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

All opinions and statements are those of the individual making the presentation and not necessarily the opinions or views of ILSI Europe or IAFP

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ILSI Europe – Vision

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

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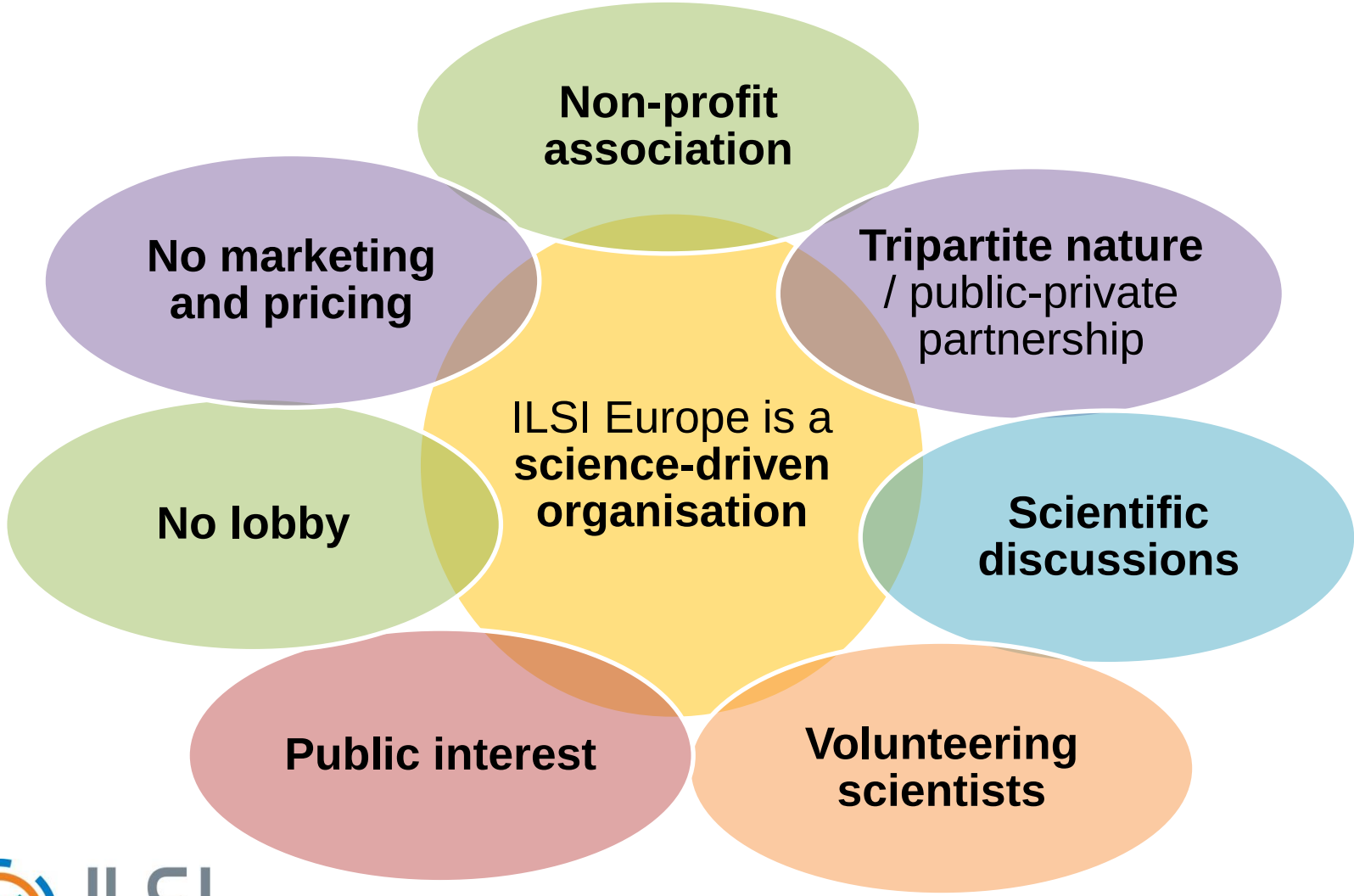
ILSI Key principles



