Justifying a lower level of *Salmonella* reduction during processing of Ready-to-Eat meats.

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What LEVEL of pathogens are of concern?

• 1 log\(_{10}\)?
  • *Listeria monocytogenes* rule for RTE meats and post-process interventions.

• 2 log\(_{10}\)?
  • *Some* company policies for RTE meats *L. monocytogenes* rule.

• 3 log\(_{10}\)?
  • *Vibrio* spp.? *L. monocytogenes* in some products?

• 4 log\(_{10}\)?
  • *Some* company policies for *L. monocytogenes* inactivation in various products.
What LEVEL of pathogens are of concern?

• 5 log$_{10}$?
  • USDA (E. coli O157:H7; Salmonella)
  • FDA (E. coli O157:H7; Salmonella)
  • Company policies (E. coli O157:H7; Salmonella, L. monocytogenes)
  • Academia (E. coli O157:H7; Salmonella, L. monocytogenes)

• 6 log$_{10}$?
  • USDA (6.5 for Salmonella)
  • FDA Seafood HACCP (L. monocytogenes)

• 7 log$_{10}$?
  • USDA (Salmonella)
  • FDA?
Who determines what level of pathogens are of concern?

- USDA and FDA regulations.
  - Cooking and Cooling requirements
  - Acidified Foods requirements, Juice HACCP, Seafood HACCP

- Scientific publications.
  - High Pressure Processing, D-value and Z-values

- Company internal process risk assessments.
  - Raw material levels.
  - Experience with recalled products

- University Extension Agents, Equipment Manufacturers, Processing Authorities....
How are these levels determined?

• Outbreak history?
• Contamination rates and levels?
• Risk Assessments throughout production, storage, etc.
How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

1.2 Risk Management Question Addressed

The proposed RTE rule has a minimum lethality performance standard of a 6.5-log reduction of *Salmonella* in meat for all categories (cooked, fermented, salt-cured, dried).

What would be the public health impact of alternative lethality standards of 5.0-log and 6.5/7.0-log reductions of *Salmonella* (7-log for products containing poultry)?
How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

Health risk associated with pathogens ingested via RTE meat and poultry products can arise from a number of exposure pathways:

- pathogens that contaminate raw materials and subsequently survive the lethality step in processing
- pathogens that contaminate products after the lethality step (e.g. during handling, before or during packaging)
- pathogens that contaminate the RTE meat and poultry products during subsequent handling in food preparation
How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

1.4 Summary of Risk Estimation Process

The public health risk associated with RTE meat and poultry products is estimated by combining evidence related to the following factors:

1. The level of contamination of raw materials.
2. The required lethality standard.
3. The extent of compliance with the standard.
4. Thermal processing safety factors (associated with any thermal lethality process).
5. Storage of the product and potential growth of surviving organisms.
6. The frequency and extent of consumer re-heating.
7. The amount of consumption of the product.
How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

The essence of the risk assessment is as follows:

1) calculate the level of contamination (i.e., the concentration) of *Salmonella* in raw materials
2) calculate the concentration of surviving organisms in finished product, given the required level of lethality
3) adjust the concentration of surviving organisms to take into account compliance with the required level of lethality and any thermal process safety factors associated with any lethality treatment applied
4) estimate the extent of population growth (if any) during storage
5) estimate the reduction in population associated with consumer re-heating of the product
6) estimate the probability of illness from the ingested dose of pathogens
7) calculate the expected number of cases of salmonellosis for a fixed mass of product (one million kilograms) and for the mass of each product that is consumed in a year
8) estimate the risk for alternate assumptions and explore the sensitivity of the risk estimate to various key variables.
How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

• Limitations and Uncertainties
  • Categorization of products
  • Pathogen burden in raw materials
  • Thermal process safety factors
  • Storage and growth
  • Consumer reheating
  • Dose-response relationship
  • Production volumes

How are these levels determined?

### Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

<table>
<thead>
<tr>
<th>RTE Product Category</th>
<th>Number of Cases per year</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 5.0</td>
<td>Split</td>
<td>All 6.5/7.0</td>
</tr>
<tr>
<td>Roast Beef, Corned Beef</td>
<td>1.2x10^{-2}</td>
<td>7.0x10^{-3}</td>
<td>7.0x10^{-3}</td>
</tr>
<tr>
<td>Fully Cooked Beef Patties</td>
<td>0.1</td>
<td>0.1</td>
<td>5.0 x10^{-3}</td>
</tr>
<tr>
<td>Cooked Pork (Cooked Ham, Pork BBQ)</td>
<td>4.6 x10^{-3}</td>
<td>2.1x10^{-4}</td>
<td>2.1x10^{-4}</td>
</tr>
<tr>
<td>Cooked Turkey (non-Deli)</td>
<td>1250.0</td>
<td>17.9</td>
<td>17.9</td>
</tr>
<tr>
<td>Cooked Chicken (Nuggets, Tenders, non-Deli)</td>
<td>40740.0</td>
<td>584.1</td>
<td>584.1</td>
</tr>
<tr>
<td>Cooked Poultry Deli Meat</td>
<td>15460.0</td>
<td>389.4</td>
<td>389.4</td>
</tr>
<tr>
<td>Cooked Chicken Patties</td>
<td>3541.0</td>
<td>50.8</td>
<td>50.8</td>
</tr>
</tbody>
</table>

How are these levels determined?

Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

<table>
<thead>
<tr>
<th>RTE Product Category</th>
<th>Number of Cases per year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 5.0</td>
</tr>
<tr>
<td>Beef / Pork Frankfurters</td>
<td>256.6</td>
</tr>
<tr>
<td>Beef / Pork Bologna</td>
<td>162.5</td>
</tr>
<tr>
<td>Poultry Frankfurters</td>
<td>3263.0</td>
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<tr>
<td>Summer Sausage, Thuringer, Cooked Pepperoni</td>
<td>715.3</td>
</tr>
<tr>
<td>Salami, Uncooked Pepperoni, Chorizo, Soudjuk</td>
<td>679.1</td>
</tr>
<tr>
<td>Meat Sticks</td>
<td>442.4</td>
</tr>
<tr>
<td>Beef Jerky</td>
<td>208.1</td>
</tr>
<tr>
<td>Uncooked Country Ham</td>
<td>0.3</td>
</tr>
<tr>
<td>Prosciutto, cappicola, pancetta, basturma</td>
<td>0.1</td>
</tr>
</tbody>
</table>

What level of *Salmonella* would you choose?

"It Depends"
-Socrates
What levels of *Salmonella* are recommended?

- Roast, cooked, and corned beef.
  - At least a 6.5-log reduction.
  - OR at least a 5-log reduction (alternate lethality).

- Cooked uncured meat patties.
  - 5-log reduction.

- Cooked poultry products.
  - At least a 7-log reduction.

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A (June 2017)
What levels of *Salmonella* are recommended?

• For other RTE meat products:
  • Shelf-stable products. Recommended 5-log reduction.
  • Cooked products. Recommended 6.5-log OR 5-log reduction.
    • There are defined cooking times and temperatures used to achieve both levels.
    • To use a 5-log reduction, establishments should provide additional support for the safety of their process.
What if a product is a mix of poultry and beef/pork?

Appendix A: Compliance Guideline use with RTE Mix of Meat and Poultry

RTE meat or poultry food products consisting of any combination of meat and poultry must meet the poultry lethality performance standard. Both the published final rule "Performance Standards for the Production of Certain Meat and Poultry Products" and Appendix A mean that cooked product with any amount of poultry needs to meet the lethality requirements for the production of fully cooked poultry products (9 CFR 381.150(a)(1)) which stipulates a 7 log Salmonella reduction. This provision is based on the FSIS national microbiological "baseline" survey of raw whole and ground meat and poultry products, which found higher levels of Salmonella in poultry than in meat. Consequently, FSIS established a higher lethality performance standard for ready-to-eat poultry products than for meat (based on highest "worst case" levels).
Supporting information for a 5-log reduction.

• Use source materials that have been tested or treated to reduce pathogens.
  • The establishment can use a cooking process that achieves a 5-log lethality of *Salmonella* if it uses source materials that have been tested or treated to reduce pathogens.
  • The establishment should provide support (e.g., Letters of Guarantee (LOG), Certificates of Analysis (COA), or sampling information) for each lot demonstrating that levels of *Salmonella* are low enough to be controlled by a process achieving 5-log reduction with an appropriate safety margin (e.g. 2 logs).
    • For example, an establishment may provide a LOG indicating that a certain log reduction (e.g. 1.5 or 2 logs) is achieved in the source materials through the use of a validated antimicrobial intervention.

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A (June 2017)
Supporting information for a 5-log reduction.

• For shelf stable products, use a combination of factors to achieve at least a 5-log reduction (e.g., treatment of source materials, marinating in low pH marinade, heat treatment, drying, and HPP).

  • For example, if an establishment can support that treating the source materials achieves a 2-log reduction of Salmonella, marinating achieves a 2-log reduction, and drying achieves another 2 log reduction, it would be able to support the safety of the product.
Supporting information for a 5-log reduction.

• Conduct a baseline study on the raw source material.
  • The baseline study should be designed such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations > 10 CFU/gram before cooking. This is based on the premise that a 5-log lethality step would reduce a *Salmonella* level of < 10 CFU/gram to < 1 CFU/100 grams and provide a 2-log margin of safety (NACMCF, 2010).
  • Consequently, the establishment should plan to collect about 10 samples per week (e.g., 500 samples per year). In addition, once the baseline is complete, the establishment should collect at least as many verification samples over a year as it did in its baseline study to ensure the ongoing effectiveness of the program.

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A (June 2017)
Tips on conducting a baseline study.

• Establishments should consider seasonality of *Salmonella* contamination.
  • Generally, the incidence of *Salmonella* on beef and pork products is highest during the three months of July through September and the lowest during the months of January through March (USDA/FSIS, 2007b).

• Establishments should consult references to determine the optimal study design.
  • For example, if the proportion of screen-test positive samples is less than 10%, then the establishment should increase the dataset size in order to obtain a sufficient number of screen-test positive samples that can be enumerated for *Salmonella*.

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A (June 2017)
Where have I heard this before????

UPDATE ON DRY FERMENTED SAUSAGE

ESCHERICHIA COLI O157:H7 VALIDATION RESEARCH

An Executive Summary Update
Prepared by Ranzell Nickelson II, Ph.D.,
Coordinator for
The Blue Ribbon Task Force of the
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Summary

• Based on risk assessments and studies, some RTE meat products may target a 5-log reduction of *Salmonella*.

• This decision is based on several factors including:
  • Meat type.
  • Processing.
  • Raw materials.
  • Your test results.
  • Validation of HACCP plans.

• How confident do you feel?

What could possibly go wrong?
Got Questions?

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