Risk-based approach for food safety assurance – an industry perspective

Dr Alejandro Amézquita
Safety & Environmental Assurance Centre
Unilever R&D Colworth
United Kingdom

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Unilever’s Safety Governance

- **Set out in Code of Business Principles**
  - Employees: safe & healthy working conditions
  - Consumers: products safe for their intended use
  - Environment: promote environmental care
  - Innovation: sound science .. rigorous standards of product safety

- **Unilever Policies**
  - Consumer Safety
  - Health & Safety at Work
  - Environment

- **Responsibility for Safety Assessments**
  - Delegated to Safety & Environmental Assurance Centre (SEAC)

SEAC’s role in Unilever

Provide independent scientific evidence and guidance so that Unilever can identify and manage:

- **Risks for consumers, workers and environment**
  - Safety of products and supply chain technology

- **Environmental impacts**
  - Sustainability of Unilever’s brands, products & Supply Chain
Safe & Sustainable Products & Processes by Design

- Safe by Design and in Execution
- Integrated assessments covering Consumer, Occupational & Environmental (COE) Safety
- Transparent & Accessible – data, expertise
- Safety Decisions are Risk-based

Unacceptable Risk  ➤  Acceptable Risk

Integrated approach to assessing and managing risks

characterise Hazards & Exposure, assess & manage COE Safety Risks

Raw materials / ingredients  ➔  COE hazards / key safety risks  ➔  C & E exposure scenarios  ➔  formal post-launch monitoring (if warranted) on-going monitoring & review of new data

Product formulations  ➔  Q & E exposure scenarios

Manufacture process  ➔  Consumer use  ➔  Disposal

Transport

safety prognosis / identify key risks & data safe by design considerations  ➔  risk assessment for clinical / consumer studies  ➔  COE risk assessment for market ➔ decision: safe or not
Key steps in food safety assurance

• Establishing a safe design
  – Identification of realistic hazards
  – Agreement on product safety benchmarks
  – Establishing effective preventative and control measures

• Establishing safety in execution
  – Implementation of agreed controls
  – Monitoring and review of safe market performance

Designing safe foods - microbiology

• Expertise, scientific and technical knowledge
• Historical evidence (products with history of safe performance)
• Benchmarks for product safety
  – Regulatory requirements (Microbiological Criteria, Performance standards)
  – Industry standards (Performance standards)
• Product design performance simulation
  – Predictive mathematical modelling
  – Risk Assessment approaches
• Validation of design
  – Challenge tests for safety (pathogens)
  – Shelf-life tests for stability (spoilage)
Governmental microbiological risk assessments (MRA)

• For public health protection, tend to be focused on one hazard in a range of food types
• Identifies aspects that have greatest impact on risk, providing focus for preventative or mitigation measures
• Identifies foods that pose greater risk, to help focus resources, e.g. for monitoring
• Identifies vulnerable groups and consumer behaviour
• May establish risk-based food safety standards, which are necessary benchmarks for ‘safety-by-design’

Application of MRA in the food industry

• Food industry can use the results of MRA to
  – learn about differences in levels of hazard control between (typical) operations
  – appreciate different intervention strategies or management options
  – insight in critical processes, handling, use
  – see examples of how to meet government requirements / performance standards
Risk-based food safety management

- **Performance objective (PO)**
  - Raw materials
  - Process
  - Packaging
  - Distribution
  - Retail
  - Consumer

- **Process criterion**
  - Manufacturing

- **Microbiological criterion (Specification)**

- **Microbiological criterion (Standard)**

- **Performance criterion (PC)**

- **FSO / PO**

**MRA use in Unilever**

- **In the context product innovation and microbiological food safety risks (pre-market)**
  - Mainly used in Exposure Assessment, examples:
    - Simulating consumer safety of complex product innovations
    - Simulating ‘safe’ changes to heat-processing for quality improvements
    - Simulating ‘safe’ shelf-life to enter new markets
    - Determining performance standards that would meet particular Performance Objective / Food Safety Objective

- **In the context of microbiological incidents in the market place (post-launch)**
Microbiology example

- Using a (probabilistic) MRA approach to establish suitability of new markets
  - Key product characteristics
    - Heat treatment > 90°C x 10min, in-pack
    - pH = 6.0
    - $\sigma_W = 0.997$
    - 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 - components

- Bacterial concentration in raw materials
  - Heat treatment
  - Bacterial heat resistance
- Time in pre-retail (transport + warehouse)
- Time in retail (local market, supermarket)
- Time in consumer fridge
- Lag time and growth rate of surviving spores, at chilled temperatures
- Temperature of pre-retail fridges
- Temperature of retail fridges
- Temperature of consumer fridges

$\Pr\{\log N > \text{benchmark value}\}$
Manufacturing aspects

- Variability in spore levels in ingredients
- Variability in spore heat resistance
- Variability in heat impact

Number of surviving spores in contaminated packs


Supply chain aspects

Consumers fridges in market 1

- Domestic fridges: market 2

based on data analysis, 26/07/2005
Risk assessment supports different market strategies

Main outcomes and recommendations

- Model resulted very informative for internal decision making and external communication:
  - learned about major risk factors
  - learned where key data-gaps were
  - defined window for testing / experimentation
- Probabilistic risk assessment facilitated realistic scenario analyses for establishing target product shelf-lives in different markets, moving away from worst-case scenarios without compromising consumer safety
  - shelf-life recommendations (for each target market) were given to the business, considering the probability of < 1/10,000 packs exceeding $10^5$ cfu/g of *B. cereus* as an acceptable criterion
A risk-based approach facilitates safe innovation

We use **scientific evidence-based risk assessment methodologies** to ensure that the risk of adverse health and/or environmental effects is **acceptably low**.

<table>
<thead>
<tr>
<th>Hazard-based</th>
<th>Risk-based</th>
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<tbody>
<tr>
<td>• check-list compliance</td>
<td>• expertise- &amp; evidence-driven</td>
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<tr>
<td>• unnecessary testing</td>
<td>• essential testing only</td>
</tr>
<tr>
<td>• doesn’t consider how product is used</td>
<td>• product use / exposure determines outcome</td>
</tr>
<tr>
<td>• yes / no decisions</td>
<td>• options to manage risks</td>
</tr>
<tr>
<td>• overly conservative</td>
<td>• uncertainties explicit</td>
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Thank you

alejandro.amezquita@unilever.com