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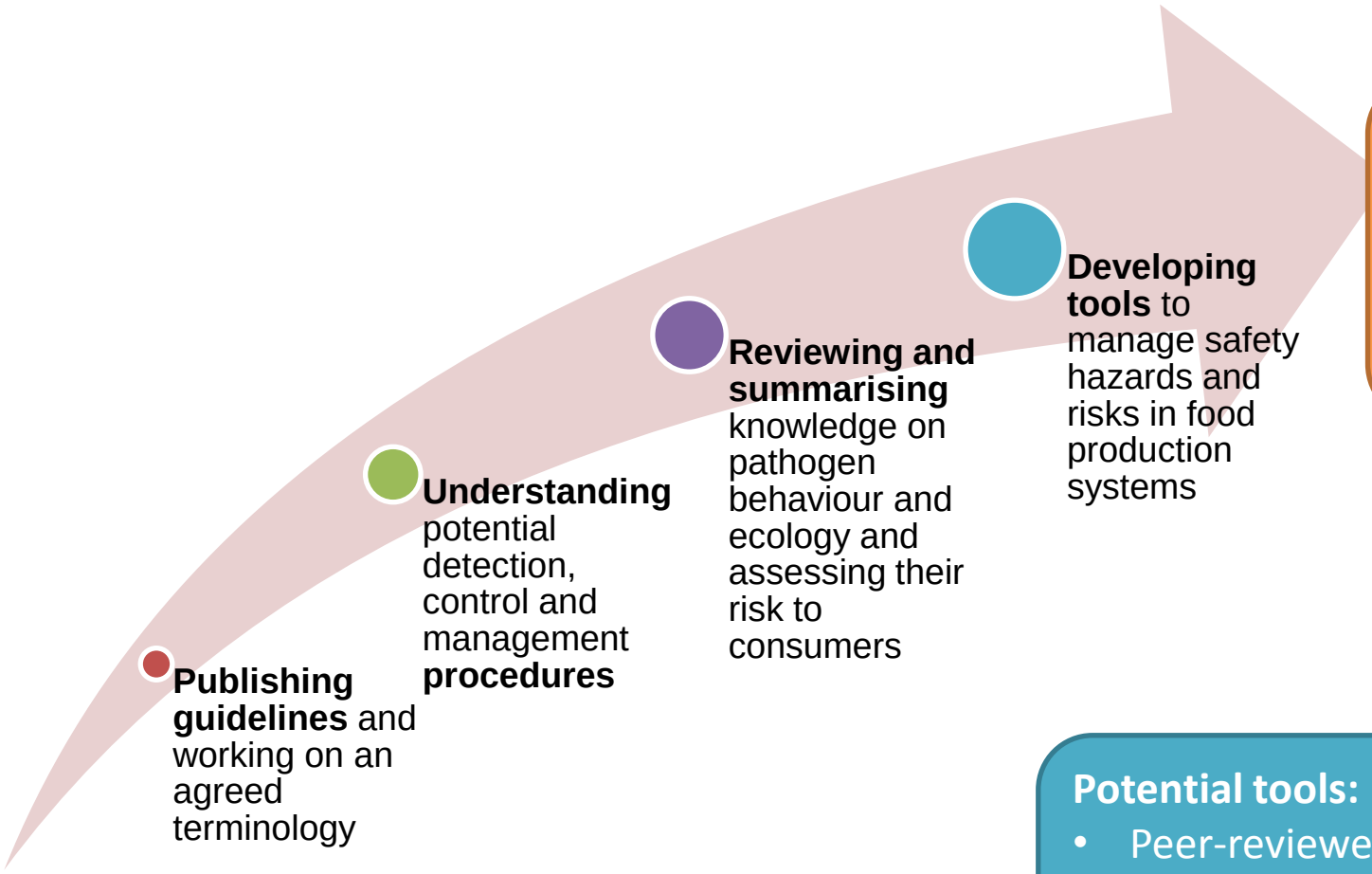
Microbiological Food Safety Task Force: Goals and tools



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

Potential tools:

- Peer-reviewed publications
- Workshops
- Webinars
- European projects

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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

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Expert group activities result in peer-reviewed publications

IAFP

- >4,000 **food safety professionals**
- Committed to ***Advancing Food Safety Worldwide***®

International Association for Food Protection®

IAFP Annual Meeting and IAFP European Symposium on Food Safety

International Association for Food Protection®

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

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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

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

Mats Peterz

Nestlé

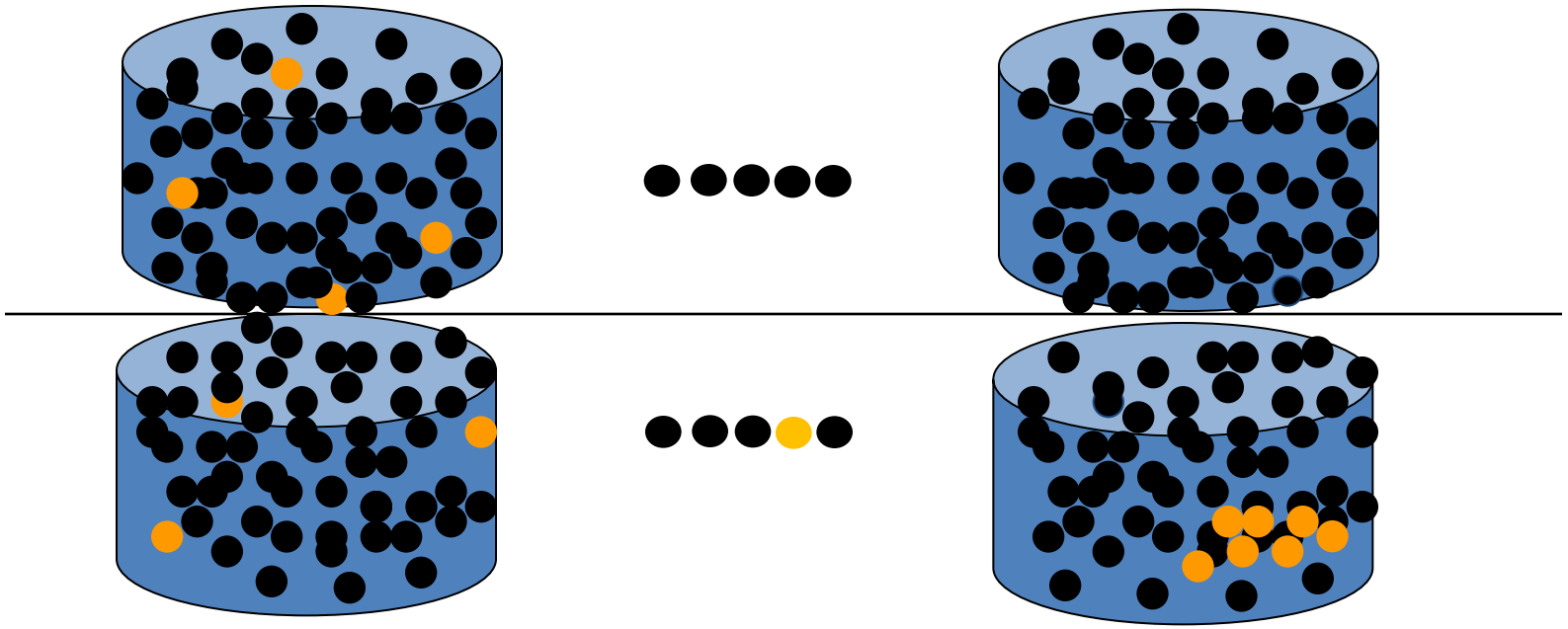
Based on a presentation from Prof. Zwietering, Wageningen University

