One Team, One Purpose

Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
FSIS Retail *Listeria monocytogenes* Pilot Project and Grinding Recordkeeping Requirements, July 2017

Kristina Barlow, Senior Microbiologist
Risk, Innovations, and Management Staff
Office of Policy and Program Development
Food Safety and Inspection Service
United States Department of Agriculture
As the public health regulatory agency in USDA, FSIS is responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is:

- Safe
- Wholesome
- Correctly labeled and packaged

Jurisdiction – slaughter through consumer sale for livestock and poultry products; egg handling through pasteurization for processed egg products. Primary statutes – Egg Products Inspection Act (EPIA), Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA)
The week of Jan. 25, 2016, FSIS launched a year-long pilot project to assess whether retailers are using the recommendations from the June 2015 “FSIS Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens,” (FSIS Retail Lm Guidance).

During the year long pilot, FSIS tracked the percent of recommendations that retailers followed, in the following four categories:

- Product handling
- Cleaning and sanitizing
- Facility and equipment controls
- Employee practices

Results were posted quarterly on the FSIS website.
Food Safety and Inspection Service
Pilot Project Results

Percent of Recommendations Retailers Followed
(Jan. 25, 2016 – Dec. 31, 2016)
• FSIS has decided to extend the pilot project until the end of Fiscal Year 2021 as part of the FSIS Strategic Plan FY 2017-2021.

• Under the Strategic Plan, FSIS will track whether delicatessens (delis) are following eight of the most important recommended actions identified in the FSIS Retail Lm Guidance (see next slide).

• The eight most important recommended actions were selected because they were:
  • Found to significantly decrease the likelihood of illness (according to the Interagency Risk Assessment--Listeria monocytogenes in Retail Delicatessens (Retail Lm Risk Assessment)),
  • Identified as FDA Food Code recommendations, or
  • Included in FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities.
1. Eliminate visibly adulterated product present in the retail deli (Directive 8010.1);

2. Refrigerate RTE meat or poultry products promptly after use (Retail \textit{Lm} Risk Assessment/FDA Food Code);

3. Do not prepare, hold, or store RTE meat or poultry products near or directly adjacent to raw products in the deli case or elsewhere in the deli area (FDA Food Code);

4. Cover, wrap, or otherwise protect all opened RTE meat or poultry products when not in use to prevent cross-contamination (FDA Food Code);

5. Ensure that insanitary conditions (e.g., flies, rodent droppings, mold, or dirty surfaces) are not present where RTE meat and poultry products are prepared, packed, and held (Directive 8010.1);

6. Clean and sanitize equipment used to process RTE products at least every 4 hours (Retail \textit{Lm} Risk Assessment/FDA Food Code);

7. Eliminate facility conditions in the deli area or storage area that could cause the products to become adulterated (FDA Food Code);

8. Ensure that deli employees handling RTE products wear disposable gloves (Retail \textit{Lm} Risk Assessment/FDA Food Code).
Food Safety and Inspection Service
Percentage of Delis Following All of the Top 8 Recommendations by Quarter

* Preliminary data
Food Safety and Inspection Service
Delis Following All of the Top 8 Recommendations by State

Less than 40% of delis following all top 8 recommendations
40 to 59% of delis following all top 8 recommendations
60 to 79% of delis following all top 8 recommendations
80% or more of delis following all top 8 recommendations
Food Safety and Inspection Service
Delis Following all of the Recommendations by Food Code Version

Percentage of Delis Following All 8 Top Recommendations by Food Code Version

Food Code Data from Association of Food and Drug Officials 2016 Survey
**Food Safety and Inspection Service**  
**Percentage of Delis Following Individual Top 8 Recommendations (Jan 2016-May 2017)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Percentage of Delis Following Recommendation (n=2251)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adulterated products present</td>
<td>1922</td>
</tr>
<tr>
<td>Refrigerate RTE products promptly</td>
<td>1864</td>
</tr>
<tr>
<td>No RTE products near raw products</td>
<td>1718</td>
</tr>
<tr>
<td>Cover RTE products promptly</td>
<td>1675</td>
</tr>
<tr>
<td>No insanitary product cond.</td>
<td>1857</td>
</tr>
<tr>
<td>Clean &amp; sanitize equip. every 4 h</td>
<td>1612</td>
</tr>
<tr>
<td>Sanitary facility conditions</td>
<td>1885</td>
</tr>
<tr>
<td>Use of disposable gloves</td>
<td>1864</td>
</tr>
</tbody>
</table>
Food Safety and Inspection Service
Recommendation That is Not Being Followed in Delis
Following 7 out of 8 Recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Percentage of Surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean &amp; sanitize equip. every 4 h</td>
<td>224</td>
</tr>
<tr>
<td>Cover RTE products promptly</td>
<td>172</td>
</tr>
<tr>
<td>No RTE products near raw products</td>
<td>120</td>
</tr>
<tr>
<td>No insanitary product cond.</td>
<td>40</td>
</tr>
<tr>
<td>Refrigerate RTE products promptly</td>
<td>32</td>
</tr>
<tr>
<td>Use of disposable gloves</td>
<td>25</td>
</tr>
<tr>
<td>Sanitary facility conditions</td>
<td>16</td>
</tr>
</tbody>
</table>
• FSIS plans to continue to analyze the data from the eight most important practices on a quarterly basis to identify areas to focus its outreach efforts.

