CONTROL OF BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS IN PRODUCTION OF DEHYDRATED PET TREATS

Peter Taormina, Ph.D.
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John Morrell Food Group

Premium Pet Health

RMC 2014

AMERICAN FARMS™

ANIMAL PLANET

Benefits of Pet Treat Consumption

- Resourceful and sustainable use of unwanted or inedible portions of food-producing animals
- Can benefit dental health of pets
- Fosters healthy human-to-pet relationships

FDA Consumer Alert - Jerky Pet Treats, October 2013

- Jerky pet treat-related illnesses involving 3,600 dogs and 10 cats in the U.S. since 2007. Approximately 580 of those pets have died.
- Within hours of eating treats sold as jerky tenders or strips made of chicken, duck, sweet potatoes and/or dried fruit, some pets have exhibited decreased appetite, decreased activity, vomiting, diarrhea (sometimes with blood or mucus), increased water consumption, and/or increased urination.
- Severe cases have involved kidney failure, gastrointestinal bleeding, and a rare kidney disorder. About 60 percent of cases involved gastrointestinal illness, and about 30 percent involved kidney and urinary systems.
- The remaining cases reported various symptoms, such as collapse, convulsions or skin issues.
- Most of the jerky treats implicated have been made in China. Manufacturers of pet foods are not required by U.S. law to state the country of origin for each ingredient in their products.

Some Major Mycotoxin Outbreaks in Pet Animals

Year	Location	Scale	Diet	Reference
1951	Southeastern United States	71 food poisoning cases of dogs (several deaths)	A brand of commercial dog food suspected to be made with contaminated corn	Bailey *et al.*, 1959
1987	Pretoria, South Africa	10 dogs dead with 1 acute, 7 sub-acute and 2 chronic cases	A brand of contaminated commercial dog food	Bastianello *et al.*, 1987
1998	United States	55 dogs dead with both acute and chronic cases	17 different formulations of commercial dog food made with two rail cars of non-uniformly contaminated corn in a milling plant in Texas in late-summer	Garland and Reagor, 2001
2005	United States	At least 100 dogs dead	19 different formulations of commercial dog food made with contaminated corn in a milling plant in South Carolina in summer	Stenske *et al.*, 2006
2006	Korea	3 dogs dead with renal failure	Fungal nephrotoxins in the diet, possibly ochratoxin and citrinin	Jeong *et al.*, 2006

From: Boermans, H.J. and M.C.K. Leung. 2007. *Intl. J. Food Microbiol*. 119:95-102

Salmonella - Summary of Human Illnesses and Outbreaks

Serovar	Year/Location	Product	Illnesses
Infantis	2012 / 13 U.S. states	Dry dog food	22
Schwarzengrund	2006-07 / 19 U.S. states	Dry dog food	70
Thompson	2004-05 / U.S. and Canada	Pet treats beef/ seafood	9
Newport	2002 / Calgary, Alberta, Canada	Dried beef pet treats	5
Infantis	1999 / Canada	Pig ear pet treats	12

Incidence of *Salmonella* on Pet Treats

Product and Incidence Rate	*Salmonella* Serotypes	Comments	Reference
48 (51%) of 94 pig ears in Canada	Various, including Infantis, Typhimurium DT 104, & Derby	Infantis isolates assoc. w/ human infection	Clark *et al.*, 2001
65 (41%) of 158 dog treats in U.S.	Typhimurium & Newport among several	Antibiotic resistant and MDR	White *et al.*, 2003
pet treats containing dried beef Texas, U.S.	MDR-*Salmonella* Newport	Cephalosporin resistance; transfer of MDR Newport to humans	Pitout *et al.*, 2003
5.3% of treats New Zealand; from Australia, China, Thailand	London, Aberdeen, Typhimurium DT104, Bradndenburg among most prevalent	Ampicillin & Gentamicin, Nalidixic acid & Streptomycin	Wong *et al.*, 2007
4% of 245 pig ear treats in Canada	Bovismorbificans, Give, Derby, and Typhimurium var. Copenhagen most prevalent	31% of isolates MDR	Finley *et al.*, 2008
24.5% of 102 pig ears Ireland, 28.4% positive by PCR	Typhimurium DT 104 & DT 120, Rissen, Livingstone, Give, and Derby were common serotypes	50% of isolates antibiotic resistant	Adley *et al.*, 2011

Overview

- Identify Types of Dehydrated Pet Treats
- Control of Hazards
  - Chemical
  - Physical
  - Radiological
  - Biological
- Dehydration Technology
  - Water activity (a_w)
- Final Product Considerations

Types of Dehydrated Pet Treats

- Biscuits
- Rawhide
- Ground, structured and formed
  - Jerky, semi-soft treats & biscuits
- Whole muscle Jerky
- Bones
- Pig Ears

Biscuits

- Multiple meat and non-meat ingredients
  - Multiple species
- Extrusion followed by Baking
- Dehydrated at ca. 175°F several hours
- Typical a_w 0.400
- Packed in boxes, bags, or bulk

Rawhide

Chemically treated hide, tendons, etc.

Pressed and flattened

or ground scraps are extruded at 200-248°F

Strips may be flavor coated

Dried at ca. 150°F several hours

Typical a_w 0.450

Packed in boxes, bags, or bulk

Structured and Formed Jerky

- Multiple meat and non-meat ingredients
  - Multiple species
  - Usually with humectants & preservatives
- Extruded paste
- Dehydrated at ca. 175°F several hours
- Typical a_w 0.665
- Packed in gas-flushed bags

Whole Muscle Jerky

- Few or no added ingredients
  - Sometimes with humectants & preservatives
  - Sometimes marinated
- Dehydrated at ca. 175°F several hours
- Typical a_w 0.450
- Packed in gas-flushed bags

Bones

- Few or no added ingredients
  - Sometimes with smoke application
- Dehydrated at ca. 175°F 16 to 36 hours
- Typical a_w 0.400 to 0.600
- Packed in bulk boxes, overwrapped film, or sealed bags

Pig Ears

Edible or inedible raw pig ears

- Usually received frozen

Dehydrated at ca. 175-200°F several hours

Typical a_w 0.300

Overwrapped film, sealed bags, or bulk boxes

Types of Dehydrated Pet Treats

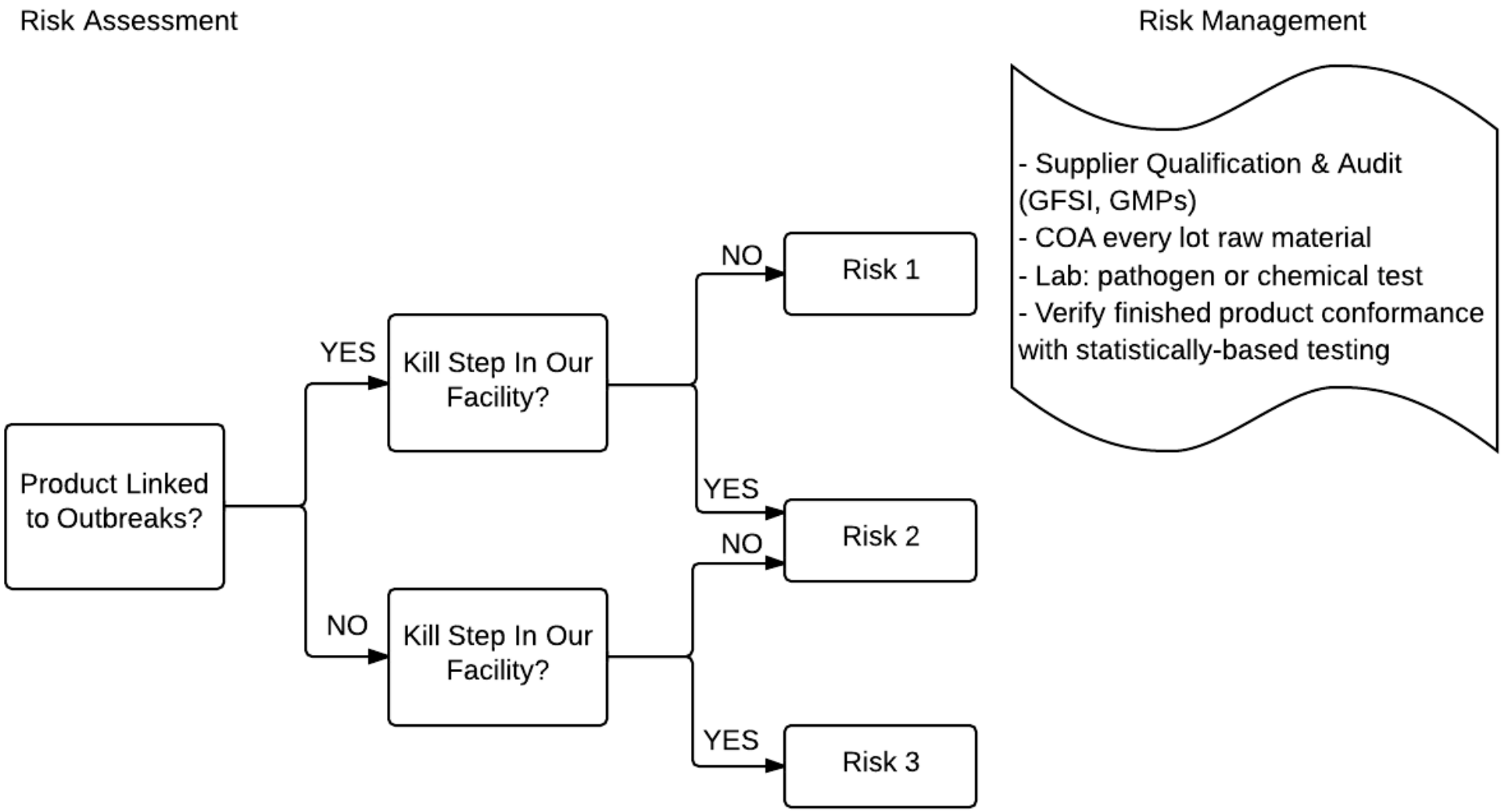
- Biscuits
- Rawhide
- Ground, structured and formed
  - Jerky, semi-soft treats & biscuits
- Whole muscle Jerky
- Bones
- Pig Ears

