

WORKSHOP 1

*The New *Listeria* Regulation*

IS THE REGULATION APPLICABLE TO YOUR PRODUCT?

Labeling, Identification, and Post-Lethality Control Alternatives

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IS THE REGULATION APPLICABLE TO YOUR PRODUCT AND WHAT IS THE APPROPRIATE POST- LETHALITY CONTROL ALTERNATIVE ?

- Step 1
 - Determine whether the product is a Ready-to-Eat (RTE) product
- Step 2
 - Determine whether the RTE product is exposed post-lethality
- Step 3
 - Determine whether the product is a deli or hotdog product
- Step 4
 - Determine the control measures used for the product and the alternative into which your product fits

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Step 1

Determine Whether the
Product is RTE

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Is the Regulation Applicable to My Product?

■ Step 1

- Determine whether the product is a Ready-to-Eat (RTE) product
 - Some products are defined by standards as RTE
 - Some products expected to be RTE
 - Some products may be RTE or may be not-ready-to-eat (NRTE)
 - Some products are labeled to represent them as RTE

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- Step 1 Continued

*Definition of Ready-to-Eat (RTE) Product
(9 CFR Part 430)*

- A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety
- May receive additional preparation to make the product taste better and/or look better
- Can include frozen meat and poultry products

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Other Regulatory Terms Defined in the Lm Rule

- Antimicrobial Agent
- Antimicrobial Process
- Deli Product
- Hotdog Product
- Lethality Treatment
- Post-lethality Processing Environment
- Post-lethality Treatment

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■ Step 1 Continued

Examples of RTE Products

*Five Categories That May Represent RTE Products
But That May or May Not Be Post-Lethality Exposed*

- Cooked or Otherwise Processed Whole or Comminuted Products
- Fermented Meat and Poultry Products
- Salt-cured Products
- Dried Products
- Thermally-Processed, Commercially Sterile Products

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■ Step 1 Continued

-- Cooked or Otherwise Processed Whole or Comminuted Products

Includes Meat and Poultry Products Such As These, or Containing These:

- Cooked/cured sausages, e.g., bologna, hotdogs, weiners, turkey franks, cotto salami, poultry roll
- Cooked/smoked sausages, e.g., berliner, cheese smokies
- Cooked sausages, e.g., pork sausage patties, brown and serve sausages
- Cooked pastrami, corned beef, roast beef, roast pork, cooked ham, fried chicken, cooked/breaded chicken nuggets

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■ Step 1 Continued

-- Cooked or Otherwise Processed Whole or Comminuted Products

Includes Meat and Poultry Products Such As These, or Containing These:

- Meat or poultry loaf, gyros
- Cooked meat or poultry chili, stew, ravioli
- Cooked pork in BBQ sauce, chicken/turkey BBQ
- Chicken burritos, pork eggrolls
- Entrees/dinners

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■ Step 1 Continued

-- Fermented Meat and Poultry Products

Includes Meat and Poultry Products Such As These, or Containing These:

Lebanon bologna
Pepperoni
Cervelat
Chorizo
Genoa or Italian salami
Summer sausage
Cacciatore (a dry sausage)

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■ Step 1 Continued

-- Salt-cured Products

Includes Meat and Poultry Products Such As These, or Containing These:

Coppa
Country ham
Parma ham
Prosciutto
Dry cured duck

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■ Step 1 Continued

-- Dried Products

Includes Meat and Poultry Products Such As These, or Containing These:

Beef sticks
Meat/poultry jerky
Basturma, Pastirma
Dried beef

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■ Step 1 Continued

-- Thermally-Processed, Commercially Sterile Products

Includes Meat and Poultry Products Such As These, or Containing These:

Canned ham

Canned soups with meat or poultry

Canned meat/poultry stew, ravioli, lasagna

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■ Step 1 Continued

-- Identifying a RTE Product

- RTE products are not required to bear safe-handling instructions (as required for non-RTE products by 9 CFR 317.2 (k)(1) and 381.125(b))
- RTE product labeling does not instruct the consumer that the product must be cooked or otherwise treated for safety
- In many cases, RTE product labeling is guided by various factors

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Step One Continued Identifying a RTE product

1. By standard of identity in regulations or policy in Food Standards and Labeling Policy Book
e.g., hotdogs are defined as “cooked” products



8 Skinless Beef Franks

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Identifying a RTE product

2. Consumer expectations/long term production practices
e.g., Pates – understood by consumers to be a RTE product



French Liver Pate with 1% Truffle

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Identifying a RTE product

3. Nutrition Labeling-
Serving size for RTE
products is based on
ready-to-serve
reference amounts
Customarily
Consumed (RACC)
- Potstickers ready to
serve = 140 grams (g)



Serving Size 8 Pcs. (140g)

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Identifying a RTE product

4. Labeling terms on
principal display
panel (PDP) of
product labels

Examples:

- Heat and serve
- Ready to eat



Simply heat and serve

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Identifying a RTE product

5. Preparation Instructions

Examples:

- Microwave Oven Preparation
- Conventional Oven Preparation

HEATING INSTRUCTIONS

STOVE TOP
It is recommended that the contents be heated to 165°F
 1. Place contents in a 2 quart covered sauce pan.
 2. Heat on medium setting for 12-15 minutes, stirring occasionally until hot.

OVEN
 1. Preheat to 350°F and place contents in covered pan or casserole dish.
 2. Heat 35-40 minutes for full container or 25-30 minutes for 1/2 container.
 Stir before serving.

