



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



FMI Antitrust Statement

FMI believes strongly in competition. Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

Association meetings or workshops by their very nature bring competitors together. It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns. Agreements to fix prices, allocate markets, engage in product boycotts and to refuse to deal with third parties are illegal under the antitrust laws. At any association meeting discussions of prices (including elements of prices such as allowances and credit terms), quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, or selling to a particular customer, should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

An antitrust violation does not require proof of a formal agreement. A discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion is enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

As a practical matter violations of these rules can have serious consequences for a company and its employees. Antitrust investigations and litigation are lengthy, complex and disruptive. The Sherman Act is a criminal statute, and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus attorney's fees.

If you have any questions or concerns at this meeting, please bring them to the attention of FMI staff.

Food Safety and Inspection Service:

Mechanically Tenderized Beef

Food Marketing Institute

November 19, 2015

Mark Wheeler, Biological Scientist
Labeling and Program Delivery Staff (LPDS)
Food Safety and Inspection Service (FSIS), USDA

Food Safety and Inspection Service: Agenda

- What is LPDS?
- Background
- The final rule
 - requirements
 - Implementation dates
 - Label examples
- Questions and Answers
 - XX
- Resources
- Contacts Information
- Questions

Food Safety and Inspection Service: LPDS Mission Statement

- The Labeling and Program Delivery Staff (LPDS) develops policies and inspection verification methods and administers programs to protect consumers from misbranded and economically adulterated meat, poultry, and egg products such that all labels are truthful and not misleading

Food Safety and Inspection Service:
**Background – Needle- or Blade-Tenderized
(Mechanically Tenderized) Beef Products (MTB)**

FSIS received petitions from Safe Food Coalition and Conference of Food Protection

- to require labels of mechanically tenderized beef products to specify that the products were mechanically tenderized.

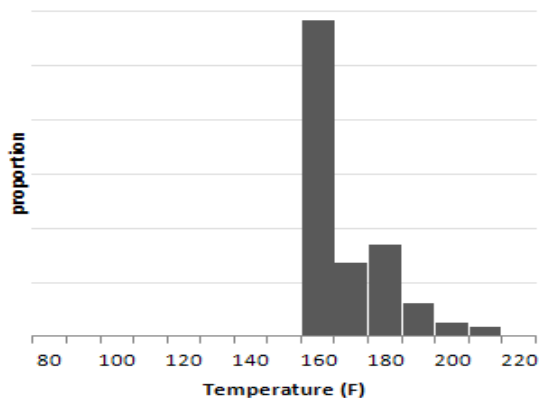
Food Safety and Inspection Service:
Background – MTB Product, continued

- Since 2003, the CDC has received reports of six outbreaks attributable to needle- or blade-tenderized beef products prepared in restaurants and consumers' homes.
- Among these outbreaks, there were a total of 157 E. coli O157:H7 cases that resulted in 27 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS).

Food Safety and Inspection Service: Background – MTB Product, continued

Benefit

- Estimate of illness from public health surveillance
 - 63,153 (annual illnesses) x 0.394 (beef attributable) × 0.079 (non-intact) = **1,965**
- Consider effect of changing cooking behavior



Decreases illnesses by 1887 to 78

Food Safety and Inspection Service: Background – MTB Product, continued

- FSIS received 122 comments on the proposed rule –(approx. 75 comments were form letters)
 - Nearly 100 comments in support of the rule requiring the descriptive designation “mechanically tenderized” because these products pose an increased risk to consumers and agree it is necessary to inform consumers that these products should be handled differently than intact products
 - Commenters also supported the need for validated cooking instructions because research supports that these products must be cooked more thoroughly to eliminate pathogens

Food Safety and Inspection Service: Background – MTB Product, continued

- Commenters opposed to the rule stated changes were unnecessary because of the presence of safe handling instructions which state raw beef products must be cooked thoroughly before consuming; that label changes will be ineffective on consumer behavior; and that the term “mechanically tenderized” is overly broad and inaccurate.