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

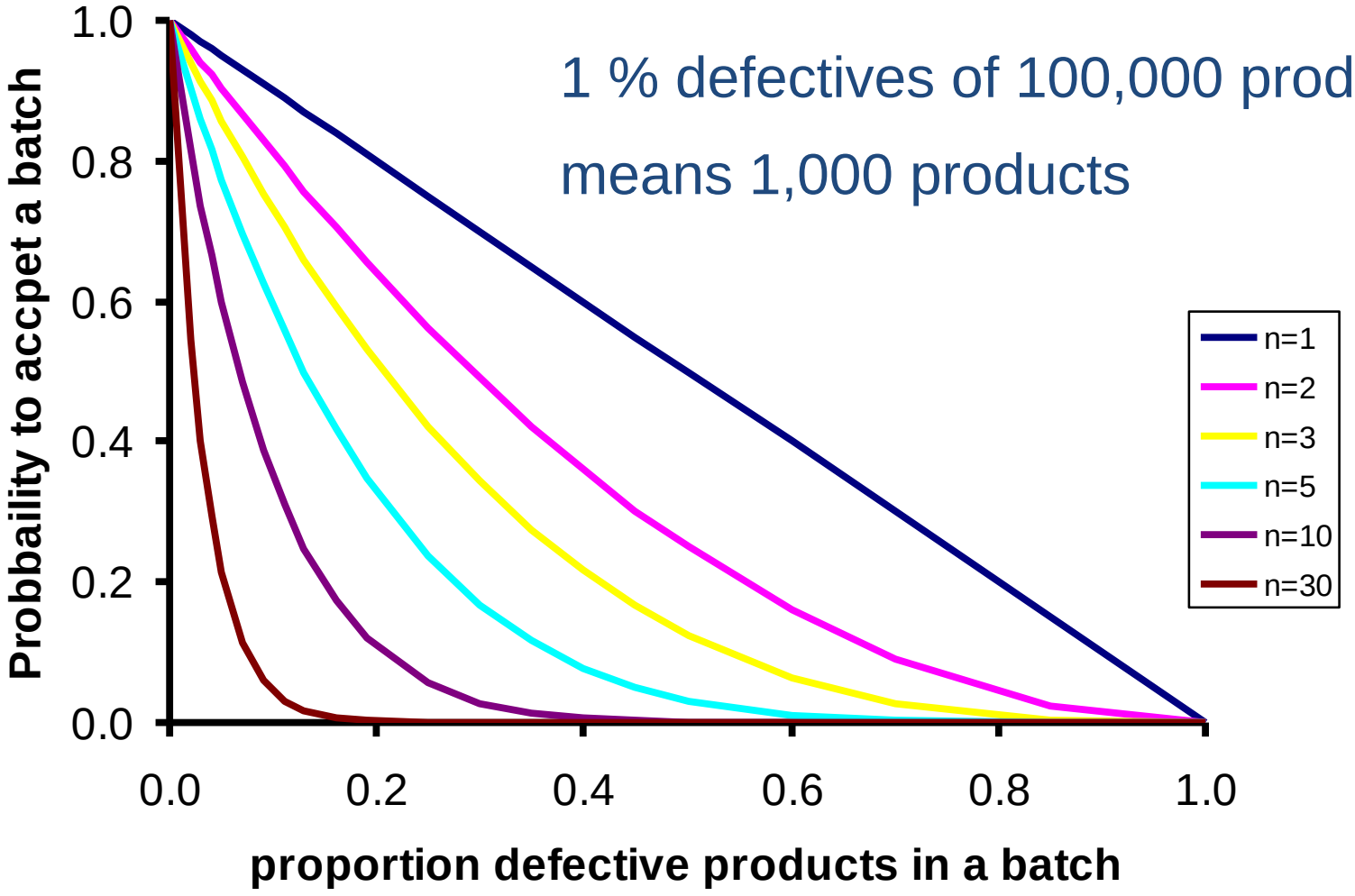
Can end product testing control food safety?

