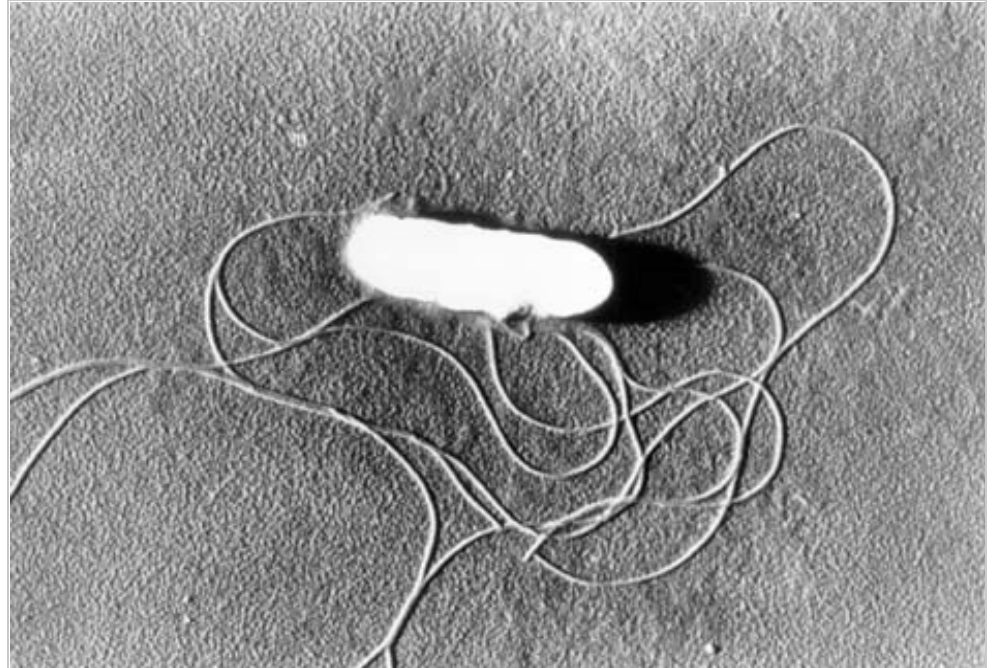


FSIS Interim Final Rule for Listeria Control

LISTERIA MONOCYTOGENES **PERFORMANCE STANDARD**

ZERO TOLERANCE





Federal Register

Friday,
June 6, 2003

Part V

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 430
Control of *Listeria monocytogenes* in
Ready-to-Eat Meat and Poultry Products;
Final Rule

9 CFR Part 430 Control of *Listeria* In Ready to Eat Meat And Poultry Products

This interim final
rule took effect on
October 6, 2003

Public Health

Best protected by control of Listeria by:

- Aggressive environmental sampling
 - Success depends on finding positive results
 - Punishment for positive results courts failure
- Effective corrective actions
- Proper equipment design
- Adherence to GMPs and SSOPs
- Product formulation (lactate salts/sodium diacetate)
- Other interventions as available

FSIS DIRECTIVE 10,240.2, *Microbial Sampling of RTE Products Produced by Establishments Operating Under a HACCP System (8/6/98; revised 12/1/00)*

***L. monocytogenes* is a hazard likely to occur ... & must be controlled through validated & verified processes ...**

FSIS DIRECTIVE 10,240.3

- **RISK-BASED PRODUCT CATEGORIES**
- **INCREASED FOCUS ON *LISTERIA* CONTROL PROGRAMS**
- **ASSESSMENT OF ENVIRONMENTAL & PRODUCT CONTACT SURFACES**

FSIS DIRECTIVE 10,240.4

- **RESPONSE TO ENVIRONMENTAL (+)**
- **STATISTICAL CONFIDENCE IN ACTIONS**
- **PREREQUISITE VS. SSOP VS. HACCP**
- **INTENSIFIED SAMPLING**

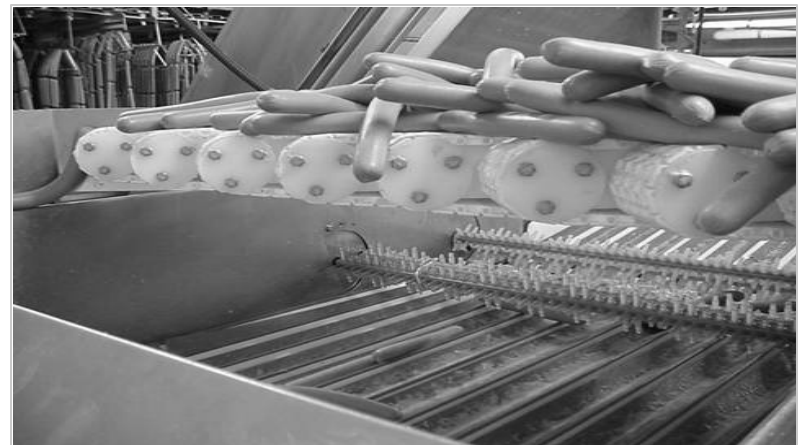
INTERIM RTE RULE

- Mandates control of *L. monocytogenes* in post-lethality exposed RTE products
- Establishes *alternative* product categories
- Requires environmental monitoring & corrective actions
- Mandates sharing of monitoring records
- Provides incentives for post-lethality control measures

REGULATORY DEFINITION

Post-Lethality Processing Environment

The area of an establishment into which product is routed after having been subject to an initial lethality treatment. The product may be exposed in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.



