Risk Analysis – Practical Examples of Where and When It Can be Applied: An Industry Perspective

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JIFSAN – FoodRisk.org

- Introduction to Unilever & Governance
- Governmental Risk Analysis driving modern food safety management
- Linking Industry's food safety management systems to Governmental Risk Analysis outcomes
- Examples of risk-based decision making in Unilever for safe food innovation

Unilever products

- Food products (50% of port-folio of consumer products)
- Home products (detergents, bleaches, etc.)
- Personal care products (deo’s, cosmetics, shampoo’s etc)

~ 170 000 employees

~ 60 billion$ annual turnover

~ 100 countries active operations

Unilever's Safety Governance

Set out in Code of Business Principles

- *Consumers*: products safe for their intended use
- *Employees*: safe & healthy working conditions
- *Environment*: promote environmental care
- *Innovation*: sound science/rigorous product safety standards

Consumer products: "Safe by design and execution"

Unilever

Six Major R&D Centres

Port Sunlight
UK

Vlaardingen
The Netherlands

Colworth
UK

Trumbull
USA

Shanghai
China

Bangalore
India

Unilever

Product Innovation Process

Breakthroughs from **Discover**

Brilliance In Product **Design**

Fast, Large Scale **Deploy**

Independent safety assessment by

Safety & Environmental Assurance Centre (SEAC)

- More than 6,000 R&D professionals
- 14 global R&D centres
- 37 regional R&D centres for adapting and implementing technical mixes in regions and countries

A Risk-based Approach to facilitate Safe Innovation

We use **scientific evidence-based risk assessment methodologies** to ensure that the risk of adverse health and/or environmental effects from exposure to chemicals used in our products is **acceptably low**.

Hazard-based

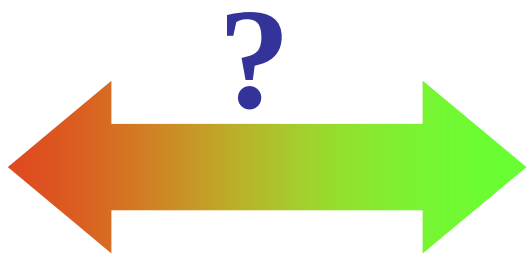
- check-list compliance
- unnecessary testing
- doesn't consider how product is used
- yes / no decisions
- overly conservative

Risk-based

- expertise- & evidence-driven
- essential testing only
- product use / exposure determines outcome
- options to manage risks
- uncertainties explicit

Roles & Responsibilities follow Risk Analysis principles

- R&R duly separated
  - Risk managers – Decision-makers in innovation process
  - Risk Assessors – Scientists responsible for product safety assessments
- Ensuring that innovation “design safety” decisions:
  - Follow a structured, systematic process
  - Are risk-based & sound science-founded
  - Transparent: accessible data & expertise



Safe by Design & Execution

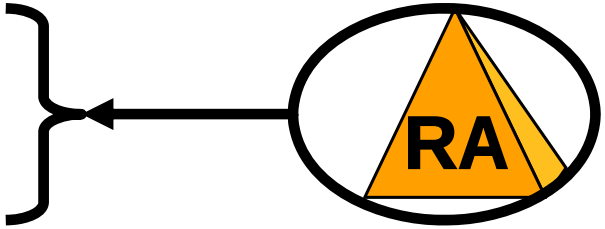
- Establishing safe product design requires understanding:
  - Product design and intended use, e.g.:
    - ingredients, processing, internal/external factors
    - processing, final formulation, handling
    - post-process contamination, intended use(r)
  - Considering the available “safety benchmarks”:
    - Guidance/guidelines from competent authorities
    - Regulations (e.g. standards, limits, criteria)
    - Industry, Internal Unilever guidance

Safe by Design & Execution

- Safe execution of the safe product design:
  - Validate design: from lab-scale to operational-scale
  - Implement design in operational management systems (using Good Practices, HACCP)
  - Verify control during manufacture
  - Run tracing & tracking system
  - Monitor & Review as appropriate

