#### **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 POSTLETHALITY 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

# Step 1 Determine Whether the Product is RTE

# 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

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

#### **■** 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

## ■ 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)

# ■ 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

#### ■ 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

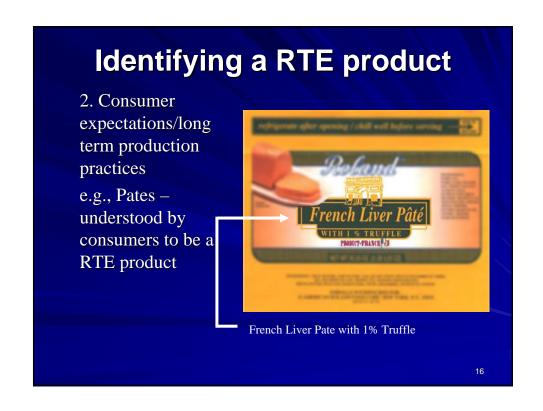
Canned meat/poultry stew, ravioli, lasagna

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#### ■ Step 1 Continued

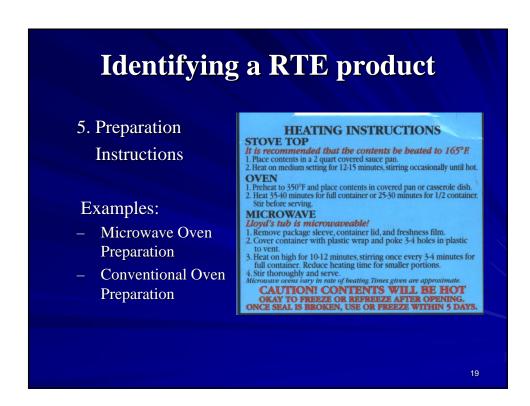
- -- Identifying a RTE Product
- RTE products are not required to bear safehandling instructions (as required for non-RTE products by 9 CFR 317.2 (k)(1) and 381.125(b)
- RTE product labeling does not instruct the consumer that the product must be cooked or otherwise treated for safety
- In many cases,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

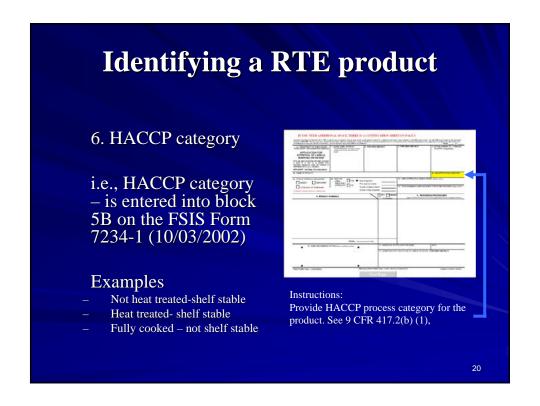












# Step 2

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

# 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

# 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 bonein hams; bologna; boiled/baked ham; roast beef; turkey breast; chicken roll

#### 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

# 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.

# 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

# **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

#### 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

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

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