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

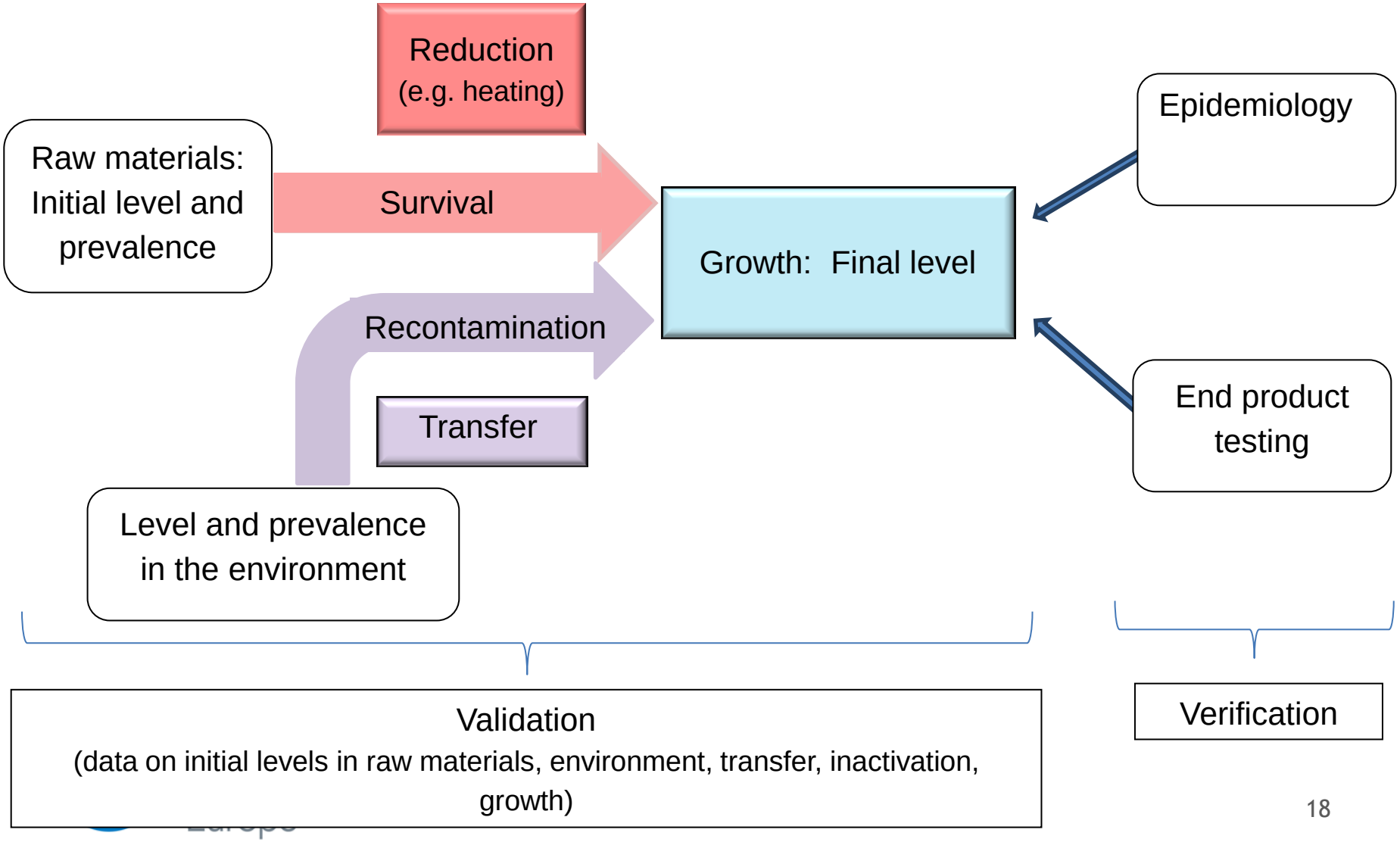
Sampling can be reduced to fortnightly if …

