

Validation and acceptance of thermal processes

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Risk Assessment Approaches to Setting Thermal Processes

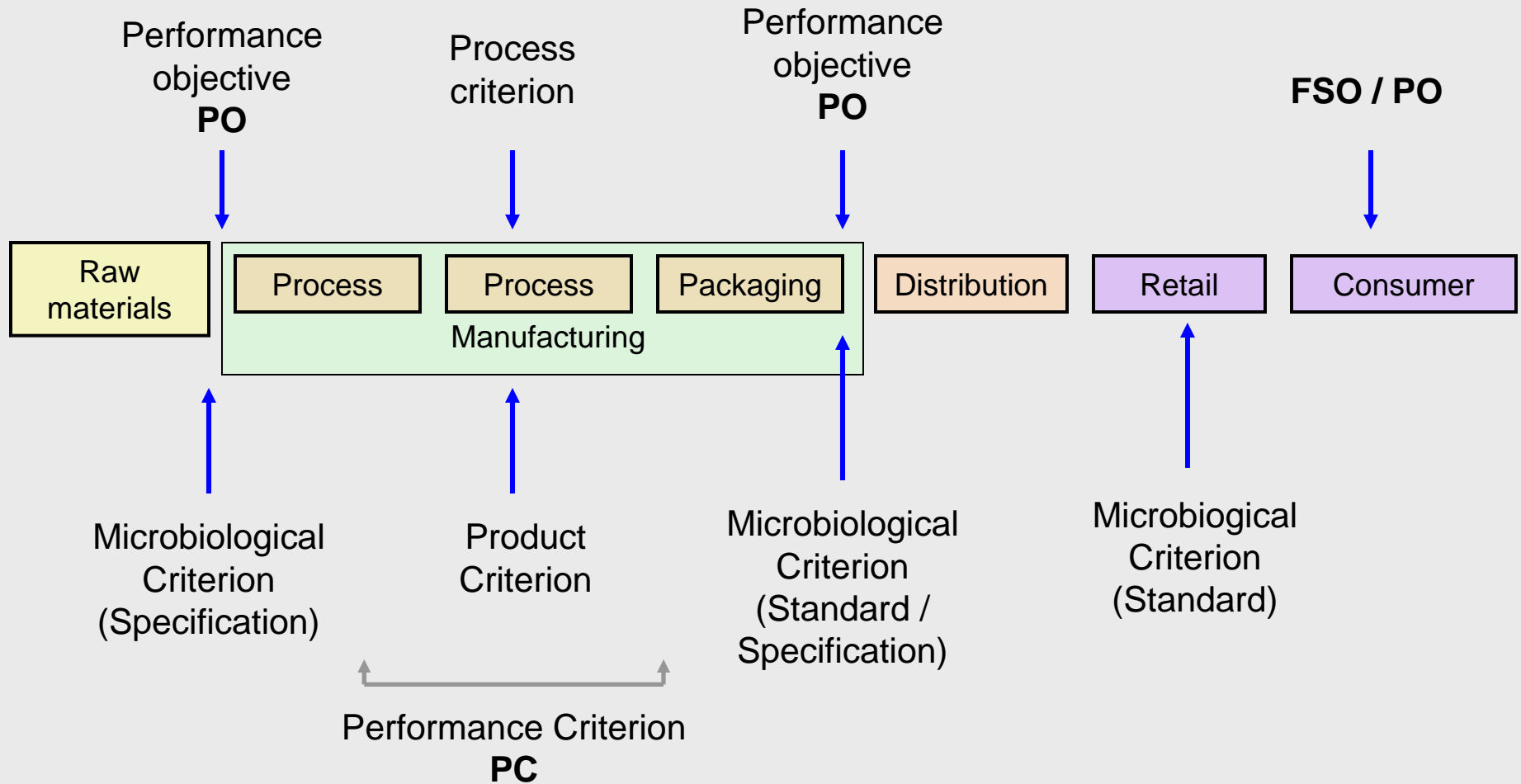
IAFP European Symposium, Berlin, 7 October 2009



Validation and verification

- 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 (CAC/RCP-1 1969)
 - **Can the control measure be effective at controlling the hazard?**
- 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** (CAC/RCP-1 1969)
 - **Is the control measure working on an ongoing basis?**

Risk based metrics



Thermal process objectives

- Regulatory standard exists outlining details of thermal process
 - Pasteurization of milk products (PMO)
 - Time and temperature for cooking of ground beef patties
 - USDA FSIS time-temperature combinations for reduction of *Salmonella* in certain meat and poultry products
- Regulatory Performance Objective exists
 - Less than 0.08 cfu/g *L. monocytogenes* at manufacturer
 - Less than or equal to 100 cfu/g *L. monocytogenes* at point of consumption
 - Absence of *E. sakazakii* in 30 x 10g infant formula at any point in the food chain
 - No more than 1 *C. botulinum* spore in 10¹² containers

Thermal process objectives

- **Regulatory Performance Criterion exists**
 - Process to achieve a 5-log reduction of enteric pathogens in juice
 - Process to achieve a > 5-log reduction of *Salmonella* in almonds
 - Process to achieve a 7 log reduction of *Salmonella* in poultry products
 - Have flexibility to design process to achieve criterion.
 - Technology
 - Conditions: Time and temperature, flow rate, product characteristics (pH, aw)
- **Industry Consensus exists**
 - ACMSF: *C. botulinum* equivalent to 90°C for 10 minutes to address non-proteolytic *C. botulinum* in chilled foods
 - 70°C for 2 minutes for “*Listeria* cook”
- **No established criteria**
 - Industry responsible for product safety
 - Reduction in *Salmonella* from roasting of cocoa beans