HAZARDS

Chemical, Radiological, Physical, Biological

FSMA Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Food for Animals

- cGMPs
- Food Safety Plan
- Hazard Analysis Risk-Based Preventive Controls (HARPC) Plan
  - Biological
  - Chemical
  - Physical
  - Radiological



Chemical Hazards

- Biogenic Amines (e.g., histamine)
- Melamine?
- Mycotoxin (from grains)
- Heavy Metals
- Antibiotic Residues
- Pesticides
- Allergens

Chemical Hazards

- Raw material
  - Supplier qualification and auditing
  - COA
  - Spot check raw material with analytical tests
  - Eliminate or reduce use of low-quality suppliers
- Address chemical hazards in HARPC Plan
  - If reasonably likely to occur, reduce hazards to acceptable level
- Verify effectiveness of control programs by analytical hold-and-test of representative finished product samples

Radiological Hazards

- Proposed § 507.33(b)(4) would require that the hazard analysis consider radiological hazards.
- Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium, strontium-90 and iodine-131.
- Section 418(b)(1)(A) of the FD&C Act requires that radiological hazards be considered, and animal food may be subject to contamination with radiological hazards, e.g., if water used to manufacture the animal food contains a radionuclide.

Radiological Hazards

- Consider raw material sources
  - Geographic proximity to nuclear power plants.
  - Potential for exposure to fallout
    - e.g., Seafood by-products sourced from Northern Pacific and Fukushima fallout region
- See if/how supplier has assessed this as potential hazard
  - If you don't know, do some testing

Physical Hazards

- Foreign material
  - Buckshot, needles
  - Wood, metal, plastic
- Bone splintering

Physical Hazards
Foreign Material

- Ground and formed jerky
- Raw material
  - Supplier qualification and auditing
  - COA
  - Spot check raw material with analytical tests
  - Eliminate or reduce use of low-quality suppliers

Physical Hazards
Bone Splintering

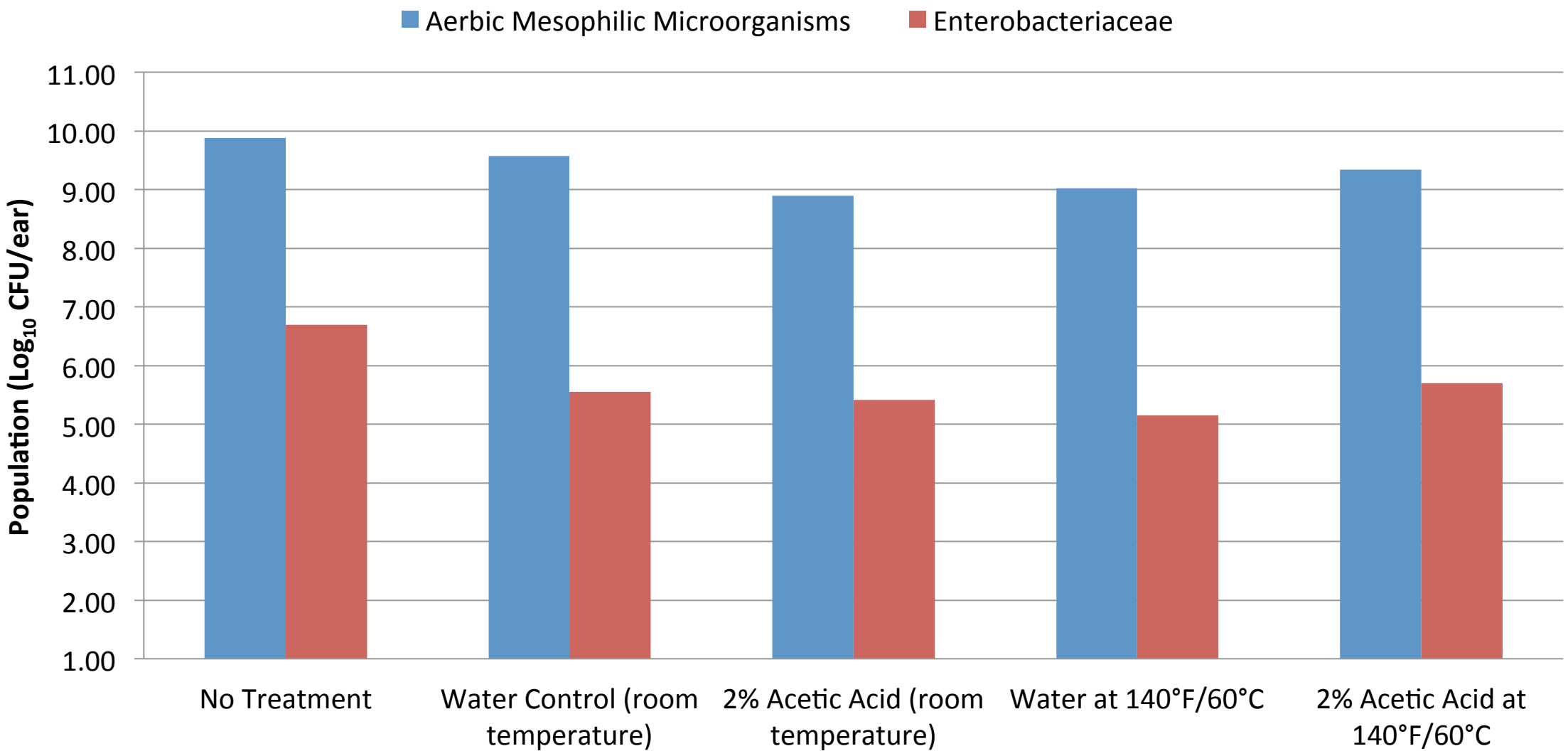
- Perform bone crush testing to measure and compare degree of splintering.
  - Adjust process if appropriate
- Affix warning statement to labels of retail packages
  - “Supervise your dog when it eats a treat”
  - “Talk to your vet about the right bone size for your dog”
- Monitor consumer complaints

Biological Hazards

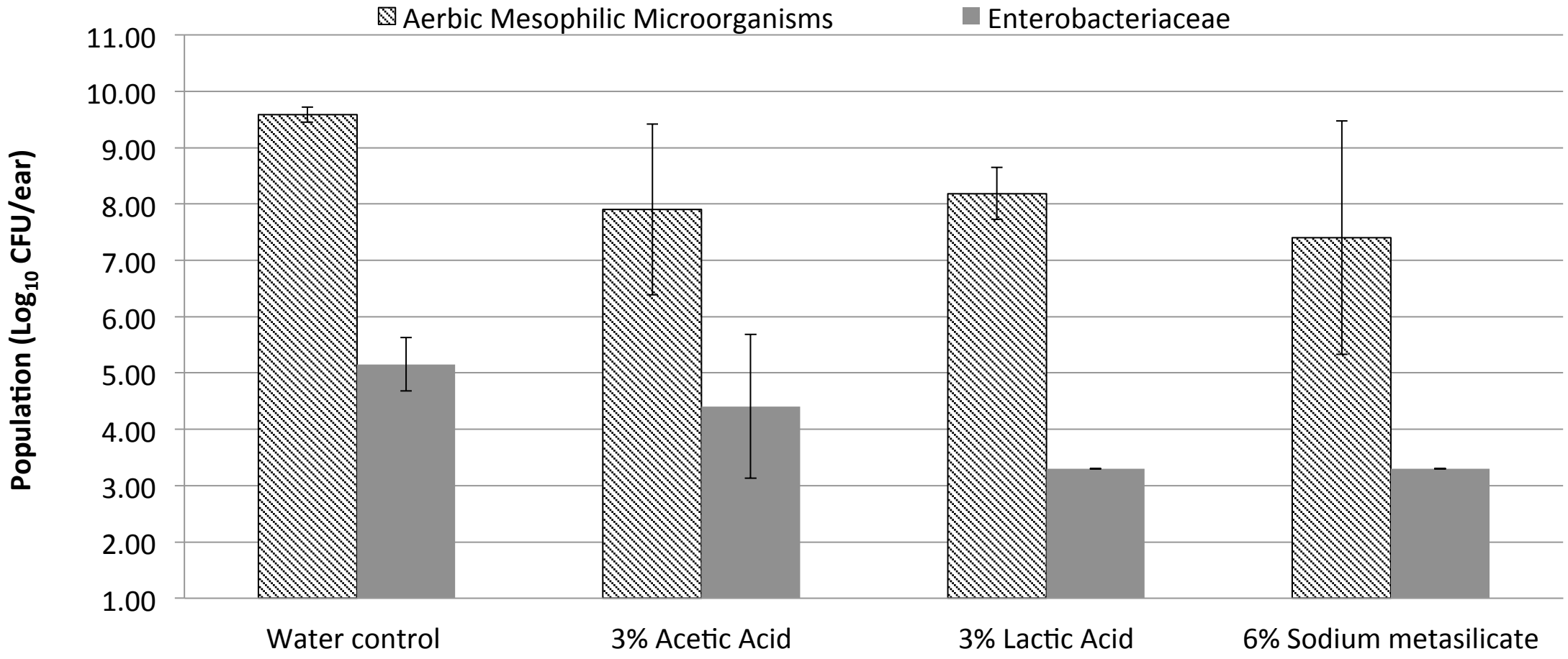
- *Staphylococcus aureus*
  - Dogs respond to staphylococcal enterotoxin administered directly into the GI tract (Warren *et al.*, 1964. J. Exp. Med. 120:561)
- *Salmonella*