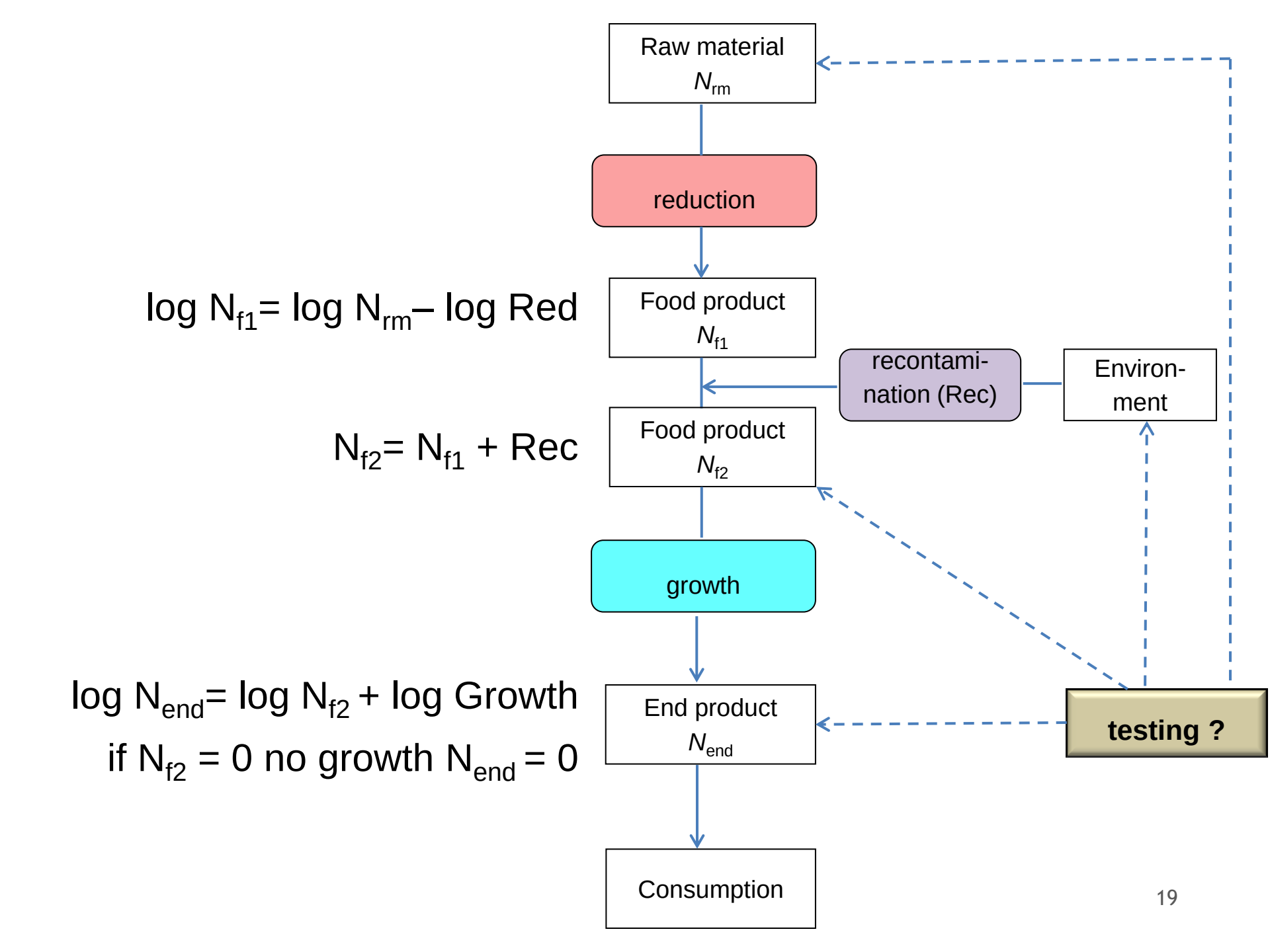
- satisfactory results have been obtained for 30 consecutive weeks
- or the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low

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^{o}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^{o}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




Raw material
N_{rm}
reduction
Food product
N_{f1}
recontami-
nation (Rec)
Environ-
ment
Food product
N_{f2}
growth
End product
N_{end}
testing ?
Consumption
$\log N_{f1} = \log N_{rm} - \log Red$
$N_{f2} = N_{f1} + Rec$
$\log N_{end} = \log N_{f2} + \log Growth$
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

Verification by MC

Monitoring CL

Validated CCPs

HACCP

PRP (GMP, GHP, ...)

Verification
by MC

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

INRA SCIENCE & IMPACT

ILSI Europe

Relevance of microbial finished product testing in food safety management

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

Food Control 60 (2016) 31–43

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Review

Relevance of microbial finished product testing in food safety management

Marcel H. Zwietering [a], Liesbeth Jacxsens [b], Jeanne-Marie Membré [c, d], Maarten Nauta [e], Mats Peterz [f, *]

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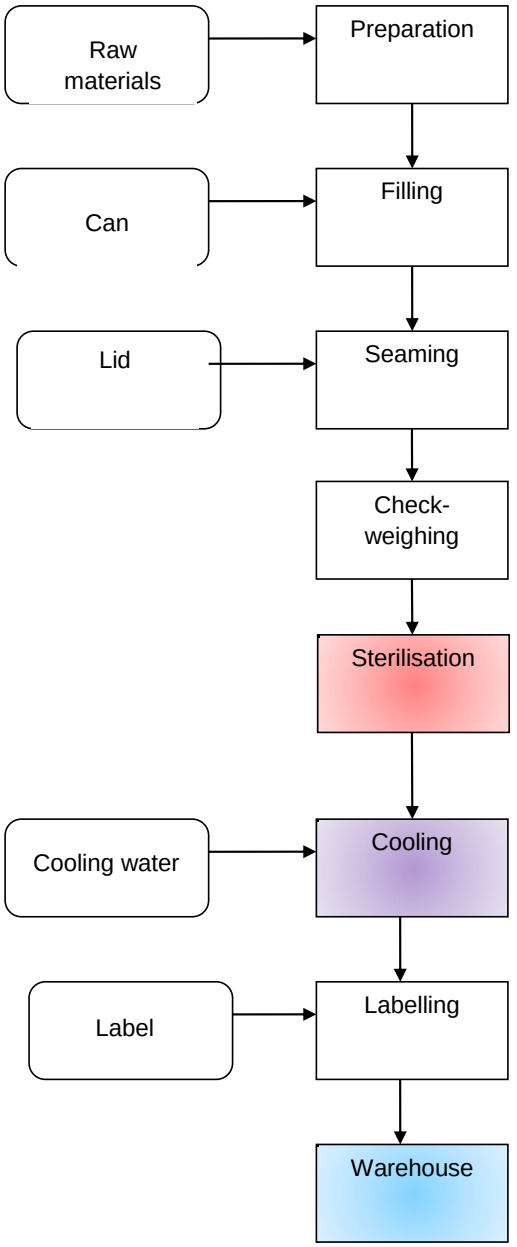
Canned foods

- A minimal $F_{121°C}$ 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.