Milestones

- June 10, 2013 - Proposed Rule published
- August 9 2013 - Extended comment period
- December 4 reopened comment period until Dec 24, 2013
- May 18, 2015 - Final Rule published
- Effective May 17, 2016

Food Safety and Inspection Service: Application of MTB regulation

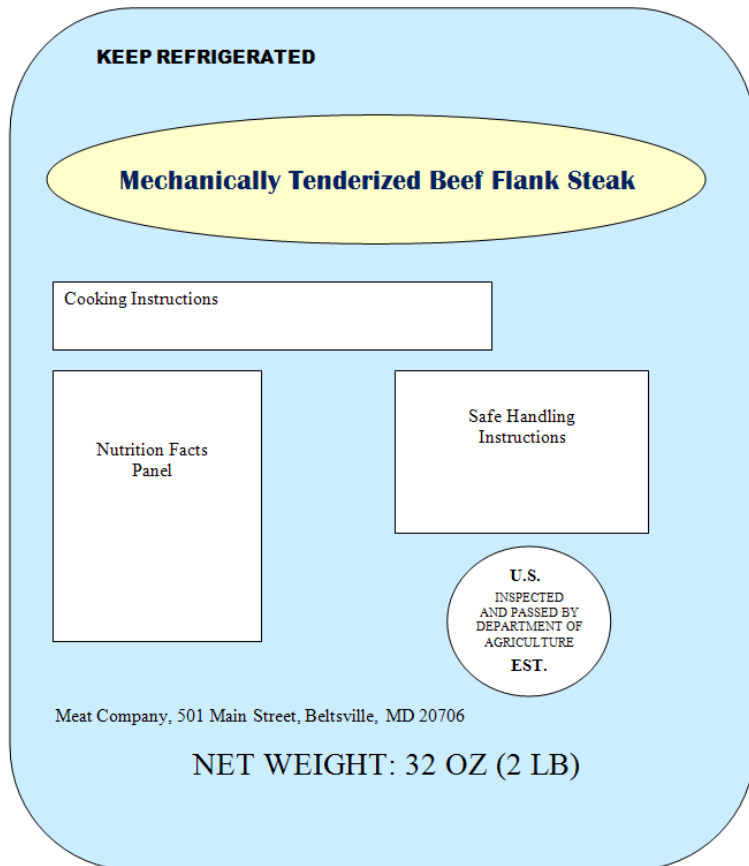
- Products covered:
 - Needle- or blade-tenderized raw beef products product destined for household consumers, hotels, restaurants, or similar institutions
- Products not covered
 - MTB Products destined to be fully cooked at an official establishment
 - Other tenderization methods, such as pounding and cubing, change the appearance of the product, putting consumers on notice that the product is not intact

Food Safety and Inspection Service: Descriptive Designation of MTB Products

Labels must bear:

- 1) The descriptive designation “mechanically tenderized,” “blade tenderized,” or “needle tenderized” and an accurate description of the beef component in the product name; and
- 2) All words in the descriptive designation be in the same style, color, and size and on a single-color contrasting background
- 3) Up and lower case allowed; however, the smallest letter must be at least 1/3 the size of the largest letter
- 4) Validated cooking instructions for subject products destined for household consumers, hotels, restaurants, or similar institutions.

Food Safety and Inspection Service: Descriptive Designation of MTB Products continued



Validated cooking instructions need to include:

- a cooking method
- that these products need to be cooked to a specified minimum internal temperature,
- whether these products need to be held at that minimum temperature or higher for a specified time before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed,
- and that the internal temperature should be measured by a thermometer.

Food Safety and Inspection Service: Cooking Instruction (Example)

- **For Food Safety and Quality Follow These Cooking Instructions:**

Gas Grill:

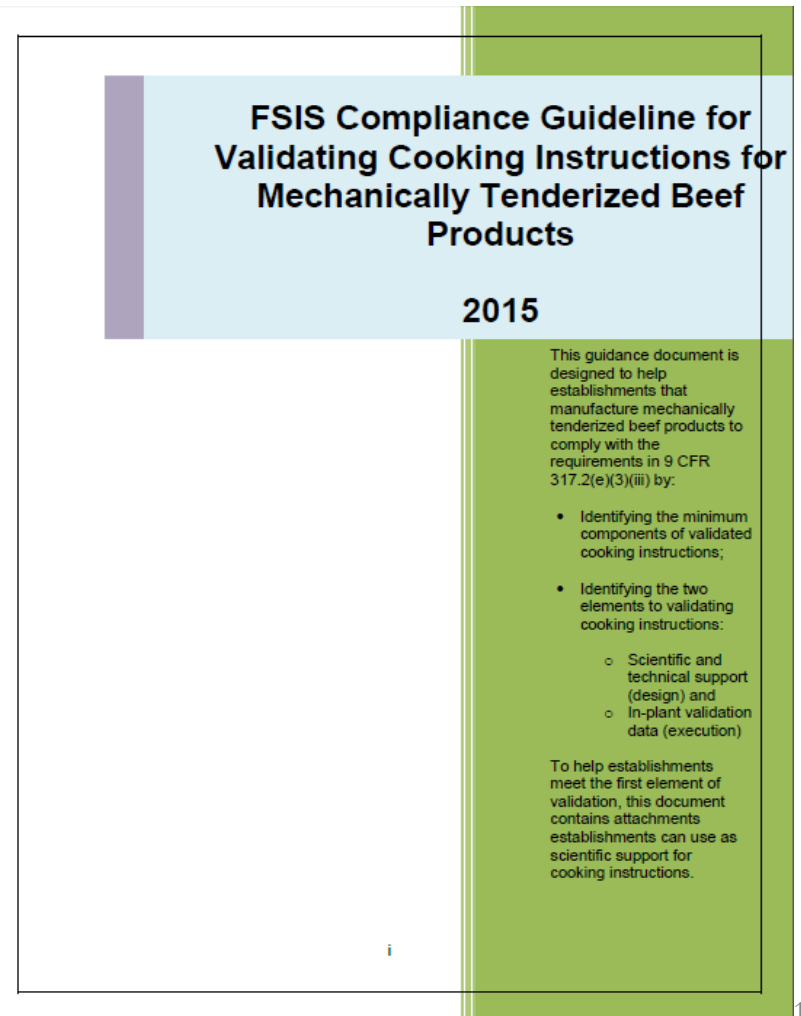
- 1) Heat gas grill on Medium-High.
- 2) Cook for 6 minutes to an internal temperature of 145°F as measured with a food thermometer. Flip steak over at least twice during cooking.
- 3) After removing from the gas grill, for safety, allow meat to rest at or above the minimum temperature of 145° F internal temperature for at least three minutes before serving.

* Please note that the above instructions are an example of cooking instructions. Your instructions may not be the same as these; however, your instructions should provide the preparer with clear instructions to get to the necessary end point temperature.

Food Safety and Inspection Service: Validating Cooking Instructions

- FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products is available here:

http://www.fsis.usda.gov/wps/wcm/connect/606919b6-5192-40bd-a32b-99a41c75eeb6/Comp_Guide_MTB.pdf?MOD=AJPERES.



Food Safety and Inspection Service:
Questions and Answers

Questions
And
Answers

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Do the new labeling requirements apply to mechanically tenderized beef products labeled or prepared at retail stores?
- **Answer:** Yes. The retail product, if mechanically tenderized and sold raw, must bear the descriptive designation and validated cooking instructions, as per the regulation.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Can “needle injected” be used as a descriptive designation on the labels of raw or partially cooked beef products that have been mechanically tenderized?
- **Answer:** No. “Needle Injected” can not be used.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Could you please clarify if beef cubed steak is subject to the requirements of mechanically tenderized rule?
- **Answer:** No. This regulation does not apply to cubed products. The regulation is specific to needle and blade tenderized beef products.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Must the label of a raw or partially cooked mechanically tenderized beef product that contains added solution declare the percentage of added solution?
- **Answer:** Yes. There are different options for labeling the product. However, in the end, the label will need to indicate that the product has been mechanically tenderized **and** declared the total amount of solution added, i.e., total pick up, to the product both by injection and tumbling.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Can the labels for mechanically tenderized beef products considered to be generic labels or are these labels that must be submitted to LPPD for approval?
- **Answer:** Yes. As stated in the rule, the labels will be considered "generic," as long as there are no unapproved special statements or claims and as long as it is in compliance with all of the other labeling regulations (refer to 9 CFR 412.2).