Controlling Biological Hazards

- Raw material control
- Processing control
  - Temperature ramp up
  - Lethality
  - Dehydration
- Post-Processing control
  - Separation
  - Sanitation
  - Environmental monitoring

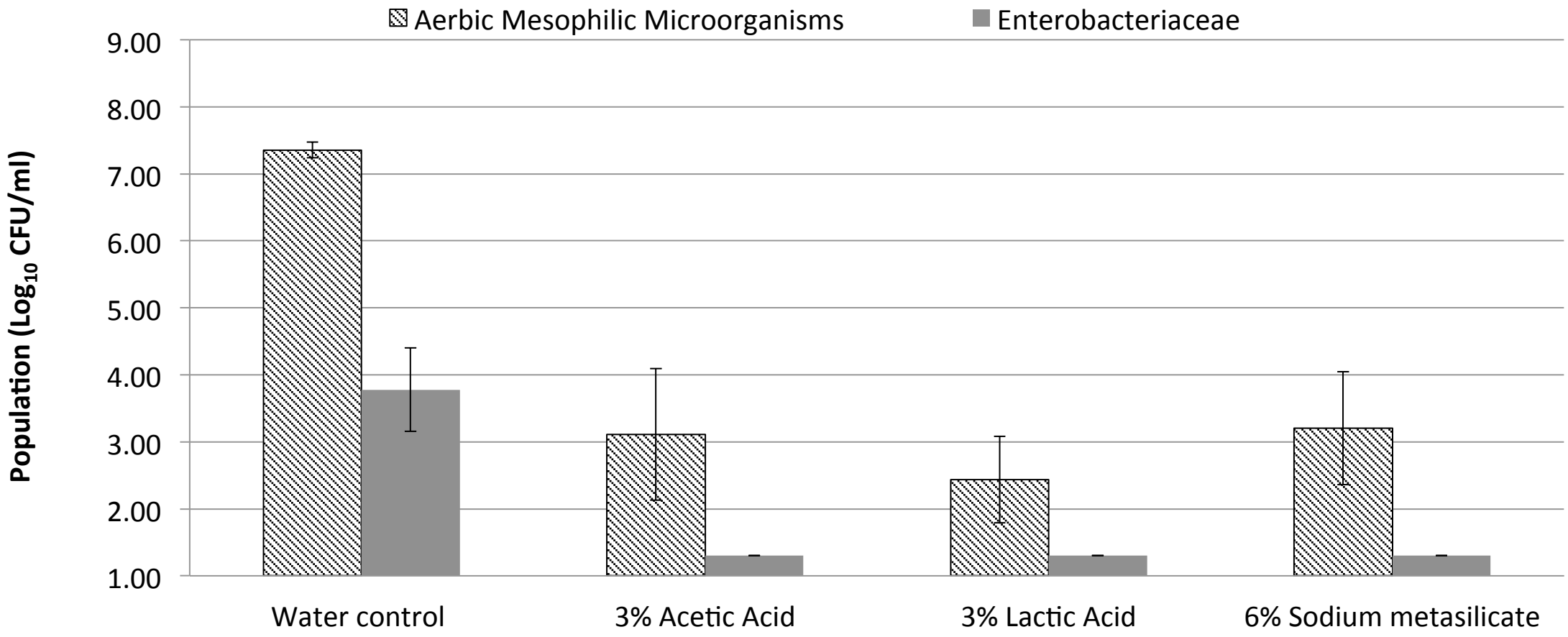


Populations of Aerobic Mesophilic Microorganisms and *Enterobacteriacea* on Raw Pig Ears After Thawing in Different Treatment Solutions at 40ºF



Raw frozen pig ears were submerged in treatment solutions at 40ºF for 24 h. Thawed pig ears were sampled by a rinse method, and rinsates were spiral plated on TSA and VRBG agar media. Each bar represents mean of three replicate tests, and brackets represent standard deviation of the mean.

Populations of Aerobic Mesophilic Microorganisms and *Enterobacteriacea* in Spent Treatments Solutions Used for Thawing Raw Pig Ears



Raw frozen pig ears were submerged in treatment solutions at 40ºF for 24 h. Treatment solutions were sampled by spiral plating on TSA and VRBG agar media. Each bar represents mean of three replicate tests, and brackets represent standard deviation of the mean.

DEHYDRATION TECHNOLOGY

Modes of Heat Transfer

- Conduction
  - Molecule to molecule
  - In meat, increases with moisture
- Convection
  - Heat moving from fluid-to-surface or surface-to-fluid
    - Velocity and temperature of fluid
  - Convection coefficient of water > convection coefficient of forced air
- Radiation
  - Heat moving directly from object to object via electromagnetic waves
- Condensation or Evaporation (indirect)

Dehydration

- Simultaneous heat and mass transfer
  - Process of removal of moisture by heat
  - Multiple factors
    - Temperature, humidity, meat composition, solutes/humectants, physical pressure, air velocity
- Water will evaporate (from the meat) until the vapor pressure of the meat is equal to the partial water vapor pressure in the air.
  - Both temperature and humidity change as air moves past moist material.

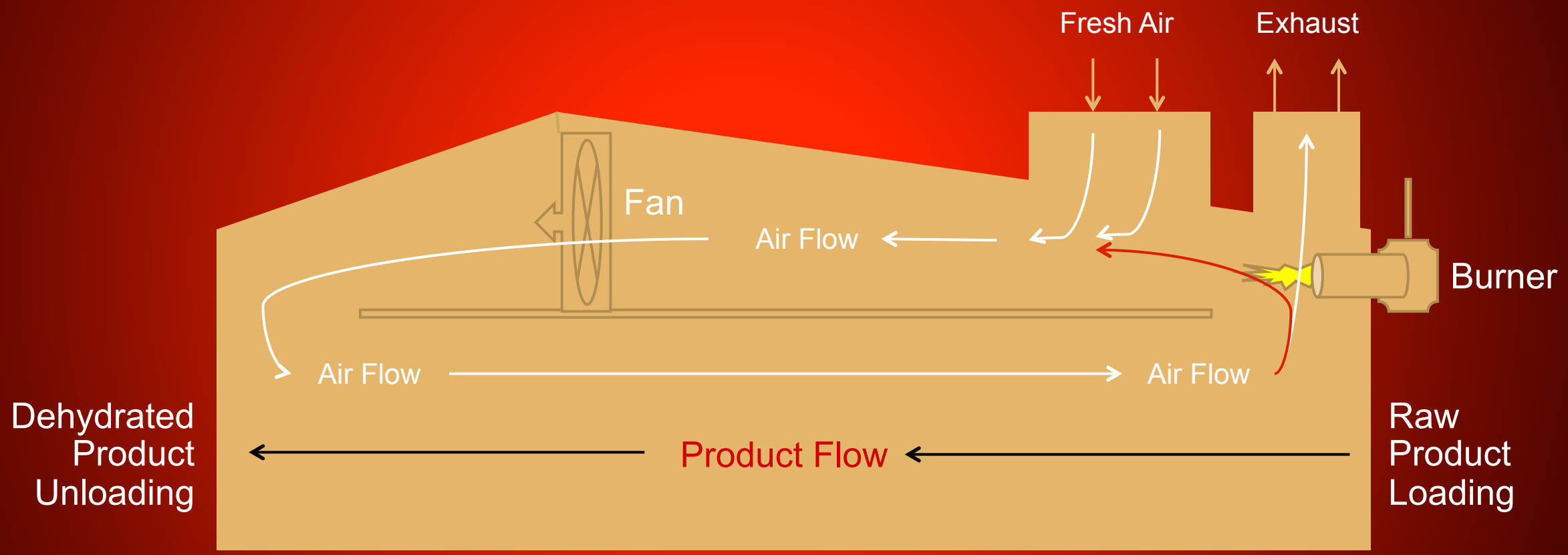
Dehydration

- Difference between dry bulb and wet bulb temperatures is an index for the driving force of heat on the material and the potential for dehumidification or vaporization of water from the raw material
- If heat transfer > mass transfer, less moisture is evaporated.
- If mass transfer > heat transfer, product cools with greater evaporation of water.

Dehydration

- The speed and effectiveness of drying processes are dependent on air velocity (Lebert *et al.*, 2005) and relative humidity (Arnau *et al.*, 2003).
- In muscle foods, water is either bound or unbound and the state of water between the two is in flux (Chang *et al.*, 1996). Some of the bound water (ca. 10%) is believed to be hydrogen-bonded with the surface of protein molecules (Chang *et al.*, 1996), while some is simply in interstitial spaces between muscle fibers and connective tissues.
- Water vapor pressure is a useful measurement of moisture content in meats, and a_w in meat products is a function of the moisture content/solid content, the components and composition of the product, the microstructure of the product, the temperature, and the state of some component solids (like sugar) (Chang *et al.*, 1996).