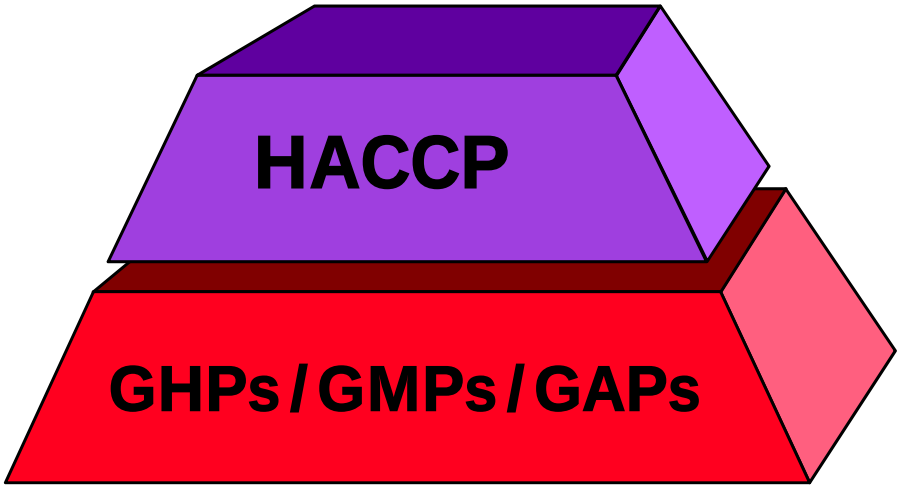
Risk Analysis: the common framework for governmental risk-based decision-making / for deriving safety benchmarks

- Risk Analysis:
  - Risk Management
  - Risk Assessment
  - Risk Communication



- Triggered by World Trade Organisation (WTO)

- Advocated by many governments and inter-governmental organisations (FAO, WHO)



Microbiological Risk Assessment: Government use?

- To systematically assess the level of risk associated to a pathogenic microorganism in a food / food category.
- To make an inventory of “typical” risk contributing and risk mitigating factors.
- To elaborate possible risk mitigation strategies (risk management options).

To provide a basis for decision-making by risk manager:

- Level of risk acceptable or not?
- Mitigation options effective and feasible?
- Implementation, monitoring and review details, standards?

Microbiological Risk Assessment Outcomes

- **Population level consumer risk:**
  - Estimated *number of cases* of illness per year per (part of) population caused by a micro-organism present in a particular food or food group

- **Individual level consumer risk**
  - Chance of illness due to consumption of a specific food-product to which a particular hazard can be associated (per serving / event)

Microbiological Risk Assessment Outcomes

- Detailed appreciation of product, process and consumer-use scenarios
- Risk estimates for different scenarios, variability, uncertainty
- Insight in critical processes, handling, use
- Knowledge about impact of intervention scenarios
- Categorisations of foods by consumer risk
- Risk based food safety standards (risk based metrics)

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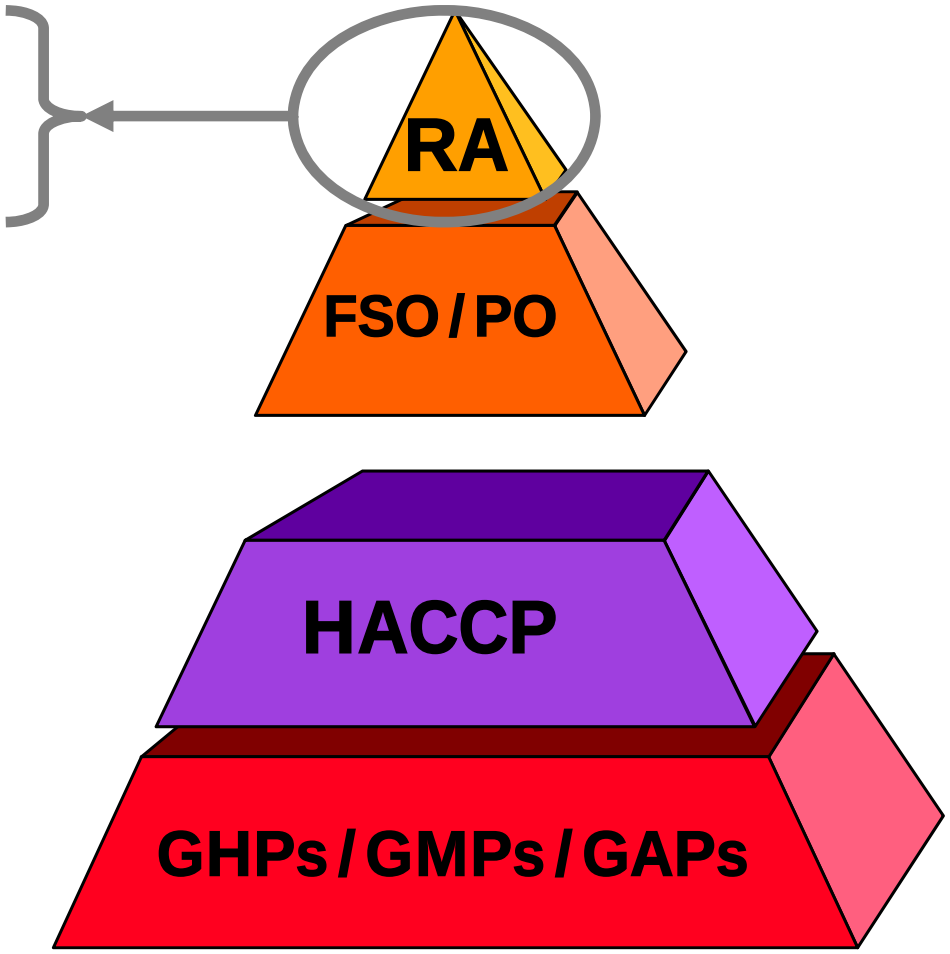