Guidelines / requirements for validation

- Specific regulatory guidance exists on submission for sterilization in drug applications:
 - [US Food and Drug Administration](#)
 - [Health Sciences Authority Singapore \(2008\)](#)
- European Hygienic Engineering and Design Group
 - [Continuous pasteurization](#)
 - [Cleaning in place](#)
 - [Aseptic processing](#)
- Institute for Thermal Processing Specialists
 - [Protocols for heat penetration studies](#)
 - [Protocols for heat distribution studies in retorts](#)

Guidelines / requirements for validation

- Almond Board of California
 - Guidelines for validation of dry roasting processes
- GMA
 - Validation of cooking instructions for NRTE products
- Experience of specialists
- ILSI Europe
 - Validation and verification
- Codex Alimentarius (CAC/GL 69)
 - Guidelines for the validation of food safety control measures

Tasks prior to validation (CAC/GL 69 – 2008)

- Identify hazards to be controlled
- Identify food safety outcomes required
 - Established by regulatory authorities
 - Established by industry consensus
 - Established by risk analysis of product, process and consumer use (HACCP)
 - P.O., P.C., PrC, PdC
- Identify control measures to be validated
 - Process Criterion for Thermal Process
 - Product and Process Criteria related to hazard control
 - Prior validation of control measures

Approaches to validation (CAC/GL 69 – 2008)

- Full chain approach
- Reference
 - Scientific / Technical literature
 - Previous validation studies
 - Historical knowledge of the performance of the control measure
- Scientifically valid experimental data that demonstrate the adequacy of the control measure
- Collection of data during operating conditions in the whole food operation
- Mathematical modelling
- Surveys

Validation example: long shelf life pasta

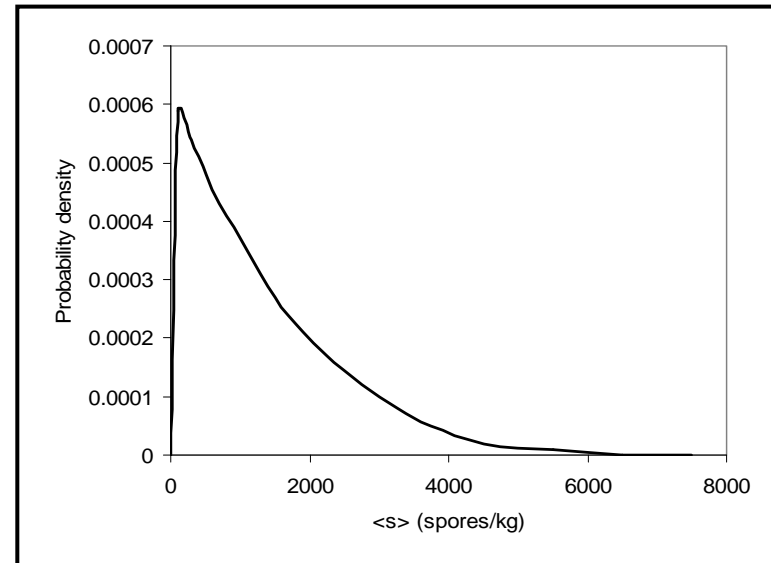
- Product:
 - Refrigerated distribution
 - Vacuum packaged
 - Ready to eat
 - In-pack pasteurized
 - Pasta and sauce with various components
 - Vegetables, mushrooms, seafood
 - Consumer shelf life 28 days
- Objectives:
 - *Listeria monocytogenes* (70°C 2 minutes)
 - Proteolytic *C. botulinum* (storage < 10°C)
 - Non-proteolytic *C. botulinum* (90°C 10 minutes)

Long shelf life pasta

- Information on the impact of non-thermal control measures.
- Information on supply chain
- Data on initial levels and distribution in raw materials
 - Surveys
 - Expert opinion
- Analysis of distribution in product



Raw material	Initial level from published data (cfu/g)	Quantity of ingredients finished products (g)
Pasta	0	175
Sauce	0	97
Vegetables	410	67
Seafood	8000	62



Long shelf life pasta

- Heat resistance of non-proteolytic *C. botulinum* under matrix conditions
- Determine D, z values, integrated lethality
- Heat distribution studies
- Validation of performance of equipment and process
- Documentation, expert review and acceptance



Validation in practice

- Validation in practice
 - Data intensive
 - Methodology requires expertise
 - Cost and time to conduct studies
 - Independent review
- Risk based approaches
 - Demonstrate conformance to regulatory P.O, P.C.
 - Demonstrate equivalence to industry standards
 - Validate control of foodborne pathogens in HACCP systems
- Complex exercises limited to areas where there is economic benefit or there is a newly identified hazard

Next steps

- Education and training of industry and regulatory authorities in the use of risk based approaches
- ILSI Europe Risk Analysis in Microbiology Task Force
 - Risk assessment approaches to setting thermal processes in food manufacture (2010)
 - Microbiological distributions in food (2010)