Under control?

How extensive the exposure?

REGULATORY DEFINITION

Post-Lethality Exposed Product

RTE product that comes into direct contact with a food contact surface after the lethality treatment in a post lethality processing environment.

How extensive?

Who's the customer?

Flash pasteurized?



REGULATORY DEFINITION

Antimicrobial Agent

“a substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism or of suppressing or limiting its growth throughout the shelf life of the product.”

Must limit growth to < 2 logs over shelf life

If growth limited to < 1 log, considered enhanced

REGULATORY DEFINITION

Antimicrobial Process

“an operation, such as freezing, that is applied to an RTE product and that has the effect of suppressing or limiting the growth of a microorganism.”

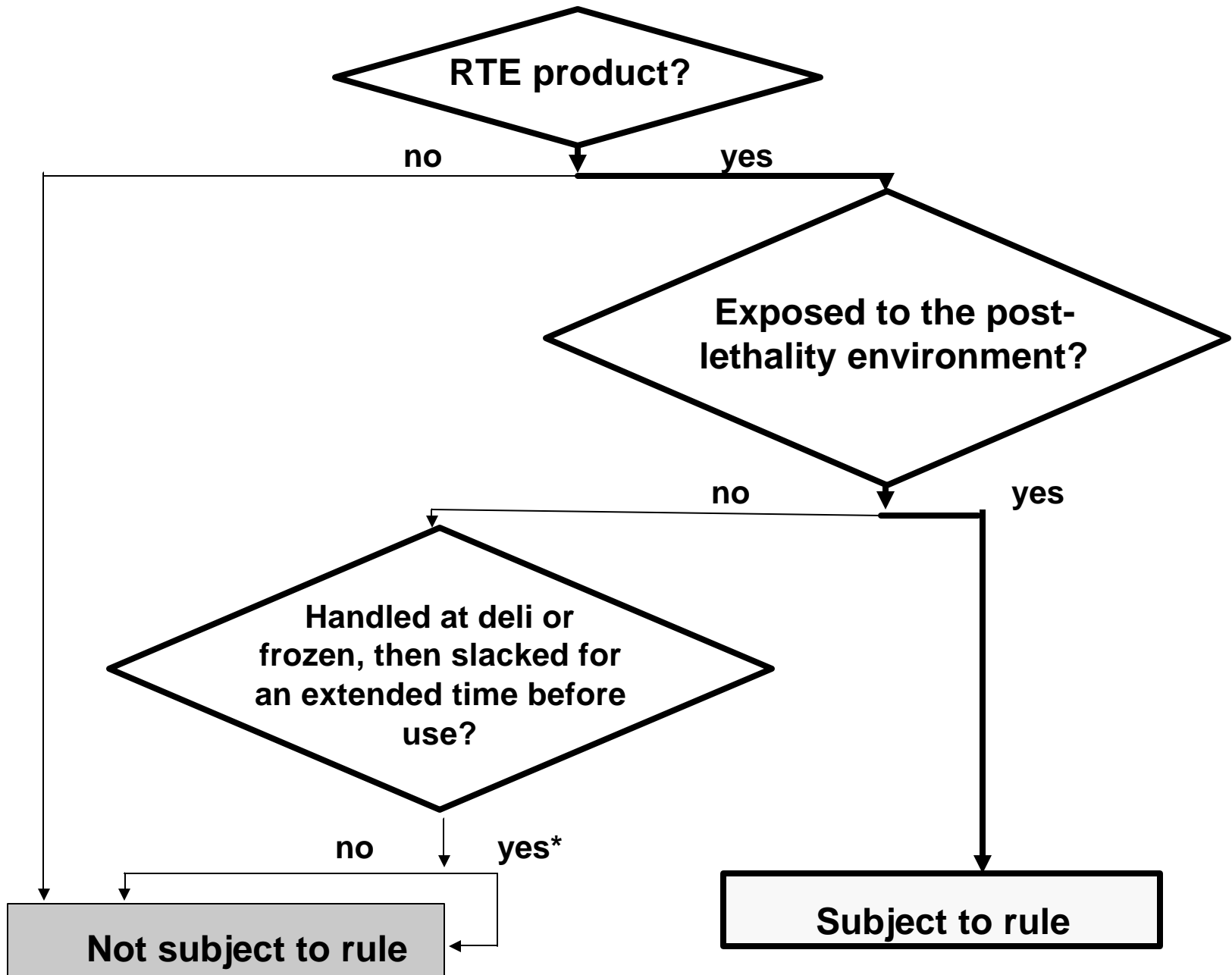
REGULATORY DEFINITION

Post-Lethality Treatment

“a lethality treatment applied to a product after post-lethality exposure. A post-lethality treatment might be an additional heat step or other pasteurization process, such as high-pressure processing.”