Industrial Drier / Dehydrator



Dehydration

- Batch process
- Batch rotation – move product from back to front.
- Batch to dry
- Continuous
- 17-19% RH at 165 to 175°F

Phases of Dehydration

1. Warming phase – high humidity (35-50%)
2. Evaporation phase
3. Transition
4. Final drying (last 10% of product moisture)

Points to Consider

- Raw product
  - Temperature
  - Load on trays or racks
- Humidity
  - Inside the chamber
  - Ambient
- Air
  - Temperature
  - Velocity
  - Flow

Case Hardening

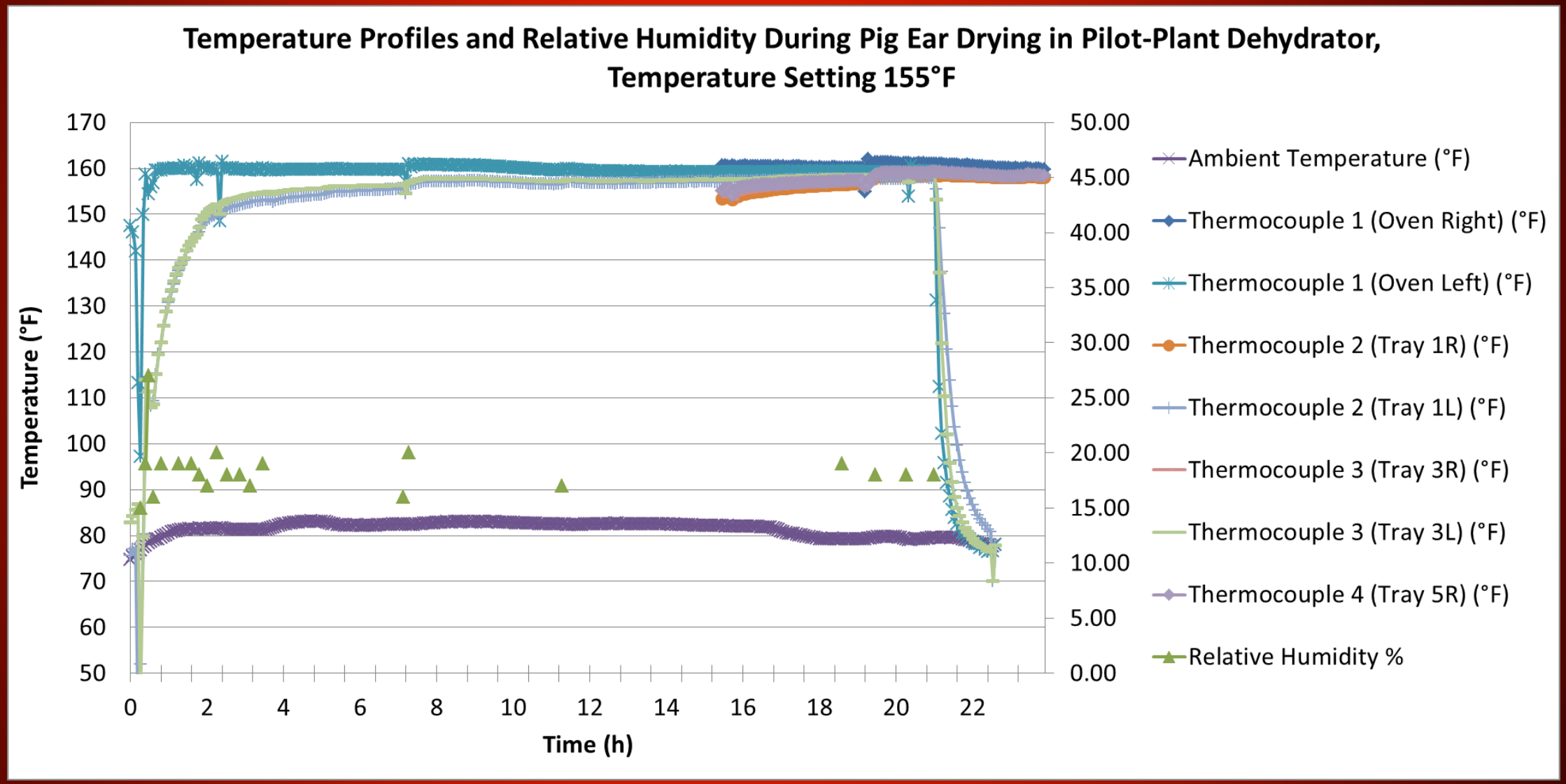
- Improper combinations of air velocity, temperature, and RH for certain products can cause surface crusting
- Traps moisture inside the permitting microbial survival or growth.

Water Activity

$a_w = P/po$

- *P* is water vapor pressure of food
- po is water vapor pressure of pure water at same temperature
- Potential of water to be vaporized
- Equal to RH% x 1/100

Validation



Validation

- Inoculate with surrogate bacterium
  - e.g., *Enterococcus faecium* NRRL B-2354
- Recover inoculum on unprocessed and processed samples
  - Citrate Azide Tween Carbonate (CATC) agar
- Calculate log reductions
  - Be careful about size and weight change of product

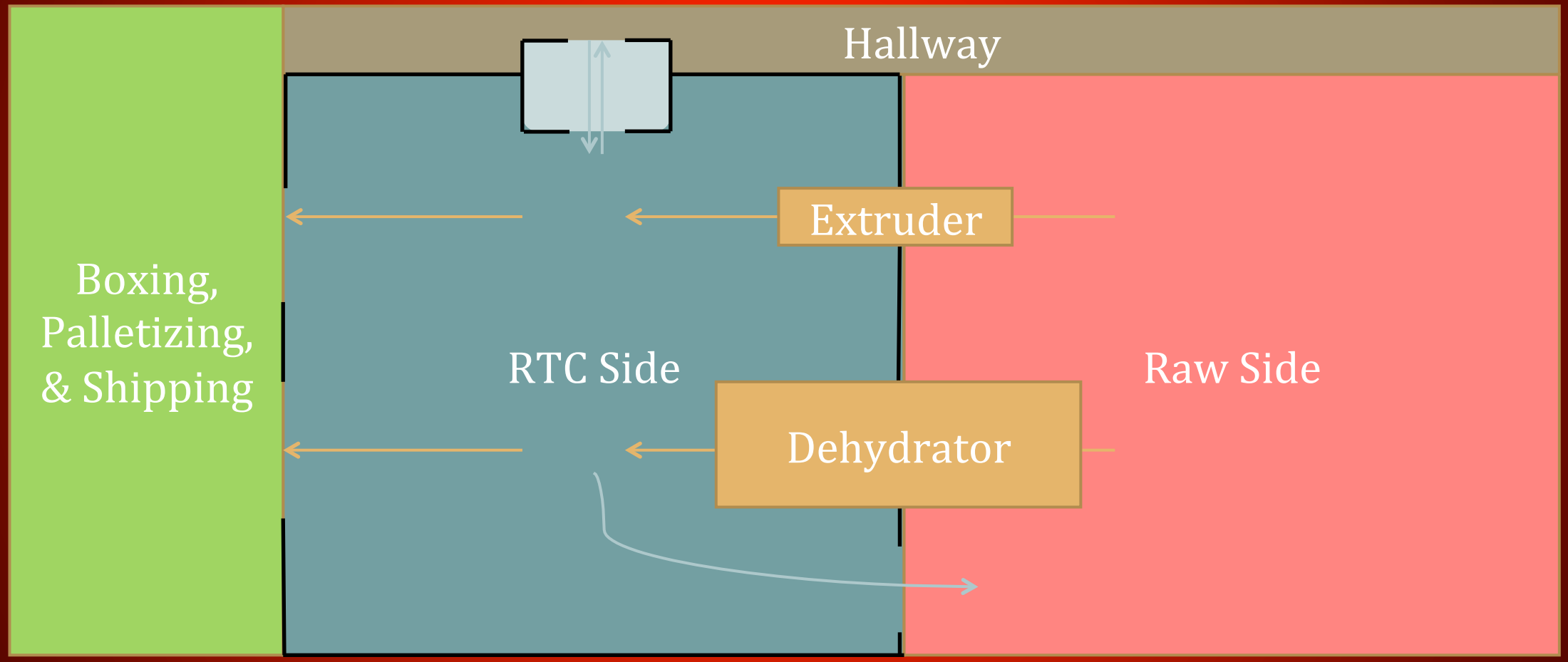
Validation

- Finished Product Testing
  - *Salmonella* and Indicator Organisms
  - Thorough coverage

FINISHED PRODUCT

Packaging & Shelf Life

Separation of Raw from Ready-To-Chew (RTC)



Sanitation of Dry Production Areas

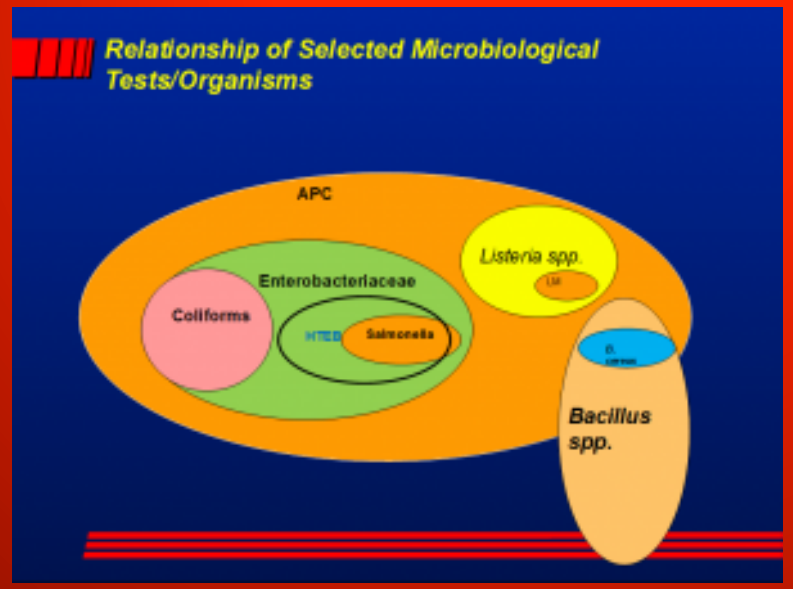
- If product is dry (low a_w)
- Sweep
- Vacuum with HEPA filtered exhaust
- Alcohol-based sanitizer
- Occasional wet sanitation – but thoroughly dry quickly afterwards.
- Must use wet sanitation when *Salmonella* has niched – wet clean and heavy sanitizer

