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

Peter Taormina, Ph.D.
Director of Science, John Morrell Food Group/
Smithfield Foods, Inc.
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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
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

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

## Salmonella - Summary of Human Illnesses and Outbreaks

<table>
<thead>
<tr>
<th>Serovar</th>
<th>Year/Location</th>
<th>Product</th>
<th>Illnesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infantis</td>
<td>2012 / 13 U.S. states</td>
<td>Dry dog food</td>
<td>22</td>
</tr>
<tr>
<td>Schwarzengrund</td>
<td>2006-07 / 19 U.S. states</td>
<td>Dry dog food</td>
<td>70</td>
</tr>
<tr>
<td>Thompson</td>
<td>2004-05 / U.S. and Canada</td>
<td>Pet treats beef/seafood</td>
<td>9</td>
</tr>
<tr>
<td>Newport</td>
<td>2002 / Calgary, Alberta, Canada</td>
<td>Dried beef pet treats</td>
<td>5</td>
</tr>
<tr>
<td>Infantis</td>
<td>1999 / Canada</td>
<td>Pig ear pet treats</td>
<td>12</td>
</tr>
</tbody>
</table>
## Incidence of *Salmonella* on Pet Treats

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

Product Linked to Outbreaks?

YES

Kill Step In Our Facility?

NO

Kill Step In Our Facility?

YES

Risk 3

NO

Risk 1

Risk Management

- Supplier Qualification & Audit (GFSI, GMPs)
- COA every lot raw material
- Lab: pathogen or chemical test
- Verify finished product conformance with statistically-based testing
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 Enterobacteriaceae on Raw Pig Ears As Affected by 30s Dip Treatments

- No Treatment
- Water Control (room temperature)
- 2% Acetic Acid (room temperature)
- Water at 140°F/60°C
- 2% Acetic Acid at 140°F/60°C

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Population (Log$_{10}$ CFU/ear)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Treatment</td>
<td>10.00</td>
</tr>
<tr>
<td>Water Control (room temperature)</td>
<td>6.00</td>
</tr>
<tr>
<td>2% Acetic Acid (room temperature)</td>
<td>9.00</td>
</tr>
<tr>
<td>Water at 140°F/60°C</td>
<td>9.00</td>
</tr>
<tr>
<td>2% Acetic Acid at 140°F/60°C</td>
<td>9.00</td>
</tr>
</tbody>
</table>
Populations of Aerobic Mesophilic Microorganisms and *Enterobacteriaceae* on Raw Pig Ears After Thawing in Different Treatment Solutions at 40°F

<table>
<thead>
<tr>
<th>Treatment Solution</th>
<th>Population (Log₁₀ CFU/ear)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water control</td>
<td>9.00 ± 1.00</td>
</tr>
<tr>
<td>3% Acetic Acid</td>
<td>8.00 ± 1.00</td>
</tr>
<tr>
<td>3% Lactic Acid</td>
<td>7.00 ± 1.00</td>
</tr>
<tr>
<td>6% Sodium metasilicate</td>
<td>6.00 ± 1.00</td>
</tr>
</tbody>
</table>

Raw frozen pig ears were submerged in treatment solutions at 40°F 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 *Enterobacteriaceae* in Spent Treatments Solutions Used for Thawing Raw Pig Ears

<table>
<thead>
<tr>
<th>Treatment Solutions Used for Thawing Raw Pig Ears</th>
<th>Populations of Aerobic Mesophilic Microorganisms (Log_{10} CFU/ml)</th>
<th>Populations of Enterobacteriaceae (Log_{10} CFU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water control</td>
<td>7.00</td>
<td>3.00</td>
</tr>
<tr>
<td>3% Acetic Acid</td>
<td>4.00</td>
<td>2.00</td>
</tr>
<tr>
<td>3% Lactic Acid</td>
<td>2.00</td>
<td>1.00</td>
</tr>
<tr>
<td>6% Sodium metasilicate</td>
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<td>1.00</td>
</tr>
</tbody>
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Raw frozen pig ears were submerged in treatment solutions at 40°F 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

- **Raw Product Loading**
- **Fresh Air**
- **Burner**
- **Exhaust**
- **Dehydrated Product Unloading**
- **Product Flow**
- **Air Flow**

Air Flow from the burner provides heat to the product, which is then dehydrated. The dehydrated product is then unloaded.
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

\[ a_w = \frac{P}{po} \]

- \( P \) 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\% \times \frac{1}{100}
Validation

Temperature Profiles and Relative Humidity During Pig Ear Drying in Pilot-Plant Dehydrator, Temperature Setting 155°F
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)

- Boxing, Palletizing, & Shipping
- Extruder
- Dehydrator
- RTC Side
- Raw Side
- Hallway
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
  - O₃, ClO₂, 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 $1.7 \log_{10} \text{CFU/sample}$.
     • 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.
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.
Population (log$_{10}$ CFU/sample) survival curves of *Salmonella* Newport 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 (log₁₀ 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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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...