• Based on the data analysis, FSIS plans to work with FDA and other public health partners to develop specific outreach materials (e.g., for slicer cleaning).

• FSIS also plans to focus its outreach efforts on retailers that have less access to guidance materials (e.g., independently owned stores, ethnic markets).

• By the end of FY 2021, FSIS expects that 64% of retailers will follow all eight of the recommended actions.

• FSIS will not perform sampling at retail delis for this project.
**FSIS Rulemaking**

- On **December 14, 2015**, FSIS published the final rule, “Records to be Kept by Official Establishment and Retail Stores That Grind Raw Beef Products.”

- The Rule became effective on June 20, 2016, and full enforcement started April 1, 2017.

- This rule is necessary to improve FSIS’s ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that may be attributable to these outbreaks.
The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of *E. coli* O157:H7 and other bacteria from one lot of product to another.

When records are available and complete, FSIS is often able to identify specific production in an official establishment.

### Status of Retail Grinding Records

<table>
<thead>
<tr>
<th>Status of retail grinding records</th>
<th>Number of investigations</th>
<th>Number resulting in recalled product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available and complete</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>Not available</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Available, but incomplete</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>
Food Safety and Inspection Service
How is the Final Rule Enforced?

• In retail stores, FSIS’ Office of Investigations, Enforcement and Audit (OIEA) Compliance Investigators verify compliance by following the instructions found in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*.

• In FSIS establishments, FSIS’ Office of Field Operations (OFO) Consumer Safety Inspectors verify compliance.
Final Rule – (1) Mandatory — verified by inspection program personnel & in-commerce surveillance by compliance investigators

§ 320.1 Records to be kept.
(b) * * *

**Added** (4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:

(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product,
(B) All supplier lot numbers and production dates,
(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next,
(D) The date and time each lot of raw ground beef product is produced, and
(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.
# Mandatory Recordkeeping

**NEW WAVE STORE**

123 Main Street

Anytown, USA, Zip Code

**FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST**

<table>
<thead>
<tr>
<th>Employee Name</th>
<th>Today's Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date and Time of Grind</th>
<th>Manufacturer Name of Source Material Used for Product Produced</th>
<th>Supplier Lot #s, Product Code and/or Pack Date of Source Material Used</th>
<th>Est. Number(s) of Est. providing source material</th>
<th>Date and Time Grinder and Related FCSs Cleaned and Sanitized</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature of Store Management Reviewer

Date
FSIS collects ground beef samples at retail under the MT05 and MT06 sampling programs.

OIEA Investigators are to collect a sample if the store is:

- Grinding source materials that are not accompanied by records of negative *E. coli* O157:H7 test results;
- Grinding store generated bench trim from non-intact meat cuts such as those that have been mechanically tenderized or enhanced (80 FR 28153);
- Not cleaning and sanitizing the grinder or other food contact surfaces between the use of different source materials;
- Using meat cuts with expired sell-by dates;
- **Grinding and failing to keep records sufficient for trace back (9 CFR 320.1(b)(4));**
- Mixing irradiated and non-irradiated beef;
- Mixing previously ground beef (regardless of source) from different sources and regrinding it; or
- Grinding under insanitary conditions.
From April 1, 2017 – May 31, 2017, FSIS has collected 10 ground beef (MT05) samples at retail stores due to the grinding records being insufficient for traceback.

- One sample tested positive for *E. coli* O157:H7 and the product was recalled. FSIS issued a Notice of Warning (NOW) to the firm for production and sale of adulterated product and record keeping violation.

FSIS presented 30 outreach presentations and webinars in FY16 and 9 in FY17.

FSIS is currently working on guidance material for grinders.
Acknowledgements

- Susan Hammons
- Carrie Clark
- Christopher Aston
- Yoel Izsak
- Jennifer Webb
- Sara Baucher
Food Safety and Inspection Service: Questions

Questions?