Dry Sanitation

- Alcohol based
  - Isopropyl and quaternary ammonium compound
- Gaseous
  - O_3, ClO_2, PAA, heat
- Sanitary equipment design
  - Packaging equipment must be cleanable
- Equipment
  - Lifts, ladders
  - Brushes, brooms, dustpans
  - Dry wipes

Monitoring the Processing Environment

- *Salmonella* environmental sampling
- Indicator organisms
  - *Enterobacteriaceae*
  - Hygienic Indicator Assay – HTEB / EB (HT)



J. L. Kornacki – Kornacki Microbiology Solutions, LLC

Salmonella Survival and Shelf Life

- Pet treats such as pig ears are dry (low water activity
- Long shelf life
- *Salmonella* survives long periods of time under dry conditions
- *Salmonella* can be transmitted from pet treats to humans or from pets to humans

Spot Inoculation

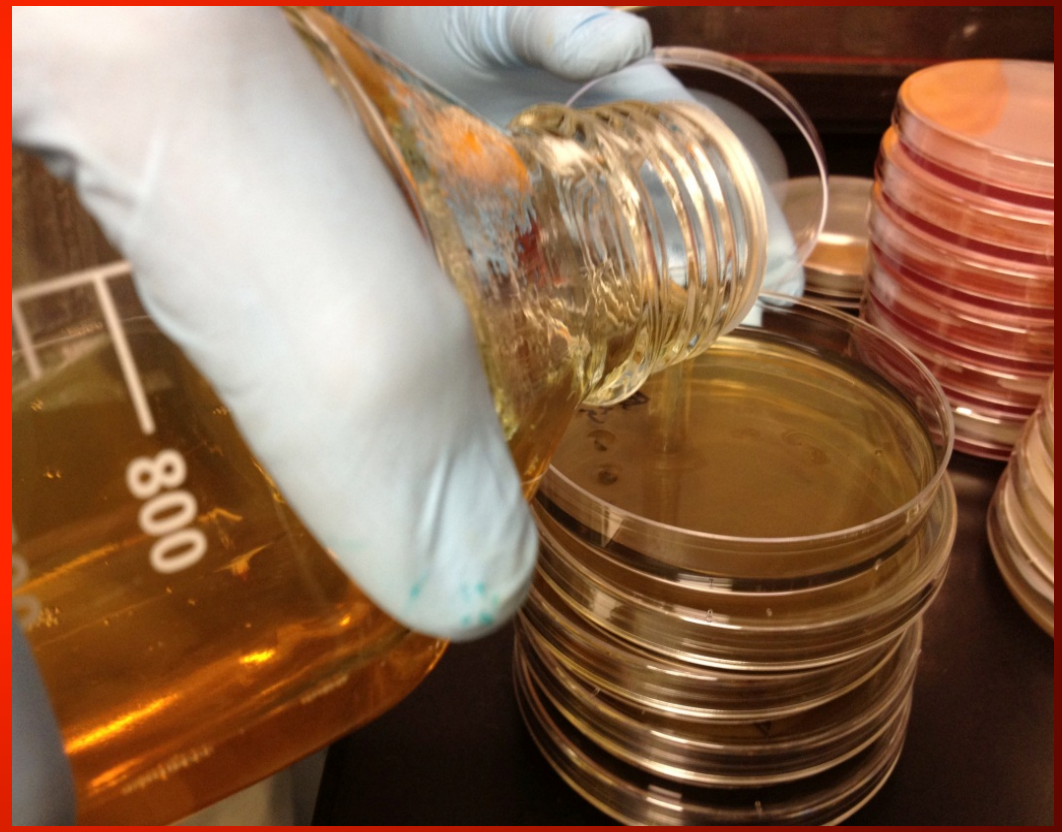
- Pig ears were spot inoculated with 4 x 50µl per sample, allowed to dry 1h
- Placed in clean plastic bags that were then sealed and stored at 4.4 or 22°C

Enumeration

- *Salmonella* was enumerated from pig ears using a rinse method:
  1. Bags were opened aseptically.
  2. 50 ml of R90 (FDA-BAM) was added to each bag.
     - R90 = Peptone, Salt, Tween Diluent
  3. Bags were shaken by hand for 30 s.
  4. Rinsate was plated or diluted and plated.
  5. Detection limit of 1.7 $\log_{10}$ CFU/sample.
     - Enrichment in Buffered Peptone Water when warranted
     - Streaked on HE agar
     - ELFA detection

Enumeration

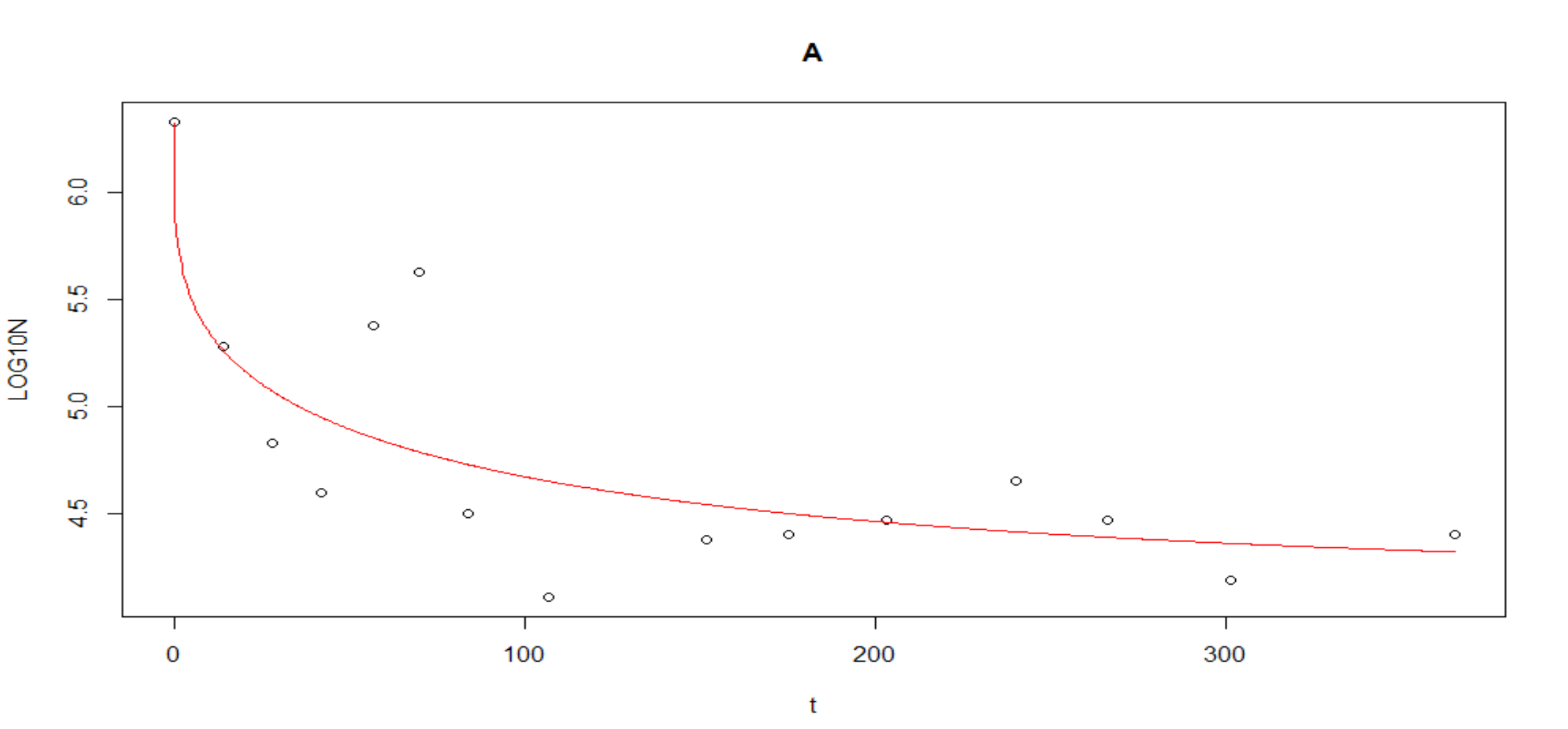
- Tryptic Soy Agar (TSA) thin agar layer
  - Overlaid with Hektoen Enteric Agar
- Incubated aerobically at 36 ± 2°C for 48 h prior to counting characteristic black colonies
- Detection limit 1.7 $\log_{10}$ CFU/sample