MICROWAVE
Lloyd's tub is microwavable!
 1. Remove package sleeve, container lid, and freshness film.
 2. Cover container with plastic wrap and poke 3-4 holes in plastic to vent.
 3. Heat on high for 10-12 minutes, stirring once every 3-4 minutes for full container. Reduce heating time for smaller portions.
 4. Stir thoroughly and serve.
Microwave ovens vary in rate of heating. Times given are approximate.

CAUTION! CONTENTS WILL BE HOT
OKAY TO FREEZE OR REFREEZE AFTER OPENING.
ONCE SEAL IS BROKEN, USE OR FREEZE WITHIN 5 DAYS.

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Identifying a RTE product

6. HACCP category

i.e., HACCP category
 - is entered into block 5B on the FSIS Form 7234-1 (10/03/2002)

Examples

- Not heat treated-shelf stable
- Heat treated- shelf stable
- Fully cooked - not shelf stable

The image shows a portion of the FSIS Form 7234-1. A blue arrow points to a yellow highlighted box in block 5B, which is used for entering the HACCP process category. The form includes various fields for product information, HACCP process details, and regulatory compliance.

Instructions:
 Provide HACCP process category for the product. See 9 CFR 417.2(b) (1),

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Step 2

Determine Whether the RTE Product Is Post-Lethality Exposed

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Step 2 Continued -- Determine Whether the Product Is Post-Lethality Exposed

- Post-Lethality Exposure
- Is there direct exposure of RTE product to a food contact surface or the processing environment after the lethality treatment?
- Examples of routes of exposure to food contact surface in processing environment
 - slicing
 - peeling
 - re-bagging
 - cooling semi-permeable encased product with brine solution

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Step 2 Continued -- Determine Whether the RTE Product Is Post-Lethality Exposed

Environmental-type Routes of Contamination

■ Direct Contact

- Direct exposure of RTE product to a food contact surface

■ Indirect Contact

- Potential contact of exposed RTE product
 - Handling a mop handle with a hand and then touching RTE product
 - Soiled apron touching product

■ No Contact

- Floors, drains, overhead structures

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Step 3

Determine Whether the Product Is a Deli or Hotdog Product

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Step 3 Continued

Is My Product a Deli or Hotdog Product?

- Now that you know which of your products is applicable to the new *Listeria* rule (i.e., post-lethality exposed RTE), determine whether your product is a **deli** or **hotdog** product, as defined in the rule

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Deli and Hotdog Products

- Deli products are RTE meat or poultry products that are typically sliced, either in an official establishment or after distribution from establishment, and typically assembled in a sandwich for consumption, e.g., spiral cut bone-in hams; bologna; boiled/baked ham; roast beef; turkey breast; chicken roll

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Deli and Hotdog Products

- Typical hotdogs are RTE meat or poultry franks, frankfurters, weiners per 9 CFR 319.180 standard (thus, does not include products like bratwurst, polish sausage, other cooked sausages covered by 9 CFR 319.140)

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Step 4

Determine the Control Measures Used for
the Product
and
the Alternative Into Which Your Product Fits

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Step 4 Into Which Alternative Does My Product Fit?

- Now that you know which of your products are covered by the new *Listeria* rule (i.e., post-lethality exposed RTE), determine which alternative control measure your product fits into.

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Step 4 Continued Into Which Alternative Does My Product Fit?

- Alternative 1 Product
 - Post-lethality treatment **and** antimicrobial agent/process
 - The Post-lethality treatment and antimicrobial agent/process must each be documented to be sufficient to provide enhanced safety.

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Step 4 Continued Into Which Alternative Does My Product Fit?

■ Alternative 2 Product

- Post-lethality treatment **or** antimicrobial agent/process
- The Post-lethality treatment **or** antimicrobial agent/process must be documented to be sufficient to provide enhanced safety.

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Step 4 Continued Into Which Alternative Does My Product Fit?

■ Alternative 3 Product

- Use of sanitation measures only (in accordance with 9 CFR 430.4 (b)(3))
 - * May have post-lethality treatment and/or antimicrobial agent/process but not documented as being sufficient to provide enhanced safety
- Special restrictions regarding potential adulteration of deli and hotdog products

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Labeling of RTE Products

- Ingredients Statements
- Claims Based on Use of Antimicrobial Ingredients and Post-Lethality Treatments

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Labeling Ingredients in Formulations of RTE products

e.g., Hotdog Ingredients: pork, water, beef, dextrose, salt, corn syrup, **sodium lactate**, flavorings (spice extractives, garlic powder), modified food starch, sodium phosphate, **sodium diacetate**, paprika, sodium erythorbate, sodium nitrite.

- Modifying an ingredients statement to add a safe and suitable antimicrobial agent may be done generically

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Labeling of RTE Products for Post-Lethality Treatment and Antimicrobial Claims

- Labels for RTE products that bear claims about antimicrobial agents in formulations and post lethality treatments **must** be submitted to Labeling and Consumer Protection Staff (LCPS) for review
- Examples of claims:
 - Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*.

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Label Claims for Enhanced Safety

- Labeling claims about the enhanced safety of a product (regarding *Listeria*) are more likely to be approved if the post-lethality treatment achieves a 1 log reduction or greater of *L. monocytogenes*, and if the antimicrobial agent or process suppresses *L. monocytogenes* growth such that there is 1.0 log or less increase throughout the product's expected shelf-life
 - ** unless compelling supporting data are provided to address less rigorous lethality/growth parameters

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Distinguishing RTE From Not Ready-to-Eat (NRTE) Products by Labeling

**Guidance provided in Attachment 2,
FSIS Directive 10,240.3 (12/09/2002)**

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The End



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