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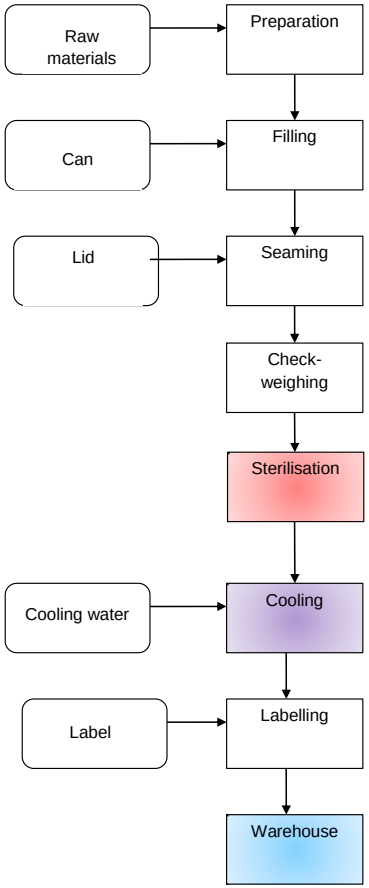
C. botulinum in a canned product



Process step	Possible microbial behaviour	Likelihood of microbial behaviour
Raw materials	Initial introduction	May happen
Sterilisation	Reduction by HT	Very effective
Post HT-process	Recontamination	Negligible
Storage	Growth	Irrelevant

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

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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)

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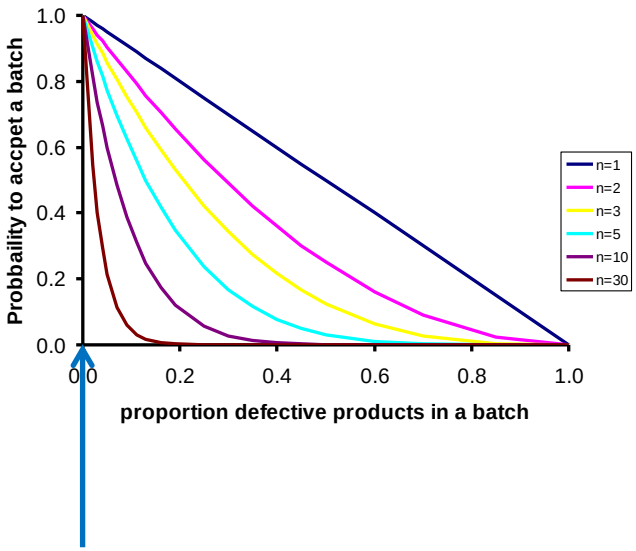
Canned foods - relevance of sampling

- Efficiency of end-product sampling?



1 per 10000

P_{target}				No detection 1 - P_{detect} n=1	***n* for 95% detection probability**
0.000001	1	per	1,000,000	0.999999	2,995,731
0.00001	1	per	100,000	0.99999	299,572
0.0001	**1**	**per**	**10,000**	**0.9999**	**29,956**
0.001	1	per	1,000	0.999	2,994

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

With a so small expected rate of defective end-products, sampling is ineffective

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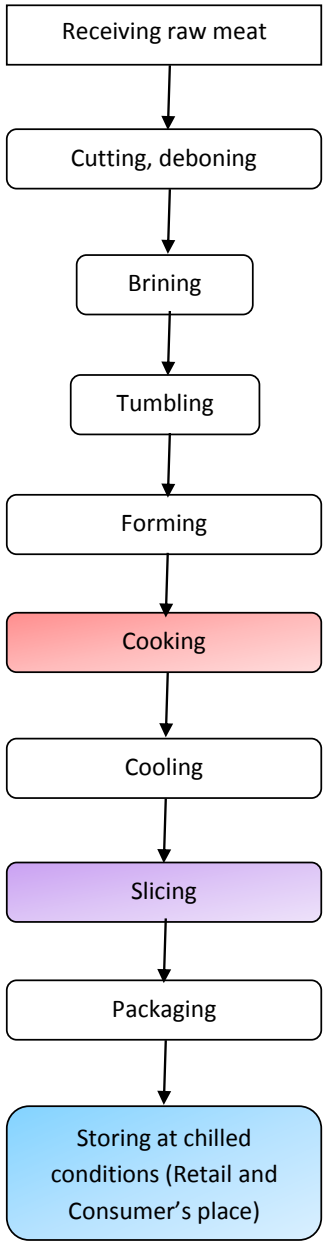
Sliced cooked Ham

- 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.