Experimental Design and Statistical Analysis

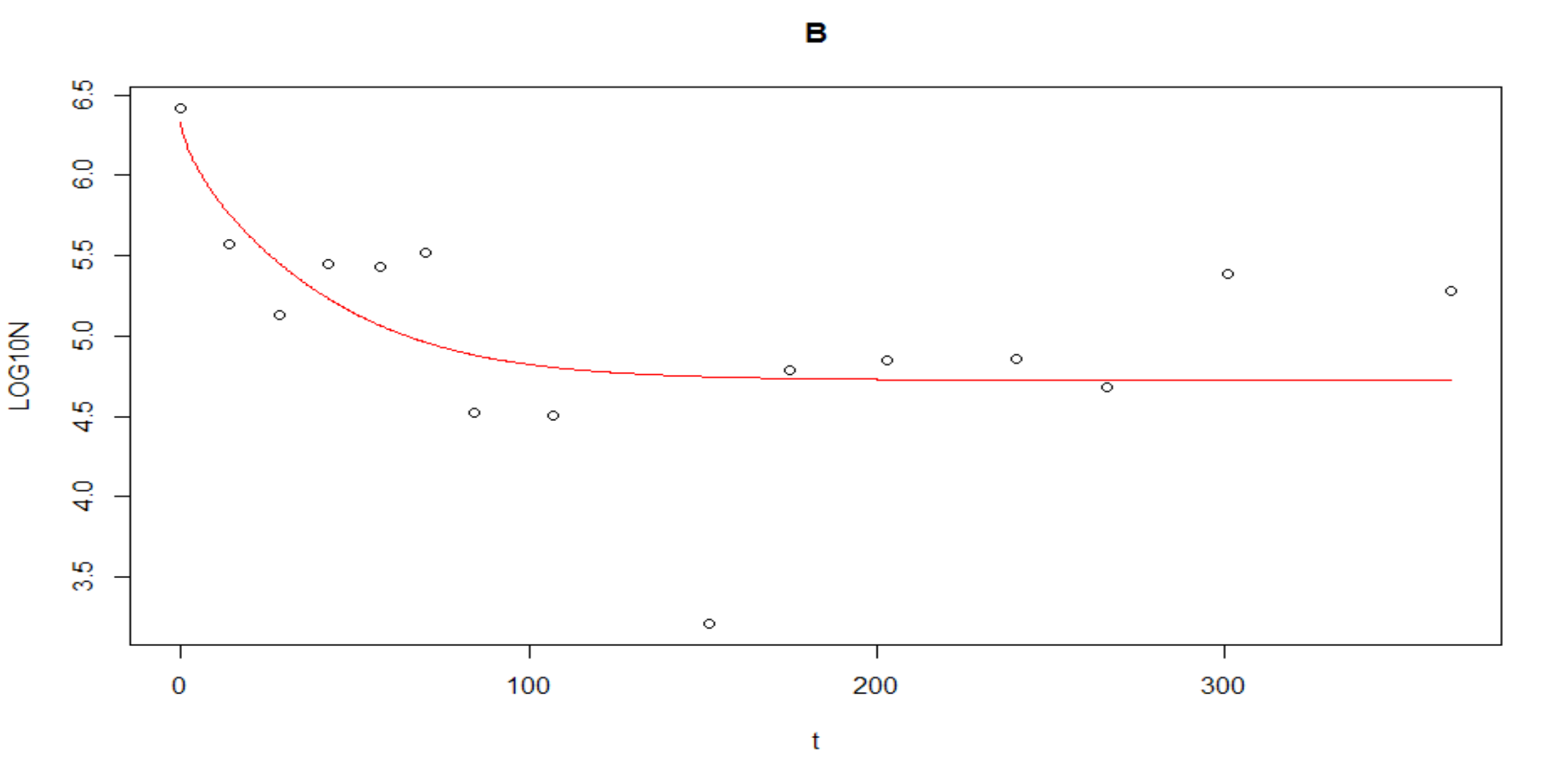
- 2 Serovars x 2 Pig Ears x 2 Temperatures
- Triplicate samples per time, plated in duplicate
- Raw plate count data were log-transformed
- Mean values per time fitted using a modified Weibull model (R)

Population (log_{10} CFU/sample) survival curves of *Salmonella* Typhimurium DT 104 on smoked pig ear pet treats during 365 day storage at 4.4 ± 0.5˚C fitted using a modified Weibull model.



Taormina, P.J. 2014. *J. Food Prot*. 77:50-6

Population (log_{10} CFU/sample) survival curves of *Salmonella* Typhimurium DT 104 on natural pig ear pet treats during 365 day storage at 4.4 ± 0.5°C fitted using a modified Weibull model.



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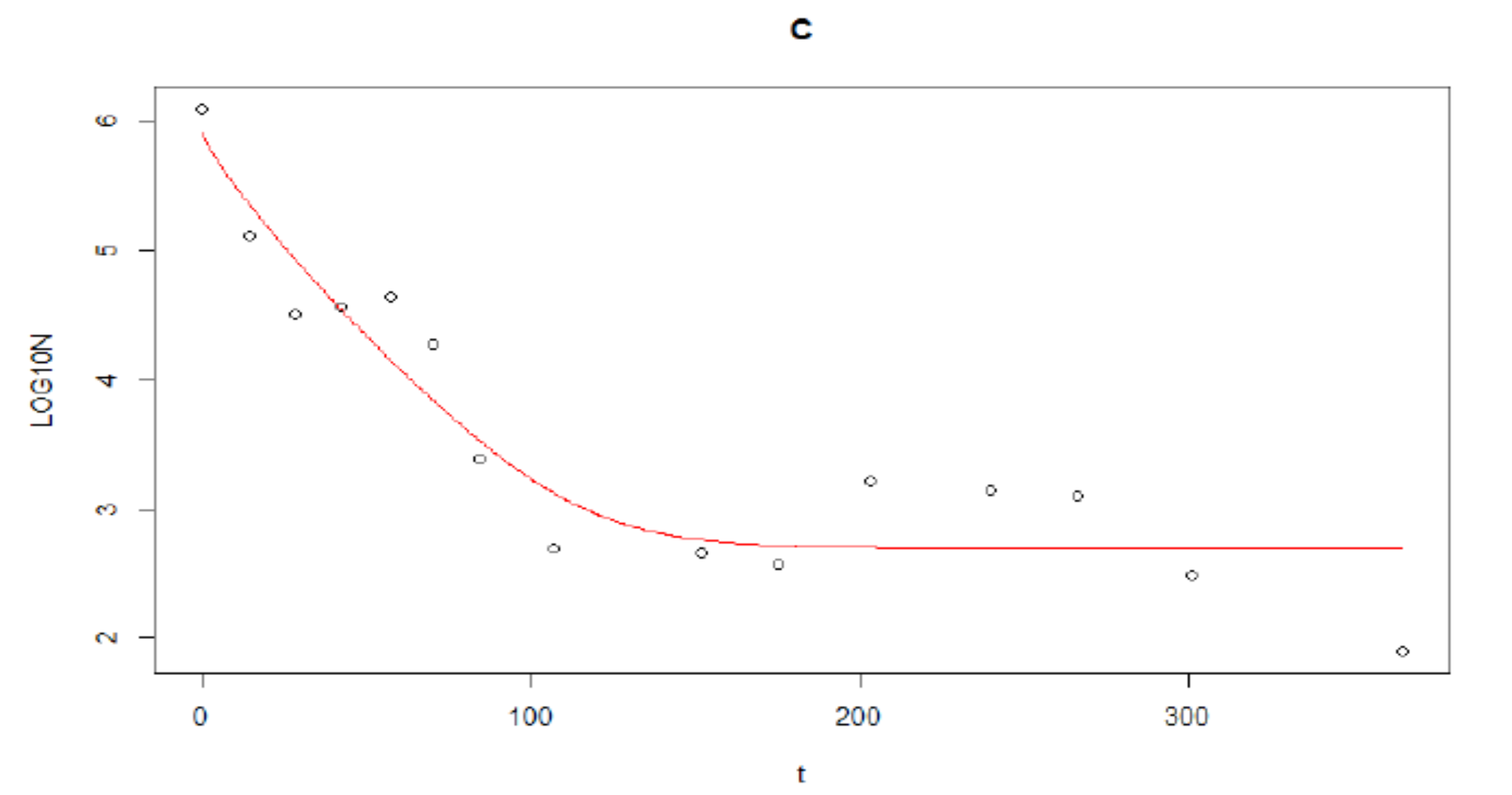
Population (log_{10} CFU/sample) survival curves of *Salmonella* Newport on smoked pig ear pet treats during 365 day storage at 4.4 ± 0.5°C fitted using a modified Weibull model.



