- **Antimicrobial resistance**
  - FP7 European project Ecology from Farm to Fork Of microbial drug Resistance and Transmission

- **Industrial MRA**
  - Industrial Microbiological Risk Assessment (MRA) in fresh produce and later on in dairy

- **Virus control options**
  - Control options for viruses in food processing

- **Meta-analysis in MRA**
  - The Use Of Meta-Analysis In Microbiological Risk Assessments

Expert group activities result in peer-reviewed publications.
IAFP

• >4,000 food safety professionals
• Committed to Advancing Food Safety Worldwide®
IAFP Annual Meeting and IAFP European Symposium on Food Safety
ILSI Europe EXPERT GROUP: History-Based Performance of the HACCP Control Systems to Verify the Effectiveness of Food Safety Management

• Marcel Zwietering, Liesbeth Jacxsens, Jeanne-Marie Membré, Maarten Nauta, Mats Peterz
Programme

Moderator: Ms Lilou van Lieshout (ILSI Europe, BE)
Moderator: Prof. Marcel Zwietering (Wageningen University, NL)

17.00 Introduction
Ms Lilou van Lieshout (ILSI Europe, BE)
Prof. Marcel Zwietering (Wageningen University, NL)

17.05 The Role of Validation, Verification and Microbiological Sampling in a
Food Safety Management System
Dr Mats Peterz (Nestlé, CH)

17.20 The Relevance of End Product Testing: The Example of Canned Foods
and Cooked Ham
Dr Jeanne-Marie Membré (INRA, FR)

17.35 FSMA: Testing as a Tool for Verifying Preventive Controls
Prof. Donald Schaffner (Rutgers University, US)

17.50 Q & A

18.00 Closure
The role of validation, verification and microbiological sampling in a food safety management system

Mats Peterz

Based on a presentation from Prof. Zwietering, Wageningen University
Introduction

- Microorganisms can be heterogeneously distributed
- Taking a sample is a stochastic process
- Performing a sampling plan (n=10) is a stochastic process
- Testing methods are not perfect

Can end product testing control food safety?
End product testing useful or lottery?

Positives mean something, negatives are no guarantee
(often only 300 g of 30,000 kg = 0.001% ; 1: 100,000)
Probability of accepting a lot, $c=0$

1 % defectives of 100,000 products, means 1,000 products
Testing frequency based on level of control and history

EU2073/2005 for *Salmonella* minced meat, meat preparations and carcases:
- shall take samples for microbiological analysis at least once a week

Sampling can be reduced to fortnightly if …
- satisfactory results have been obtained for 30 consecutive weeks
- or the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low
Validation - Monitoring - Verification

• **Validation**: Obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome
  • prove that $72^\circ$C 15 s gives a 6 D reduction for *Listeria* in milk

• **Monitoring**: a planned sequence of observations of control parameters to assess whether a control measure is under control
  • continuous verification of $T=72^\circ$C and residence time

• **Verification**: The application of procedures and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended
  • microbial testing to verify *Listeria* absence in 5 times 25 ml of milk
Validation / Verification

Validation
(data on initial levels in raw materials, environment, transfer, inactivation, growth)

Verification

Epidemiology

End product testing

Raw materials: Initial level and prevalence

Survival

Transfer

Level and prevalence in the environment

Reduction (e.g. heating)

Growth: Final level

Recontamination
\[
\log N_{f1} = \log N_{rm} - \log \text{Red}
\]

\[
N_{f2} = N_{f1} + \text{Rec}
\]

\[
\log N_{end} = \log N_{f2} + \log \text{Growth}
\]

if \( N_{f2} = 0 \) no growth \( N_{end} = 0 \)
Examples of Information Sources

Validation:
- Scientific literature
- Databases
- Base line studies
- Predictive microbiology
- Risk assessments
- Specific experiments (e.g. challenge tests)

Verification:
- Microbial testing
- Consumer complaints
- Authority testing
- Reports on outbreaks, zoonosis and recalls
HACCP

Validated CCPs

Monitoring CL

Verification by MC

PRP (GMP, GHP, ....)
Conclusions

• All samples negative is no guarantee of safety
• A positive sample is indicating unsafety
• Sampling is useful for verification