Risk Management decision-making

Risk Level (RL)

RISK ANALYSIS

Risk Assessment

Risk Management

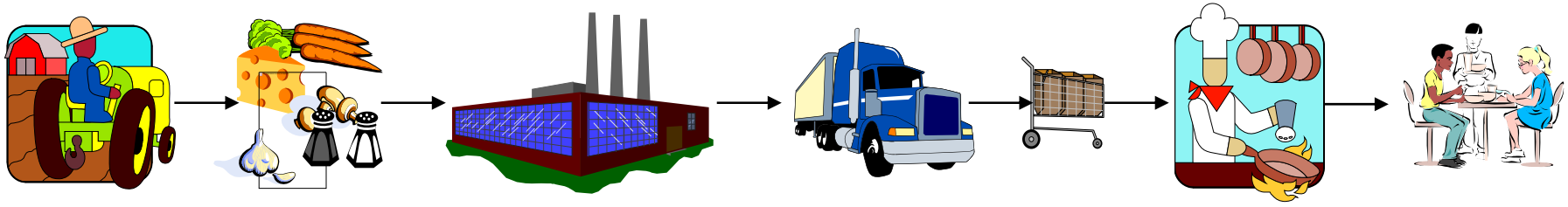
Risk Communication

Decision(s) by risk managers

Policy Level of risk (PL): ALOP[1] or public health goal

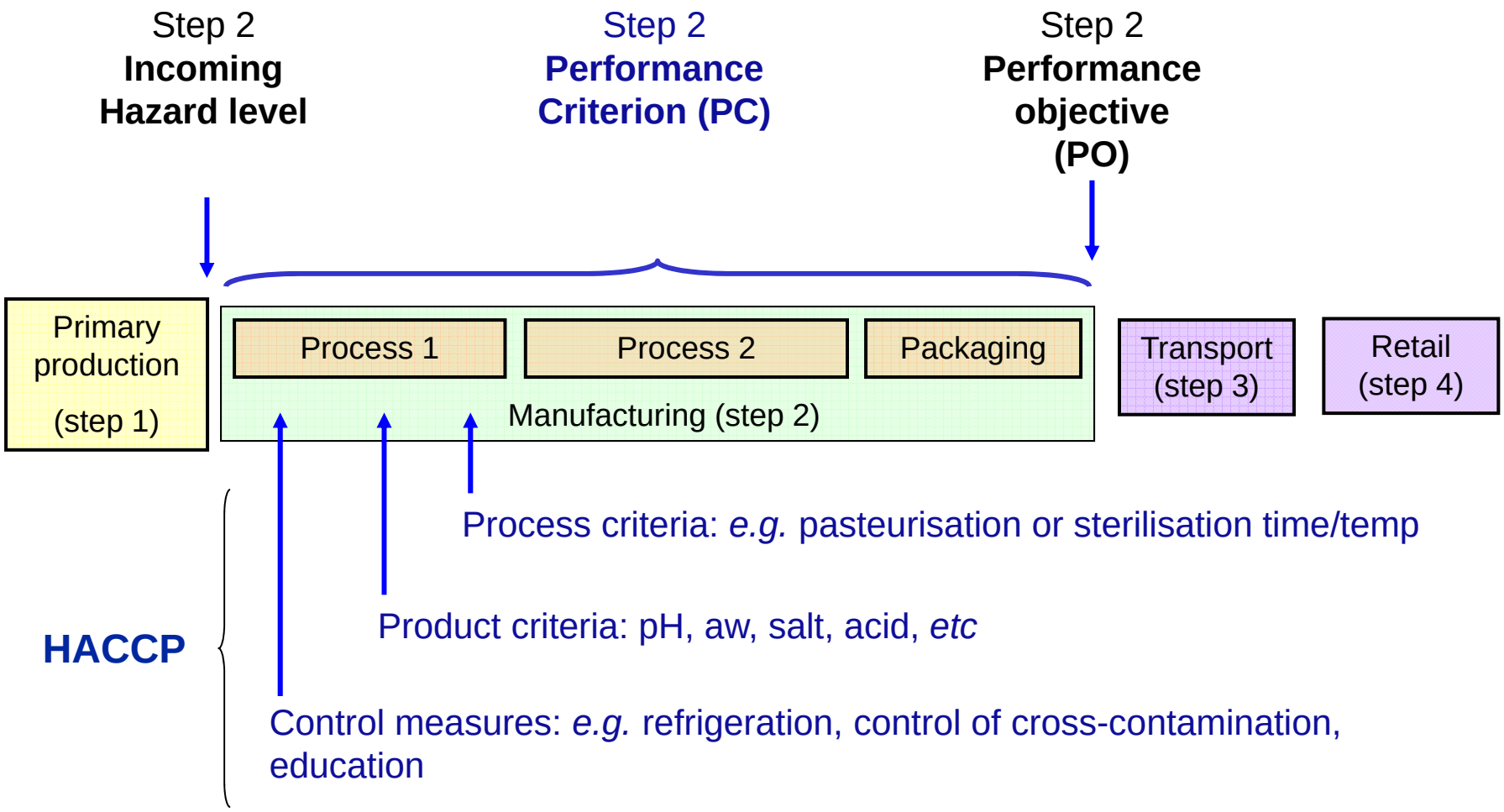
PO

FSO



[1]: ALOP, Appropriate Level Of Protection

How to operationalise risk-based metrics?



Are Risk Analysis & (Inter)Governmental Risk Assessment relevant for food industry?

- Yes, food industry can use results of such studies to:
  - appreciate different intervention strategies and risk management decisions on RM options
  - get insight in risk food categories, risk contributing and risk mitigating factors, scenarios
  - obtain new/key inputs for “safe design and execution”
  - Industry can apply the same principles and methods to designing safe food products

Are Risk Analysis & (Inter)Governmental Risk Assessment relevant for food industry?

- But, industry does not have to perform MRAs:
  - Proper implementation of good practices (pre-requisites) + HACCP principles should operationalise "safe designs", considering all significant hazards

- And, industry will need to invest
  - significant resources/expertise are required to draw benefits from (inter)gov. MRAs & RA methodology

Principles of Risk Analysis

- Common framework for decision making
  - Systematic (structured, phased)
  - Transparent (specifies knowledge, data; assumptions; uncertainties)
  - Objective (sound science and peer review)