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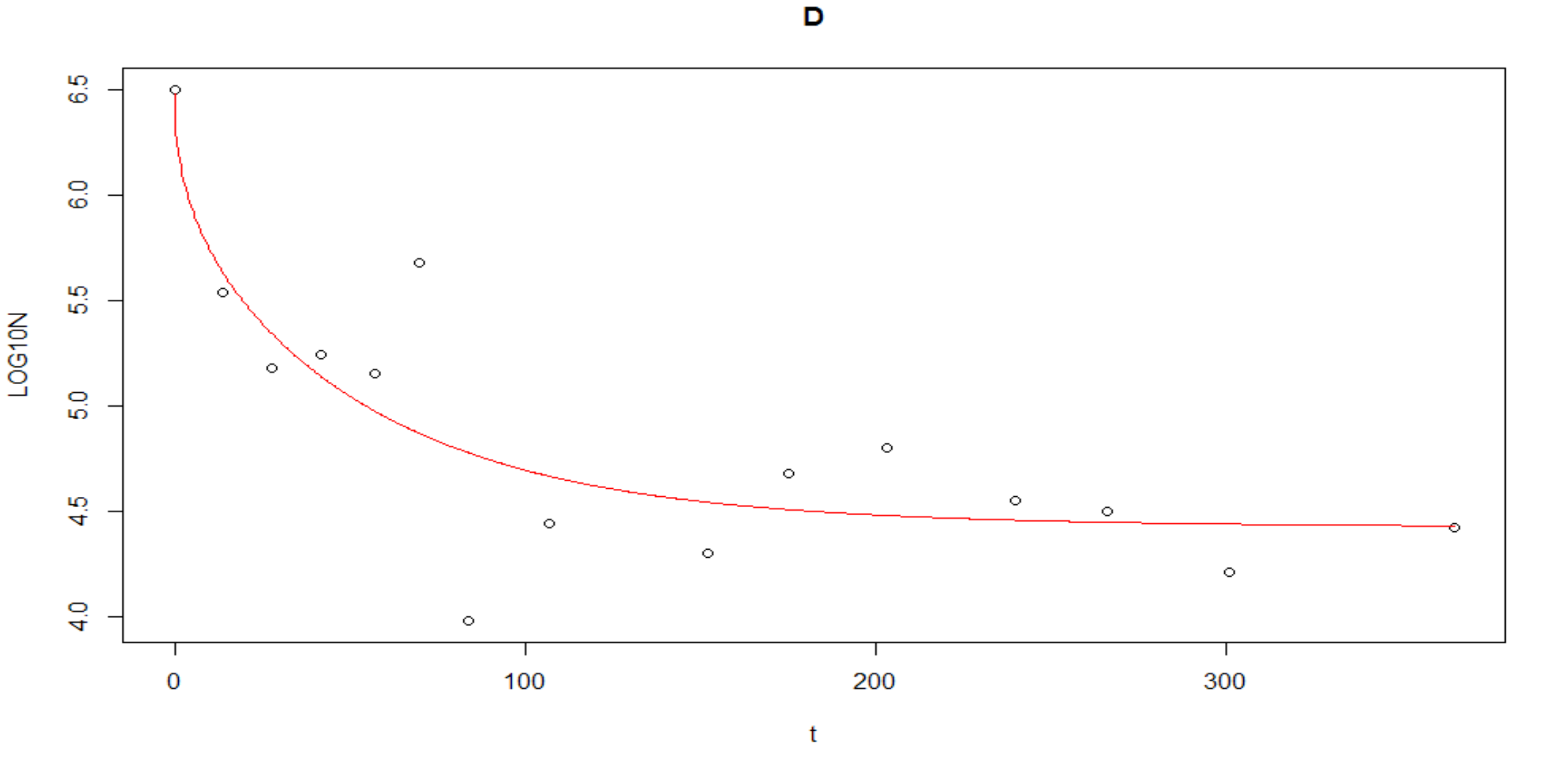

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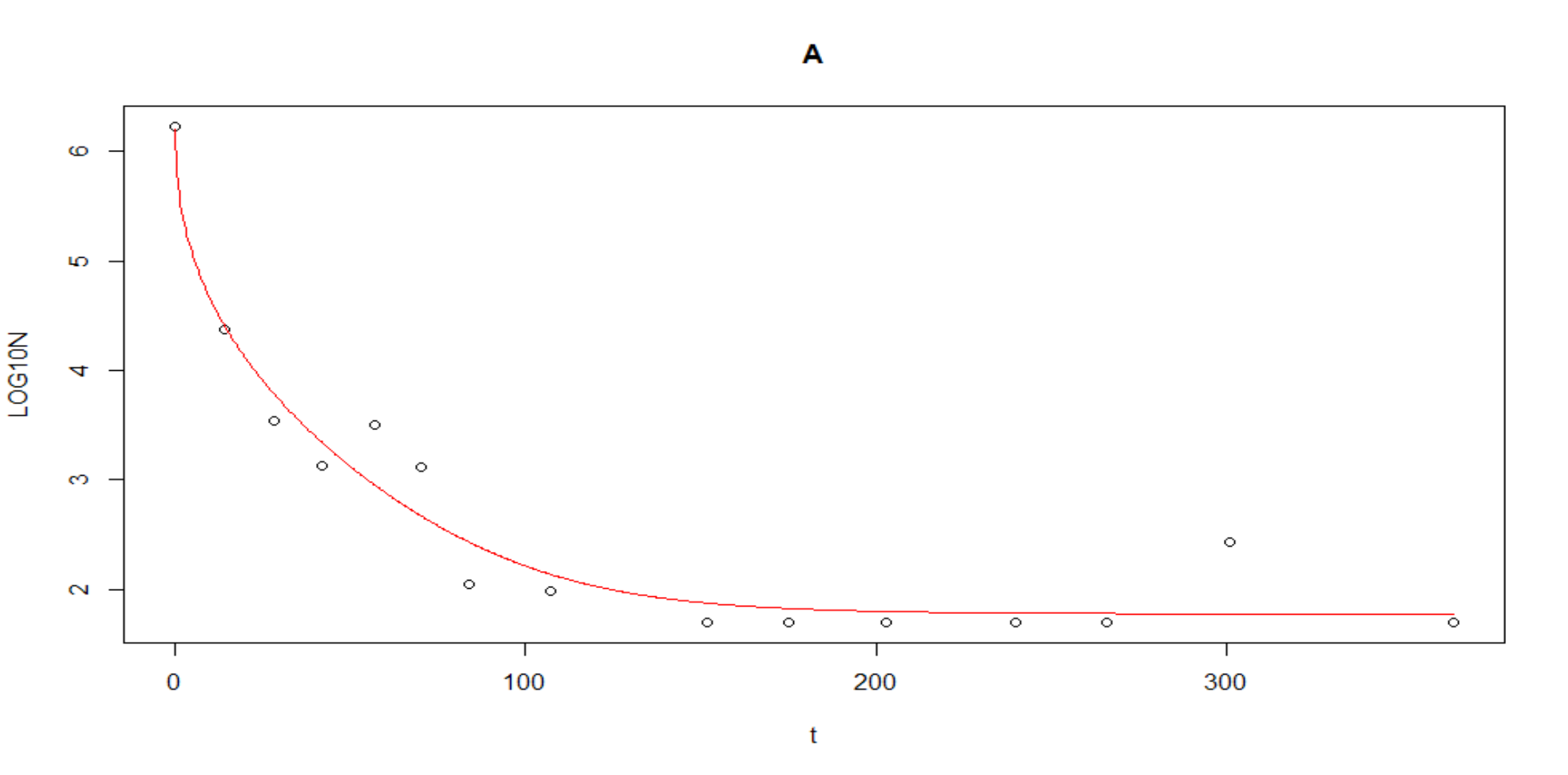
Population (log_{10} CFU/sample) survival curves of *Salmonella* Typhimurium DT 104 on smoked pig ear pet treats during 365 day storage at 22 ± 2°C fitted using a modified Weibull model.



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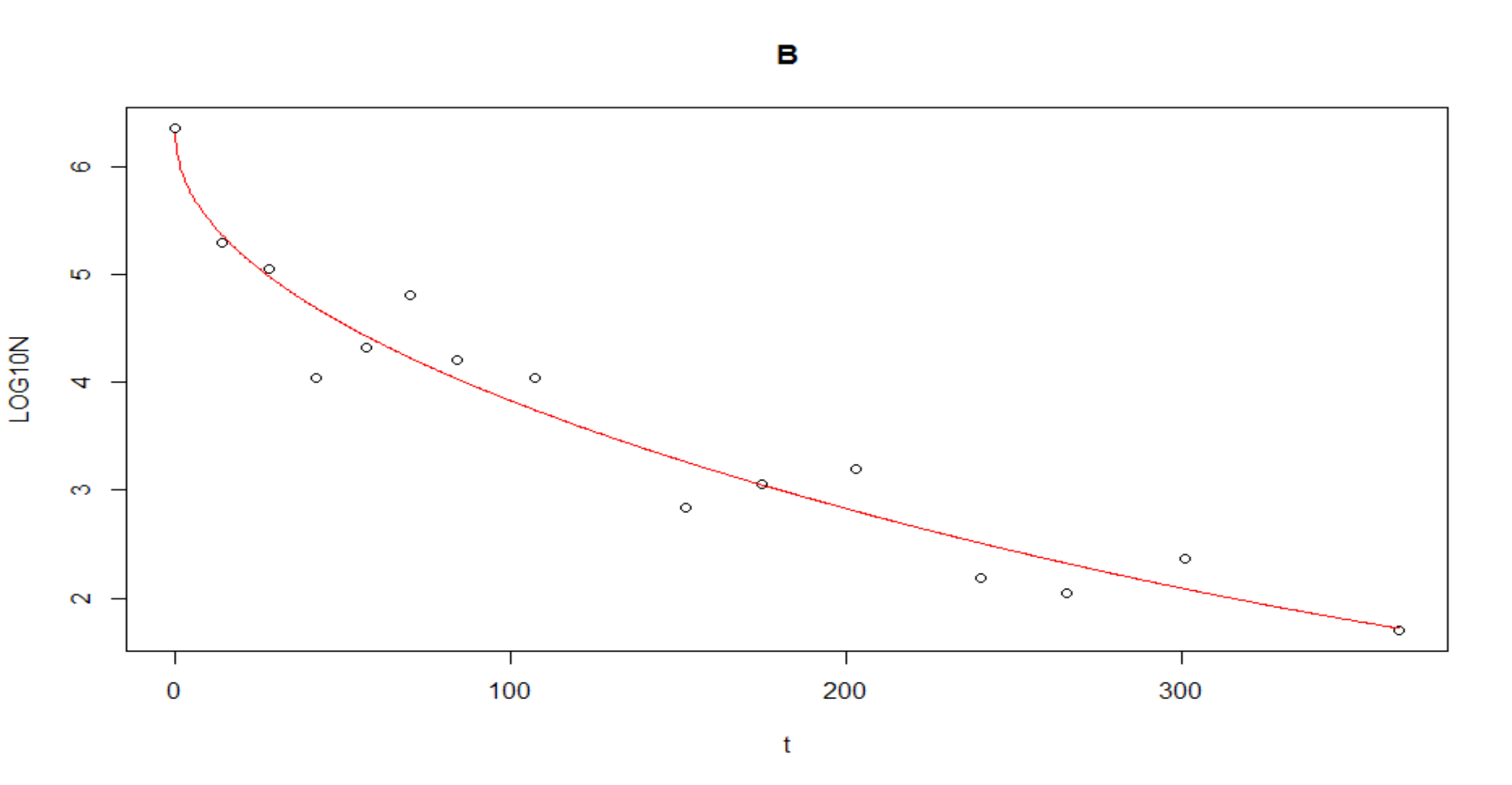