NOTE: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** Does a specific cooking method need to be part of the cooking instructions for mechanically tenderized beef products destined for HRI?
- **Answer:** Yes. The Rule is specific that the 4 pieces of information must be included on the product label. Whenever applicable, validated cooking instructions must include (1) the method of cooking; (2) a validated minimum internal temperature that would destroy pathogens throughout the product; (3) a statement as to whether the product cooked in the manner described also needs to be held for a specified time at the specified temperature or higher before consumption; and (4) instruction that the internal temperature should be measured by use of a thermometer.

Food Safety and Inspection Service: Questions and Answers, continued

- **Question:** For the upcoming Mechanically Tenderized Labeling and Validated Cooking Instruction requirements, can establishments use a grid or table format to display cooking times and temperatures based on product thickness? For example:

Cook the following size steaks on a grill heated to medium-high for the time indicated until the steak reaches 145 as measured with a meat thermometer. Then allow to rest for 3 minutes.

Size (Thickness)	Cooking time
0.5"	1 ½ min, flip and cook for 1 ½ min
1.0"	1 ½ min, flip and cook for 2 min
1.5"	2 min, flip and cook for 2 min
2.0"	2 ½ min, flip and cook for 2 ½ min
2.5"	2 ½ min, flip and cook for 3 min
3.0"	3 min, flip and cook for 3 min
3.5"	3 min, flip and cook for 4 min

- **Answer:** A chart would be acceptable, as long as the requirements for the validated cooking instructions were met, e.g., identifying a cooking method, a statement as to whether the product needs to be held for a specific time at the specified temperature or higher before consumption, and instruction that the internal temperature should be measured by the use of a thermometer.

Food Safety and Inspection Service: Available Resources on MTB

MTB Final Rule:

<http://www.fsis.usda.gov/wps/wcm/connect/ea5a6c2e-a3d0-4990-9479-755e82f5ceb2/2008-0017F.pdf?MOD=AJPERES>

FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products:

http://www.fsis.usda.gov/wps/wcm/connect/606919b6-5192-40bd-a32b-99a41c75eeb6/Comp_Guide_MTB.pdf?MOD=AJPERES

MTB Proposed Rule:

<http://www.fsis.usda.gov/wps/wcm/connect/741a8b94-85b0-4800-963e-ad0517838a02/2008-0017.pdf?MOD=AJPERES>

Added Solution Final Rule:

<http://www.fsis.usda.gov/wps/wcm/connect/942b0716-42a9-4d0e-8e5f-3ba4d2dfc70d/2010-0012.pdf?MOD=AJPERES>

Food Safety and Inspection Service: Available Resources on Labeling

FSIS Main Labeling Website:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>

LSAS:

<http://lsas.fsis.usda.gov>

Generic Labeling Resources:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies>

FSIS Directives:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives>

Submit questions through askFSIS <http://askfsis.custhelp.com>

Call LPDS at (301) 504-0878

Call RIMS at (301) 504-0890

Food Safety and Inspection Service: Available Resources: askFSIS

For Labeling Questions - askFSIS <http://askfsis.custhelp.com>

- Use the “Submit A Question” tab, and enter the following:
- Subject Field: Enter **Mechanically Tenderized**
- Question Field: Enter your question with as much detail as possible.
- Product Field: Select **Labeling** from the drop-down menu.
- Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu
- Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu
- When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

Food Safety and Inspection Service: **Available Resources: askFSIS**

For Validation or Cooking Instructions Questions - askFSIS
<http://askfsis.custhelp.com>

- Subject Field: Enter **Topic Name (e.g., Validation of cooking instructions)**
- Question Field: Enter question with as much detail as possible.
- Product Field: Select **General Inspection Policy** from the drop-down menu.
- Category Field: Select **Sampling** from the drop-down menu.
- Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

Food Safety and Inspection Service: Contacting LPDS or RIMS by Phone

- When leaving a phone message
 - 301-504-0878 general voice mail for LPDS or 301-504-0890 for RIMS
 - Speak slowly and clearly
 - Provide your name and phone number, repeat number
 - Specify the topic of your question (not “labeling”)

Food Safety and Inspection Service:

Questions?