  - Open (improved internal / external stakeholder involvement)
  - RM/RA responsibilities duly separated

Principles help decision-making in complex situations, key to future review

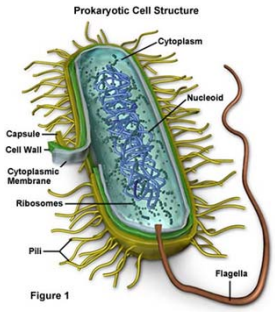
Methodologies used in RA/MRA can be used for risk-based decision-making on safety product designs

- Compiling comprehensive data package for innovations involving fresh fruits
- Simulating ‘safe’ changes to heat-processing for quality improvements
- Simulating ‘safe’ shelf-life to enter new markets
- Simulating consumer safety of complex or radical product innovations
- Determining performance standards that would meet particular PO / FSO

Case study 1

Simulating ‘safe’ changes to

heat-processing for quality improvements



Optimizing thermal process based on product & process specifics and new benchmarks

- Challenging UK default process target (70°C/2min for 6 log reduction of *Listeria* in raw chicken meat):
- Rationale:
  - The target organism for a product may not be *Listeria*
  - The level of contamination of the raw material may be lower
  - Variability in strain heat resistance; not always worst case
  - Process control may be better than "*industry standard*"
  - New risk-based product safety benchmarks, using risk-management-metrics (hypothetical)

E.g. Cooked chicken – *Listeria monocytogenes*

<0C = no growth

Chicken intake

Frozen storage

Final product Acceptable level

$1x10^{4.2}$ cfu/g

$1x10^{4.2}$ cfu/g

100cfu/g

2.2 log reduction

E.g. Cooked chicken – *Salmonella* spp.