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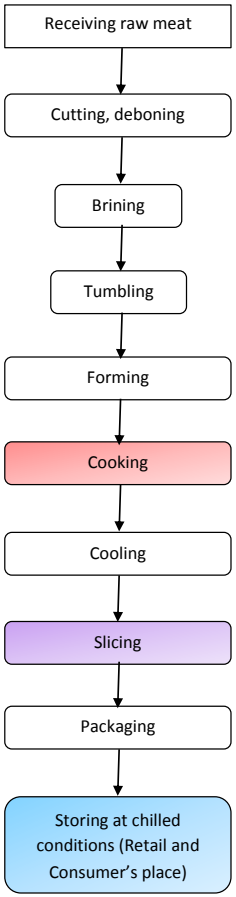
L. monocytogenes in cooked ham



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

% contaminated end-product might be non negligible

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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

.../...

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Cooked ham - Verification

- Literature studies

Products and origin	Sample size (g)	No. of positive samples/no. of samples	Prevalence (%)	Reference
Luncheon meats, USA	25	82/9199	0.89	Gombas et al., 2003
Ham, Brazil	25	1/65	1.5	Martins and Germano, 2011
Ham, United Kingdom	100	40/949	4.2	Little et al., 2009
Cooked ham, Belgium	25	54/879	6.1	Uyttendaele et al., 1999
Prevalence estimates			**Mean 3.2**	

Literature and Epidemiological data: prevalence : 3 to 5% (+ batch Variability)

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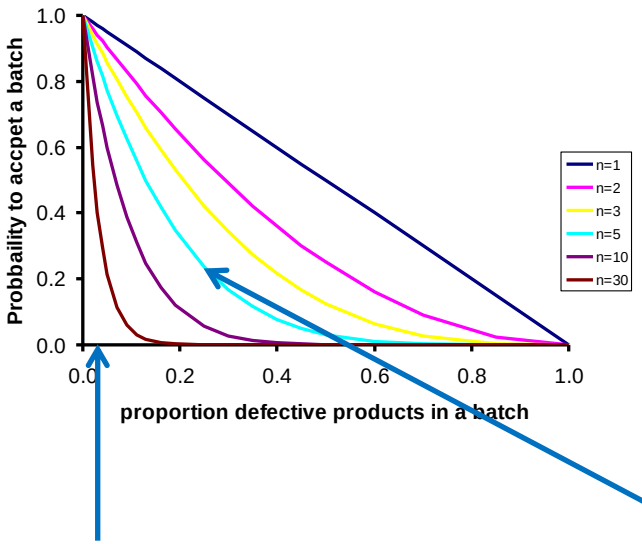
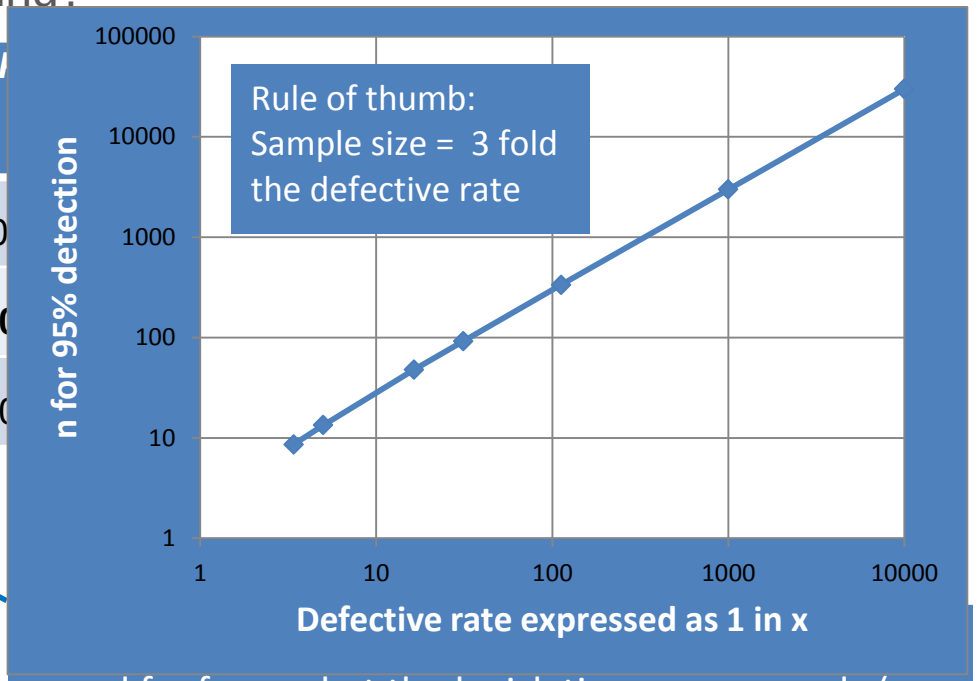
Cooked ham - relevance of sampling

- Efficiency of end-product sampling?