*Control* of safety is only to a very limited extend supported by end-product testing
Case studies

The relevance of end-product testing is described and evaluated for two case studies:

- Canned food (*Clostridium botulinum*)
- Cooked sliced ham (*Listeria monocytogenes*)
The relevance of end product testing: the example of canned foods and cooked ham

Jeanne-Marie Membré
Relevance of microbial finished product testing in food safety management

Marcel Zwietering, Liesbeth Jacxsens, Jeanne-Marie Membré, Maarten Nauta, Mats Peterz
Canned foods

- A minimal $F_{121^\circ C}$ value of 3 minutes is used to guarantee sufficient reduction of *Clostridium botulinum* spores (for non-acid products).
  (Often $F_{121}$ is much higher in practice to also inactivate spoilers)

- With a >12D processing, there is very low probability of survival of spores.

- Likewise, in hermetically sealed cans, the recontamination is prevented.
C. botulinum in a canned product

<table>
<thead>
<tr>
<th>Process step</th>
<th>Possible microbial behaviour</th>
<th>Likelihood of microbial behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>Initial introduction</td>
<td>May happen</td>
</tr>
<tr>
<td>Sterilisation</td>
<td>Reduction by HT</td>
<td>Very effective</td>
</tr>
<tr>
<td>Post HT-process</td>
<td>Recontamination</td>
<td>Negligible</td>
</tr>
<tr>
<td>Storage</td>
<td>Growth</td>
<td>Irrelevant</td>
</tr>
</tbody>
</table>

% contaminated end-product extremely low (<< 1/10,000)
Canned foods - Verification

- External sources to verify the level of end-product contamination
  - RASFF Portal (European Rapid Alert System for Food and Feed)
  - European Union summary reports
  - Literature studies

- RASFF Portal (1998-2013):
  - 3 notifications in 16 years

- EFSA Report (2010-2012):
  - About 10 outbreaks per year, not necessarily from industrially canned products

Overall number of reported cases within Europe is rather low (annual European domestic market: 8 bn kg of canned foods)
Canned foods - relevance of sampling

- Efficiency of end-product sampling?

<table>
<thead>
<tr>
<th>$P_{\text{target}}$</th>
<th>$P_{\text{detect}}$</th>
<th>$n$ for 95% detection probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.000001</td>
<td>1 per 1,000,000</td>
<td>0.9999999</td>
</tr>
<tr>
<td>0.00001</td>
<td>1 per 100,000</td>
<td>0.999999</td>
</tr>
<tr>
<td>0.0001</td>
<td>1 per 10,000</td>
<td>0.99999</td>
</tr>
<tr>
<td>0.001</td>
<td>1 per 1,000</td>
<td>0.999</td>
</tr>
</tbody>
</table>

Huge (non-realistic) sampling plans will be necessary!

With a so small expected rate of defective end-products, sampling is ineffective.
Sliced cooked Ham

- Cooked boneless, formed premium ham
- Effective thermal treatment (70°C for 40’)
- Relatively high probability of recontamination by *Listeria monocytogenes* at the slicing steps
- *L. monocytogenes* is able to grow under chilled conditions.
**L. monocytogenes in cooked ham**

<table>
<thead>
<tr>
<th>Process step</th>
<th>Possible microbial behaviour</th>
<th>Likelihood of microbial behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>Initial introduction</td>
<td>May happen</td>
</tr>
<tr>
<td>Cooking</td>
<td>Reduction by HT</td>
<td>Very effective</td>
</tr>
<tr>
<td>Post HT-process</td>
<td>Recontamination</td>
<td>Possible (e.g. from slicer)</td>
</tr>
<tr>
<td>Storage</td>
<td>Growth</td>
<td>Expected at chilled temperature</td>
</tr>
</tbody>
</table>

% contaminated end-product might be non negligible
Cooked ham - Verification

• External sources to verify the level of end-product contamination
  • RASFF Portal (European Rapid Alert System for Food and Feed)
  • European Union summary reports
  • Literature studies