<7C = no growth

Chicken intake

After storage frozen or chill

Final product Acceptable level

1500cfu/g → 1500cfu/g → 0.04cfu/g

4.6 log reduction

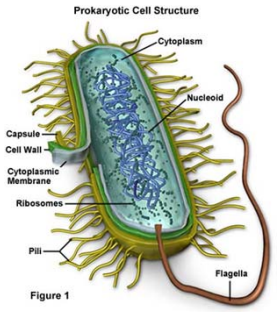
Absent in 25g

Specification

Unilever

Case study 2

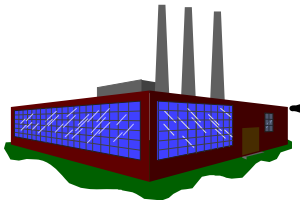
Simulating ‘safe’ shelf-life for new markets



Assessing suitability of different markets

- Key product characteristics
  - Heat treatment > 90ºC-10min, in-pack
  - pH= 6.0
  - A_w=0.997
  - Stored at chilled temperatures
- Relevant hazard?
  - *Bacillus cereus*
  - Benchmark: 10^5 cfu/g
- Design question?
  - The likely failure rate to meet benchmark on different markets (differing in temperature in value-chain & consumer home)?

Exposure assessment: key components



Bacterial concentration in raw materials

Heat treatment

Bacterial heat resistance

Prevalence and Bacterial concentration in processed food

Time in pre-retail (transport + warehouse)

Time in retail (local market, supermarket)