1 per 31



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

…/…

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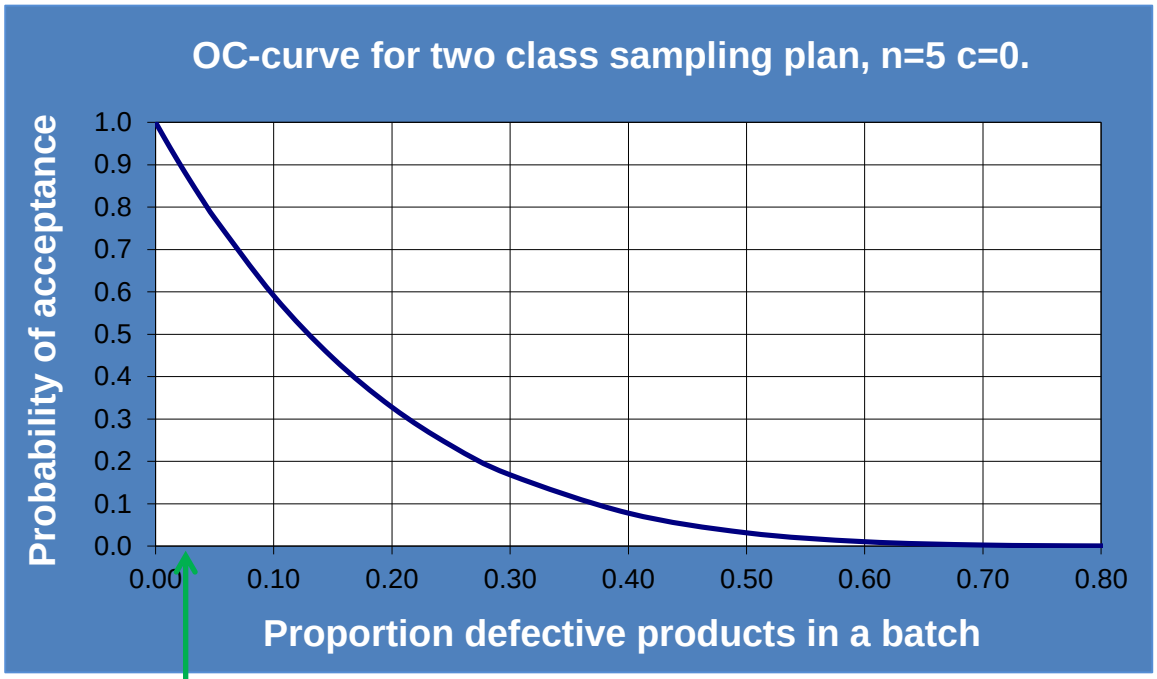
Cooked ham - relevance of sampling

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



85% to accept the batch with n=5

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.

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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).

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FSMA: Testing as a tool for verifying preventive controls

Prof. Donald Schaffner

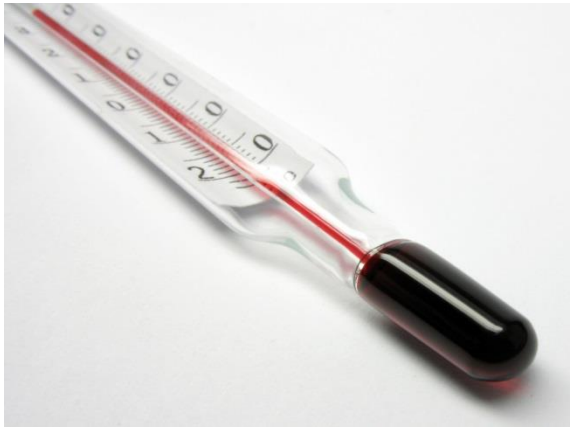
RUTGERS
UNIVERSITY

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

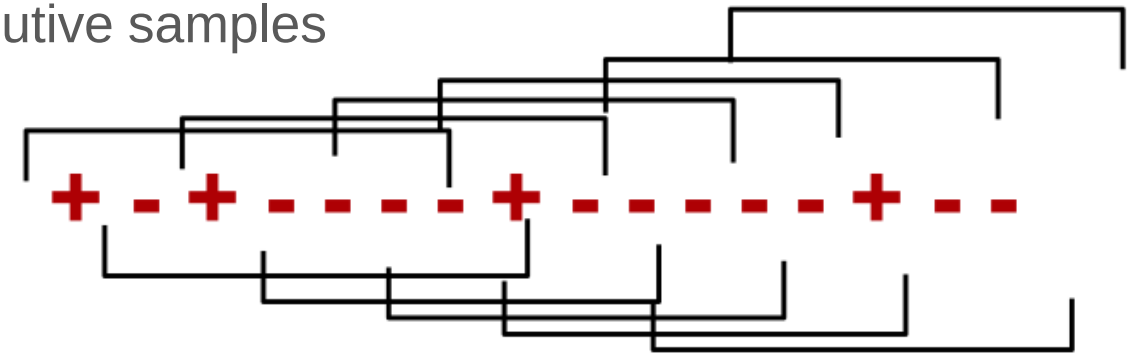
- Consider the production of a food that uses a 5-log thermal inactivation of *Salmonella*
  - Prior surveys that indicated that the level of *Salmonella* in the raw material is <1 CFU/100 g
- Monitoring
  - time and temperature achieved during the thermal process.
- Verification
  - periodically examine 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
  - Buchanan, R. L., and D. Schaffner. 2015. FSMA: Testing as a Tool for Verifying Preventive Controls. Food Prot. Trends. 35:228-237.

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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

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