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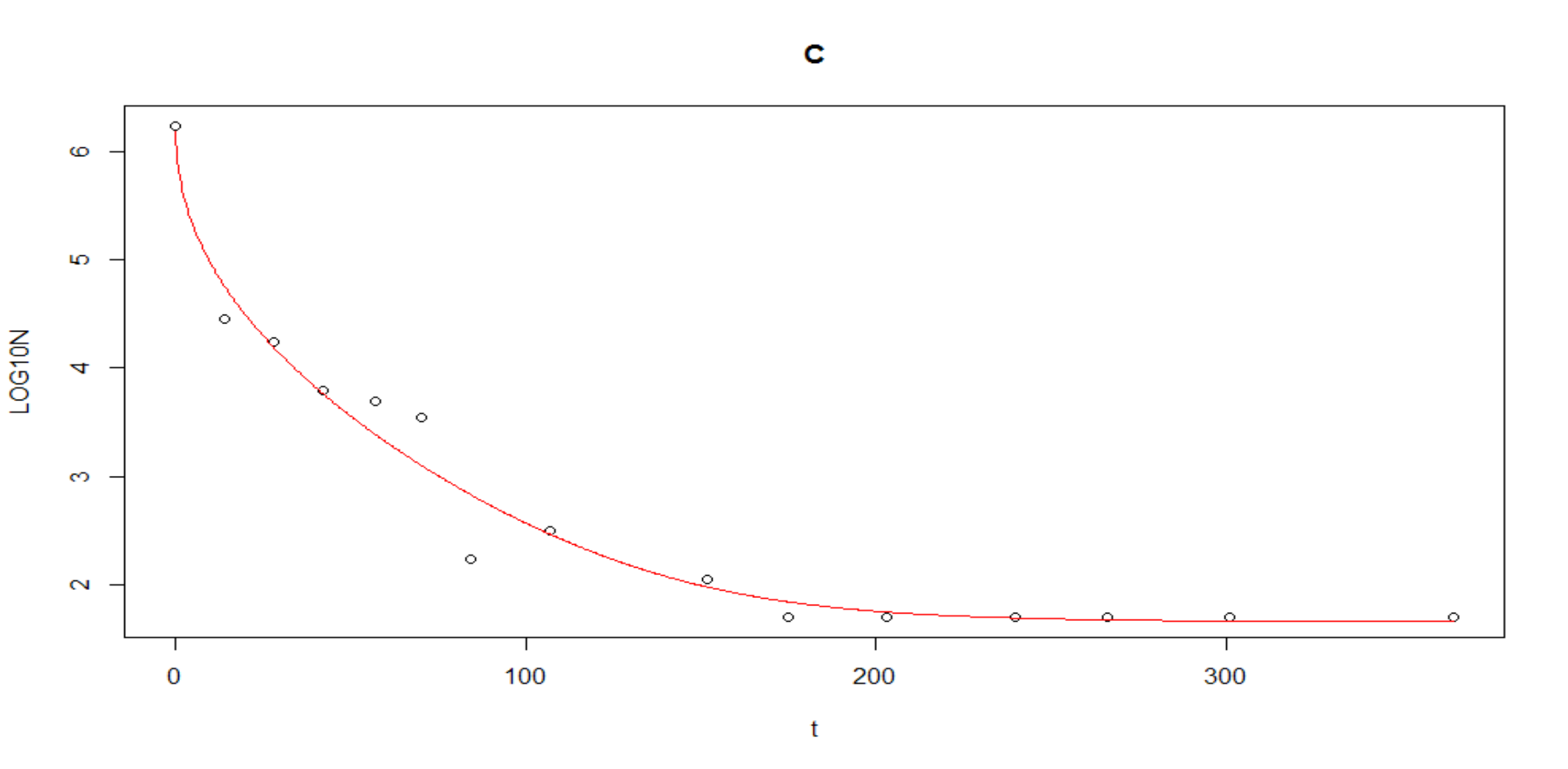

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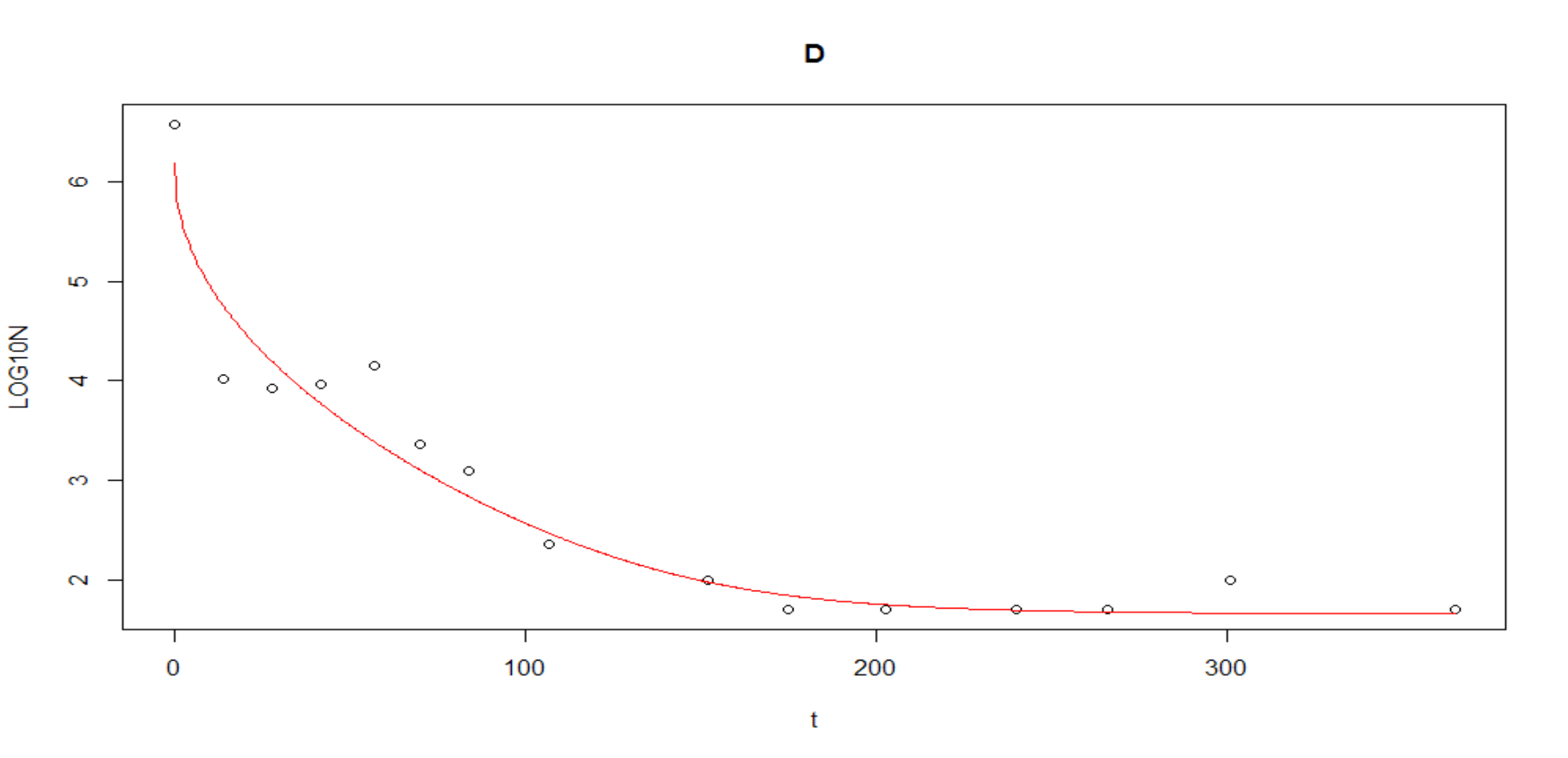

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Summary - Control of Hazards

- Chemical & Radiological
  - Supplier qualification and auditing
  - Spot check raw material with analytical tests
  - Eliminate or reduce use of low-quality suppliers
  - Address chemical hazards in HARPC Plan
    - Reduce hazards to acceptable level
  - Verify effectiveness of control programs by analytical hold-and-test of representative finished product samples

Summary - Control of Hazards

- Physical
  - Supplier qualification and auditing
  - Spot check raw material for foreign objects
  - Address physical hazards in HARPC Plan
    - Reduce hazards to acceptable level
    - Monitor complaints
    - Modify process as needed

Summary - Control of Hazards

- **Biological**
  - Raw material supplier qualification and auditing
  - Build microbiological database on raw material with testing
  - Eliminate or reduce use of high pathogen load suppliers
  - Design and validate sufficient kill step to prevent growth of *S. aureus* and destroy *Salmonella*.
    - Dehydration Technology & Validation
    - Water activity (a_w)
  - Apply proper cleaning and sanitation to RTC environment
  - Monitoring RTC processing environment for *Salmonella* or appropriate index organisms
  - Hold-and-Test occasional finished product to verify effectiveness of control program
  - Consider post-lethality treatments for further risk reduction (e.g. HPP or irradiation)

Acknowledgements

- Paul Metzler, Microbiologist, JMFG

Thank you…