Lag time and growth rate of surviving spores, at chilled temperatures

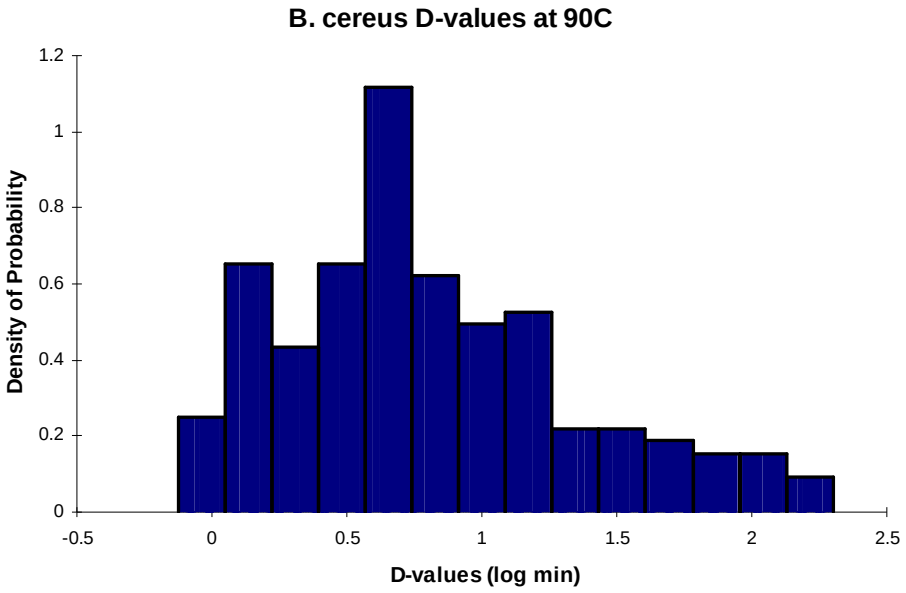
Temperature of pre-retail fridges

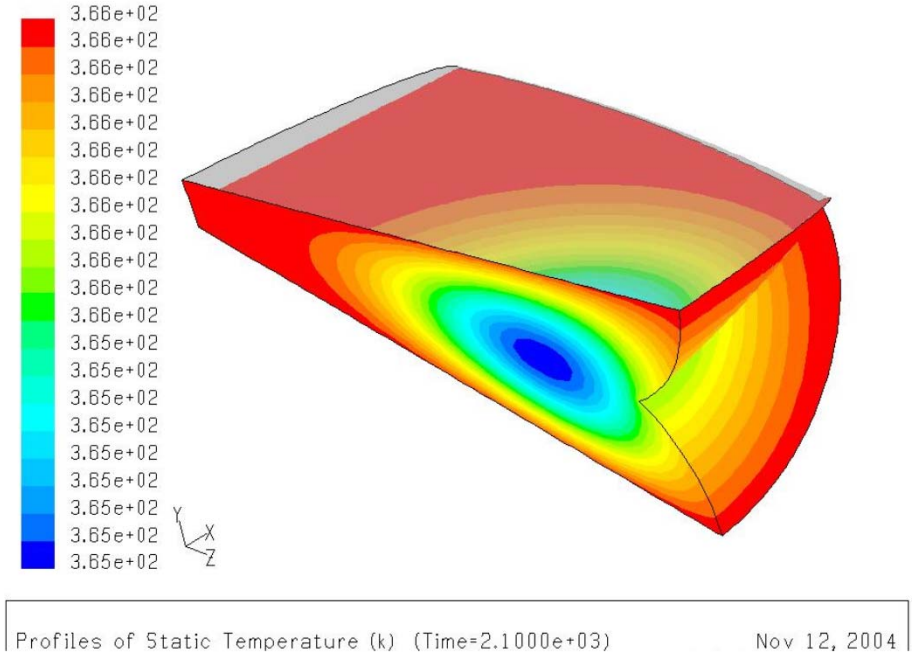
Temperature of retail fridges

Time in consumer fridge

Temperature of consumer fridges

Heat Treatment aspects/inactivation

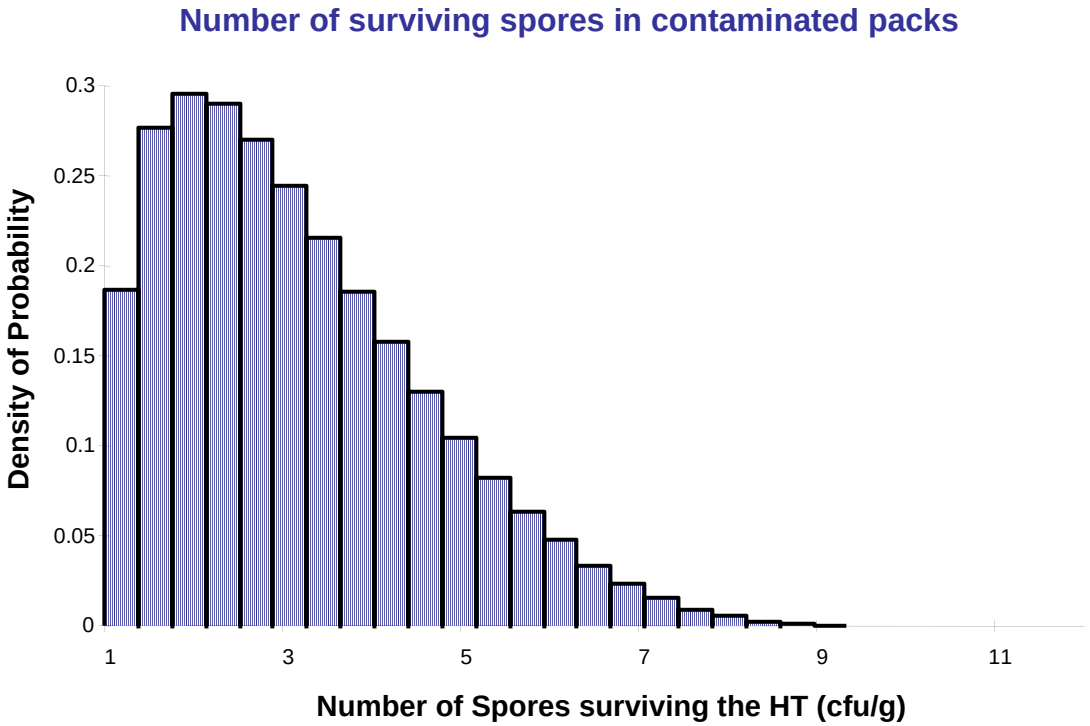




Variability in spore heat resistance

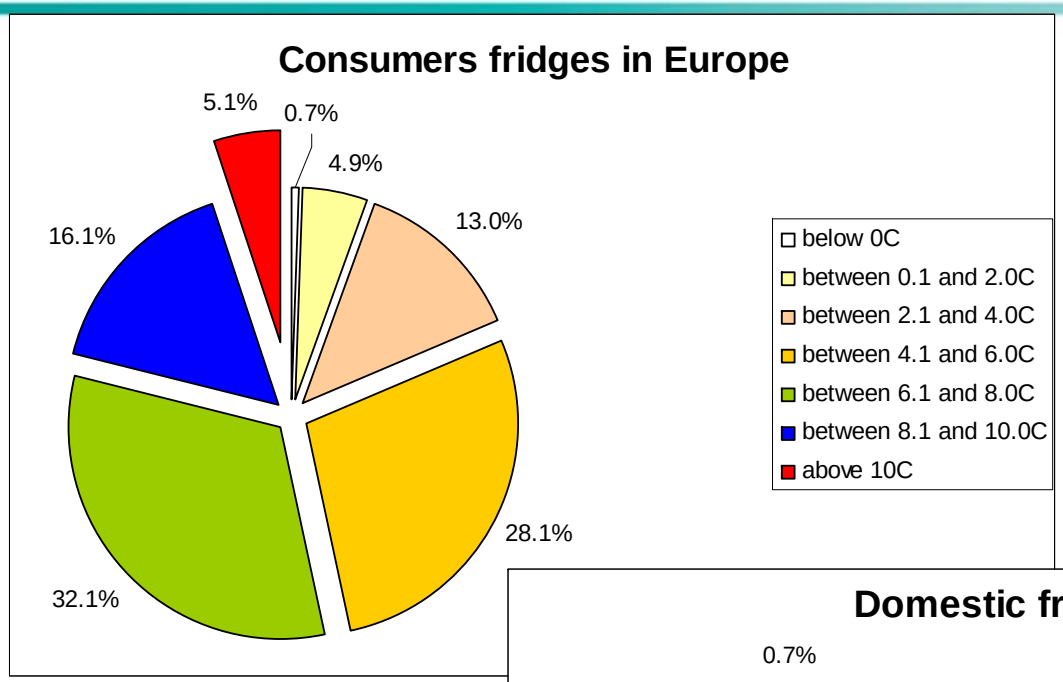
Variability in heat impact

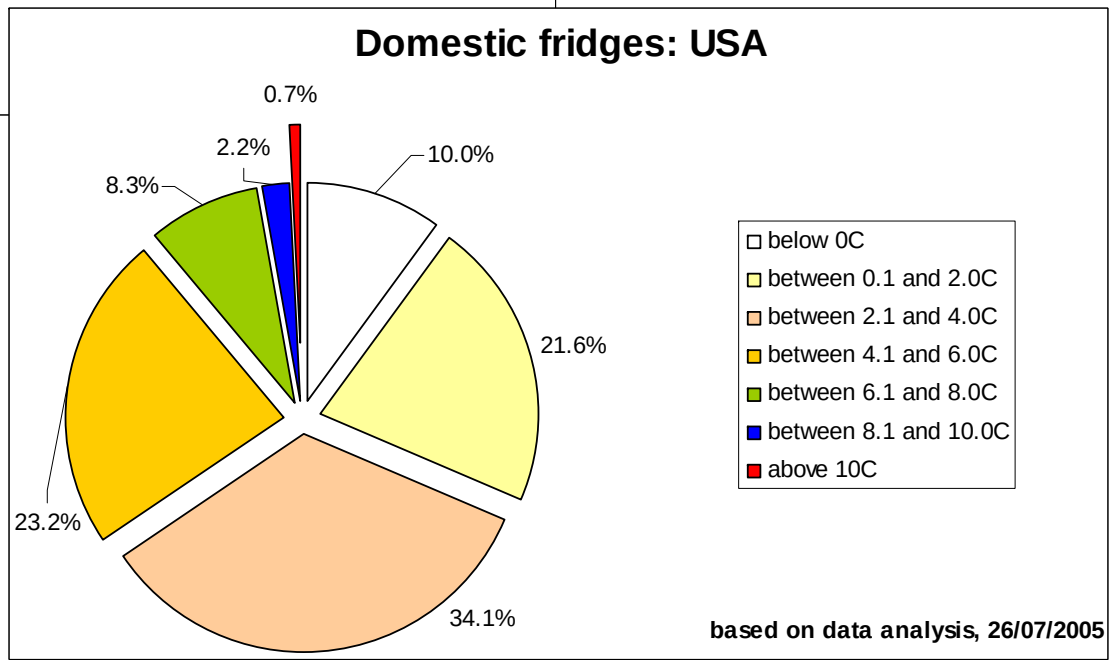
Heat Treatment aspects/survivors