• RASFF Portal (1998-2013):
  • 19 notifications in 16 years (8: company’s own tests, 11: official tests of products on the market)

• EFSA Reports (2010-2012):
  • On average 5.1% of samples from pig-meat, cooked, ready-to-eat products collected at retail in 2011 and 2012 were *L. monocytogenes* positive
## Cooked ham - Verification

- Literature studies

<table>
<thead>
<tr>
<th>Products and origin</th>
<th>Sample size (g)</th>
<th>No. of positive samples/no. of samples</th>
<th>Prevalence (%)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luncheon meats, USA</td>
<td>25</td>
<td>82/9199</td>
<td>0.89</td>
<td>Gombas et al., 2003</td>
</tr>
<tr>
<td>Ham, Brazil</td>
<td>25</td>
<td>1/65</td>
<td>1.5</td>
<td>Martins and Germano, 2011</td>
</tr>
<tr>
<td>Ham, United Kingdom</td>
<td>100</td>
<td>40/949</td>
<td>4.2</td>
<td>Little et al., 2009</td>
</tr>
<tr>
<td>Cooked ham, Belgium</td>
<td>25</td>
<td>54/879</td>
<td>6.1</td>
<td>Uyttendaele et al., 1999</td>
</tr>
</tbody>
</table>

### Prevalence estimates

|                          | Mean 3.2       |

**Literature and Epidemiological data: prevalence : 3 to 5% (+ batch Variability)**
Cooked ham - relevance of sampling

- Efficiency of end-product sampling?

... and far from what the legislation recommends (e.g. the European Commission recommends a sampling plan of 5 units)

Rule of thumb:
Sample size = 3 fold the defective rate

Defective rate expressed as 1 in x

Proportion defective products in a batch

Probability to accept a batch

<table>
<thead>
<tr>
<th>n</th>
<th>n=1</th>
<th>n=2</th>
<th>n=3</th>
<th>n=5</th>
<th>n=10</th>
<th>n=30</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
<td>0.8</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>0.0</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
<td>0.8</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

.../...
Cooked ham - relevance of sampling

- A sampling plan of 5 units (European Commission recommendation)

85% to accept the batch with n=5

1 per 31
Cooked ham - food safety management

• Control measures
  • Preventing recontamination by *L. monocytogenes* at the slicing steps.
  • Best practises on cleaning and operations of the factory environment around the slicer and packaging equipment.

• Sampling plan
  • A *L. monocytogenes* monitoring plan around the slicers (environment, equipment in contact with the product, floor… etc.) is recommended.

.../...
Cooked ham – e.g. targeted sampling plan (focused on the environment)

• Sampling plan in the environment (adapted from the New South Wales Food Safety Authority of Australia, 2008):
  • It is recommended that at a minimum, businesses operators sample five environmental sites for *Listeria* spp. monthly.

• Actions in case of positive sample found:
  • Immediately investigate the potential cause of the problem and initiate corrective action in accordance with its food safety program.

• Sampling plan following the corrective actions:
  • Increase the frequency of environmental testing, for instance from monthly to weekly testing, and continue to test until the environmental swabbing program has achieved three consecutive negative sampling results.
Conclusions

• Assurance of food safety cannot be based on end-product testing

• An efficient food safety management system must be implemented
  • Based on the HACCP principles and with proper pre-requisite programmes
  • Identifying what the crucial step(s) in the process are
  • Monitoring results at CCPs are vital (↔ information on the variability and consistency of process parameters), e.g.
    • **Canned Product: thermal process is a crucial step**
      • E.g. relevant records: temperature and holding time
    • **Cooked ham: slicing step is a crucial step**
      • E.g. relevant records: cleaning procedures

• End-product testing can be used for verification of the implemented food safety management system → Particularly true if end-product defective rate is relatively high (e.g. cooked ham, where inter-batch variability is high).
FSMA: Testing as a tool for verifying preventive controls

