New Surrogates in Low-moisture Food/Petfood Process Validation, Are We Ready to Use Them?

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Foodborne Outbreaks

From 2007 to 2015:
(WHO, Foodborne disease burden epidemiology reference group, 2015)

- 600 million cases of foodborne illnesses
- Resulting in 420,000 deaths

Annually costing $15.6 billion in US:
(Buzby J.C. et al., USDA, 1996)

- Salmonella ($3.6 billion)
- Campylobacter ($1.9 billion)

Herbs, Spices and Nuts ≈ 20% PetFood Increasing market

Main problems LMF

- Few bacteria could cause illness
- *Salmonella* persisting up to 5 years (Uesugi *et al.*, 2007)
- Able to grow in optimal conditions
- Low amount of bacteria in the product → problem of detection

Low moisture food category:
- Spices and dried herbs
- Dried fruits and vegetables
- Cereals and grain
- Dried protein products
- Confections and snacks
- Nuts and nuts products

The joint FAO/WHO expert meeting on microbiological hazard in spices and dried aromatic herbs, 2014, Preliminary Report
FAO/WHO expert consultation on ranking of low moisture foods in support of microbiological risk management, 2014, Part I Main report
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Sources of pathogen contamination

Cross contamination

- Harvesting
- Transportation to manufacturing site
- Storage and product processing
- Packing and distribution

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**Food Safety Plan**

- **HACCP:** Hazard Analysis Critical Control Point
- **Microbiological Sampling Plan**

  Hazard identification → Critical limits → Monitoring and verification procedure

  Routine sampling plans are not likely to be sufficient for validation studies.
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Need of Preventing Controls
The most sweeping reform of US food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.

Final Rule: Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals. November 2015
Final Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. September 2015

REACTION → PREVENTION

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Hazard Analysis and Risk-Based Preventive Controls (HARPC). Sec 103

- Hazard Analysis
- Preventive Controls
- Corrective Actions
- Verification
- Recordkeeping
- Written Plan and Documentation

Process Validation

Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.” – 21 CFR 117.3
Process Validation

Validation establishes the scientific basis for process preventive controls in the Food Safety Plan
May include:
• Using scientific principles and data
• Use of expert opinion
• Conducting in-plant observations or tests
• Challenging the process at the limits of its operating controls

SURROGATES
SURROGATES

Non-pathogenic organism which mimics process resistance of target organism and is suitable for use in validation work.

- Non-pathogenic
- Similar or greater resistance compared to the pathogen
- Scientifically reliable correlation need to be established
- Easy to detect and enumerate
- Will not establish itself as a “spoilage” organism in the processing facility
**Enterococcus faecium as Salmonella surrogate**

- *E. faecium* NRRL B-2354 strain well characterized
- High thermal resistance
- Widely used by Food companies and inter-professional associations

**Pediococcus acidilactici ATCC 8042**

Evaluating *Pediococcus acidilactici* and *Enterococcus faecium* NRRL B-2354 as Thermal Surrogate Microorganisms for *Salmonella* for In-Plant Validation Studies of Low-Moisture Pet Food Products.
Ceylan et Bautista, 2015

**Pantoea agglomerans SPS2F1**

Guidelines for Validation of Dry Roasting Processes.
ABC, 2007
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Universal Surrogates

DIFFICULT ¿ ? ¡ ! impossible

Pathogen

Food Matrix

Surrogate

Intervention Strategy
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Research and Development Surrogate Program

- **Surrogate strain Identification**
  - BSL1 Status ➔ Lack of standard criteria
  - BSL1 Certification ➔ Recognition by authorities

- **Qualification Surrogate Vs Pathogen**
  - Intervention: temperature, pressure, etc.
  - Pathogen way of contamination
  - Physiological state ➔ Surrogate behaviour

Studies could be done by laboratories, Universities and R&D Departments of Food Companies

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**Surrogate Nowadays Limits**

- Inoculation technique

- Surrogate concentration threshold
- Food Matrix diversity & inoculation protocol
- Variation on food matrix physico-chemical characteristics
- Surrogate state standardization
- Surrogate shelf-life and transport
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Food Companies

To validate a variety of processes for numerous products

USE OF SURROGATES

- BSL1 status and certification by an official agency
- Introduction of bacteria in high concentration in a food facility
- Specific surrogate detection and enumeration
- Cleaning procedures

Process Validation means less routine controls and batch release

Ready for the shift of the paradigm

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Evaluating *Pediococcus acidilactici* and *Enterococcus faecium* NRRL B-2354 as Thermal Surrogate Microorganisms for *Salmonella* for In-Plant Validation Studies of Low-Moisture Pet Food Products. Ceylan and Bautista 2015 JFP

**Objectives:** Evaluation of potential surrogate against 7 Salmonella serovars in dry petfood at several temperature (60 to 87.8°C) and % moisture (9.1 to 27%)

Surrogate behaviour depending on process and food matrix parameters
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Comparison of validation study using liquid and dry surrogates:

- Steam pasteurization equipment, capacity of 1000kg/h of chilli powder
- *E. faecium* NRRL B-2354 used as a surrogate of *Salmonella*

**Liquid Surrogate**

- Bacterial suspension sprayed on the chili powder, and equilibrated
- Pouches with Inoculated product $10^7$cfu/g
- Pouches are inserted in the equipment during a production, among chilli powder
- Recovered and enumerated
- Treatment time is 6min
- Equipment capacity is limited to 500kg/h
- 110°C temperature to reach the 5 log reduction
- Due to the limited heat penetration within the pouch, treatment parameters are stabilised are over estimated

**Dry Surrogate**

- Surrogates produced industrially following a food grade fermentation process
- They reach high concentration of $10^{10}$ cfu/g
- Ready to use surrogate is mixed with 1000kg of chili powder
- Inoculated powder is processed and sampled for enumeration
- Treatment time is 3 min
- Equipment capacity reached 1000kg/h
- 105°C temperature to reach the 5 log reduction
- No heat penetration limitation allows a more accurate validation
- Better product and less energy consumption
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Take home message

Good Surrogates must be:

- Well Characterised and Controlled
- Food Grade Quality Manufactured
- Ready to Use and Flexible
Thanks for your attention

To be continued…

The surrogate company