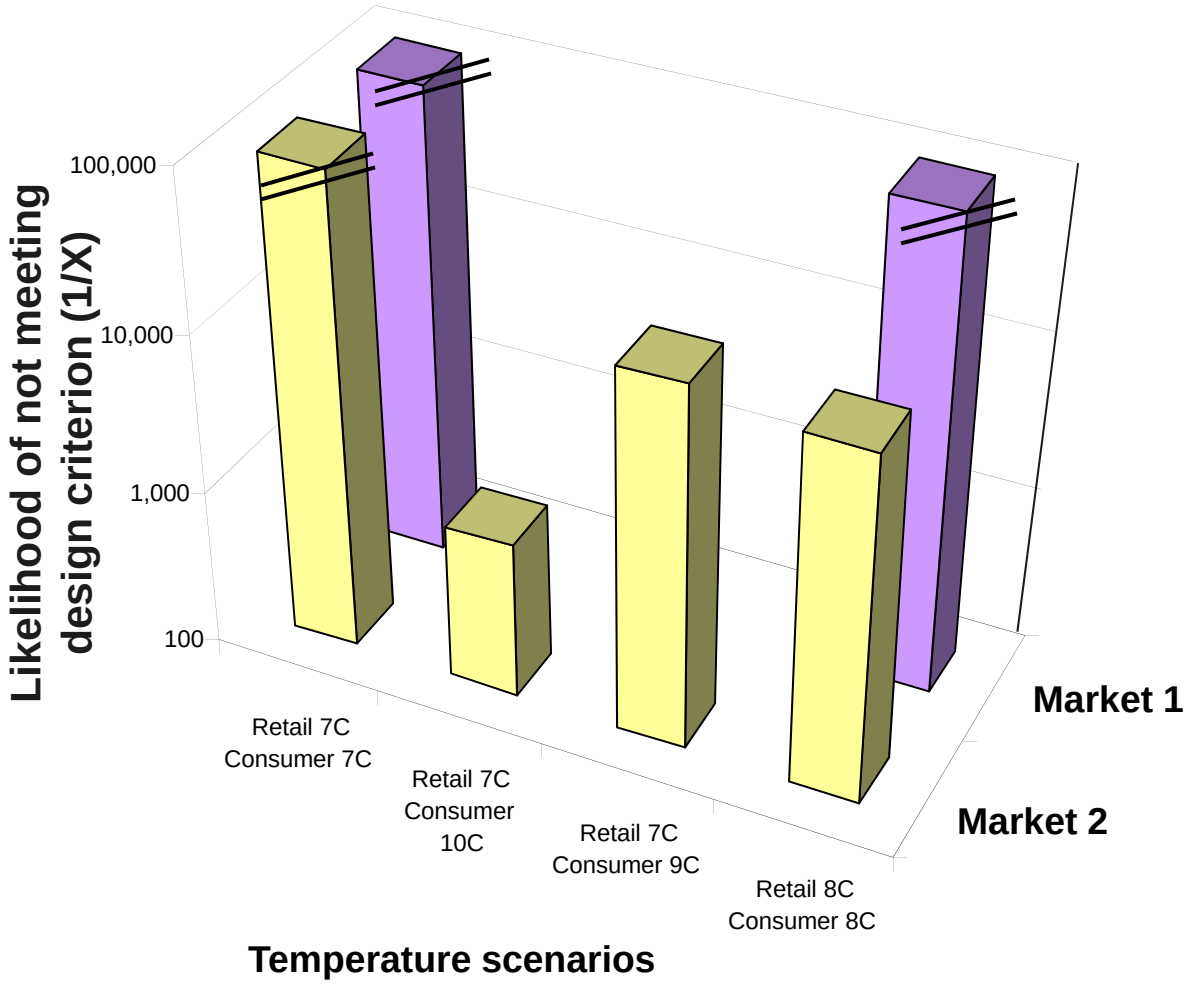
J.-M. Membré, A. Amézquita, J. Bassett, P. Giavedoni, C. de W. Blackburn, L.G.M. Gorris. 2006. A probabilistic modeling approach in thermal inactivation: estimation of postprocess Bacillus cereus spore prevalence and concentration. Journal of Food Protection, 69: 118-129.

Temperatures in cold-chain





Predicted failure rates on different markets for different temperature scenarios



Risk-based decision-making in safe product innovation: using risk assessment principles and methodologies

A new tool in the safe food “design toolbox”

- Focuses on exposure phase to develop view on safety
- Used additionally to: safe history of use, product experience, scientific expertise, predictive modelling, validation, etc.
- Combines predictive microbial modelling with process modelling and scenario analysis
- May simulate market reality (variability & uncertainty) better
- Can form a basis for informed, risk-based decision-making by industry on safe food product designs

Unilever

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Thank you for your attention

谢谢你