Prof. Donald Schaffner
Background

- FDA Preventive Controls proposed rule reviewed ~1 year by Office of Management and Budget (OMB)
  - OMB struck provisions requiring product testing, environmental monitoring, and supplier approval and verification
  - OMB review helps ensure that agencies carefully consider consequences (including both benefits and costs)
- RLB and DWS Approached by the PEW Charitable Trusts in 2013 to develop a scientific “white paper” re: microbiological testing in the context of FSMA preventive controls rule
- The FPT article is that report, these slides provide a summary
Definitions

- Monitoring
  - Measurements and observations taken in real-time
  - Designed to insure proper functioning food safety system
  - Think HACCP CCPs or GMPs

- Verification and validation
  - Is the system is continuing to function as intended?
Definitions: Verification vs. Validation

- Plan says “cook to at least 160° F (71.1 °C)” and product is cooked to 161° F (71.7 °C).
  - Verified
- Plan says “cook to at least 160° F (71.1 °C)” and the product is cooked to 159° F (70.6 °C).
  - Not verified
- Plan says “refrigerate to 45° F (7.2 °C) to control Salmonella growth”
  - Valid
- Plan says “refrigerate to 45° F (7.2 °C) to control Listeria growth”
  - Invalid
Definitions

• Science-based: Uses the best scientific information we have, within a regulatory framework
  • Temperature limits for growth of *Salmonella* vs. *L. monocytogenes*
  • Correlation of indicators with pathogens
• Risk-based:
  • According to Codex Risk is “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food” so a risk-based system considers that probability
Three types of testing

- Traditional lot testing
- Environmental testing
- Process control verification testing
Traditional lot testing

• Purpose: examine a product lot for which you have no information (e.g., port of entry)
• Should not be necessary under HACCP
• When part of food safety (e.g. “test-and-hold/hold-and-release”), function is as preventive control and not verification tool
• Effectiveness decreases substantially when “defect rate” drops below 2 – 3%
• Limited use for foods with limited shelf life
Environmental testing

• Testing of both non-food contact surfaces and food-contact surfaces
  • interpretation and significance of the findings are substantially different

• Environmental testing is typically a verification activity designed to access effectiveness of sanitation/prerequisite programs

• Might also be “sanitation control point”
  • ATP testing is a sanitation monitoring activity
Process Control Verification Testing

Example

• Consider the production of a food that uses a 5-log thermal inactivation of *Salmonella*
  • Prior surveys that indicated that the level of *Salmonella* in the raw material is <1 CFU/100 g

• Monitoring
  • time and temperature achieved during the thermal process.

• Verification
  • periodically examine finished product samples for indicator microorganism or for *Salmonella*
Testing Example

• What to do if…
  • CCP monitoring indicates the process was functioning properly but…
  • testing indicates that a microbiological indicator or pathogen was present

• Possible explanations
  • raw materials had significantly increased levels of contamination
  • new source of contamination after thermal treatment
  • the thermal process was not functioning properly, despite indications to the contrary
Process control testing for verification

- Limited number of tests across lots over time (vs. extensive testing of each lot)
- Can use statistical process control
- Examples:
  - *Salmonella* test once per day, presence/absence, more than 1 positive sample in a 7-day period indicates loss of control
  - Lack of generic *E. coli* in two 10-ml samples per 1000 gallons of juice, two positive assays in a moving window of seven consecutive samples
Process Verification Testing checklist

• If “yes” answers are provided to all questions below
• Then specifics of testing program (sampling plans, frequency of testing, and actions to be taken) can be developed for process verification
  • Not currently doing “test and hold/hold and release”? 
  • Are practices that lead to increased pathogen risk known? 
  • Is testing feasible (commonly available test, affordable, etc.)? 
  • Are there indicators or pathogens that can be used to check for loss of control? 
  • Is there regulatory or industry guidance on appropriate microbe levels or frequency?
Summary

• Not all “microbial testing” is the same
  • Traditional lot testing
  • Environmental testing
  • Process control testing for verification

• Testing has a role to play in insuring food safety

• For more information
The 7 principles of HACCP

1. Conduct a Hazard Analysis
2. Identify Critical Control Points (CCPs)
3. Establish Critical Limit(s)
4. Establish Monitor of the CCP
5. Establish Corrective Actions when a CCP is not under control
6. Establish Record Keeping Procedures
7. Verification
Contact Information for Presenters

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