Must achieve at least a 1 log reduction

If reduction is 2 log or greater, considered enhanced



* Not subject to the rule, but 9 CFR 417 does require the establishment to address product handling after the product has left the establishment

RISK RANKING

Higher
sanitation



PL treatment or
AM agent/process
+ sanitation

Lower
PL treatment and
AM agent/process

ROUTINE ENVIRONMENTAL TESTING

Alternative 3

Corrective Actions

Intensified Testing

Lot Release Criteria

FCS

**Trigger & Conditions
for Hold & Test**

Alternative 2

FCS

**Trigger for
Hold & Test**

Alternative 1

Voluntary

Environmental Sampling Program Requirements

- Alternative 2
 - Implement Food Contact surface testing
 - Identify conditions for hold/test implementation
 - State testing frequency, sample size and site
 - Support Food Contact surface testing frequency
 - Incorporate this testing program into HACCP, SSOP, or pp
 - Data available to FSIS
- NOTE: There is no requirement for environmental sampling if only alternative 1 products are manufactured at the facility
- Alternative 3
 - Same as alternative 2 unless Deli and/or hot dog items produced in alt. 3 - if so, program must also
 - Verify corrective actions via follow-up testing
 - During follow-up testing, if second positive occurs, hold product lots implicated
 - Test held lots
 - Support product testing methodology

Current FSIS Interpretation

Type of Sample and Result	FSIS Interpretation
PRODUCT	
Lm	Adulterated
L or L-like	Deemed Adulterated
FOOD CONTACT	
Lm	Adulterated
L or L-like	Not Adulterated, but increased regulatory oversight
Non Food Contact	
Lm	Not Adulterated, increased regulatory oversight
L or L-like	Not Adulterated, increased regulatory oversight

Interim RTE Rule concepts

USDA-FSIS has issued a science-based directive on pathogen sampling to assure:

- removal of penalties for aggressive sampling
- credit for a science based sampling program
- differentiation of product that will not support the growth of *L. monocytogenes*

Verification Testing by FSIS

- FSIS to sample products based on following priority list:
 - Post-Lethality exposed RTE Alternative 3 Products
 - Deli Meats
 - Hot Dogs
 - Deli salads, pate, meat spreads
 - Other
 - Post-Lethality exposed RTE Alternative 2 Products
 - Products with growth inhibitor only
 - Products using post-lethality treatment
 - Post-Lethality exposed RTE Alternative 1 Products
 - RTE Products not subject to the rule, e.g.. cook-in-bag
- When FSIS attains alternative and volume info. as requested via Notice 49-04, a new risk-based RTE sampling program will be implemented

Directive Requirements

- FSIS Product testing - prioritized based on product risk (alternative designation) plus product category (hot dogs, deli meats, other)
- Environmental testing by FSIS only as directed by DO, performed by trained FSIS individuals
- CSI's - focus on Manufacturer's adherence to their program
- CSO involvement - intensive review of program design and validation documentation per 9 CFR Part 430

Industry Response to FSIS RTE Directive 10,240.4

- SSOP revised to include pathogen environmental monitoring or pp implemented
 - Revisions reviewed with local FSIS Inspectors
- HACCP plans for RTE products reassessed
 - Environmental monitoring program referenced at processing steps where RTE product is exposed post-cook prior to packaging
 - Decision Document developed supporting scientific basis of monitoring programs

Industry Response to FSIS RTE Directive 10240.4

- Environmental monitoring program managed as regulatory program, accessible to FSIS
 - Programs revised to include product testing trigger
 - Data shared
 - Positive findings must be addressed with corrective actions as described in program
 - Corrective action documentation available for FSIS review

USDA Microbiological Sampling Plans

Three different sampling programs addressed by FSIS Notice 61-04 addressing FSIS Directive 10.240.4

- ALLRTE
 - Random selection of both post-lethality and non post-lethality exposed RTE products
- RTERISK1
 - ◆ Exposed and non-exposed products based on the priority list found in 10.240.4
- RTE1
 - Directed solely at post-lethality exposed RTE products

Two Phases to RTE1

- Phase one began in January 2005
 - Targeted risk-based sampling plan
 - Plants producing products exposed to the processing environment after the lethality step
- Phase two began in October 2005
 - Designed to address the Agency's concern over a lack of validation data for Alternative 2 products
 - Includes a FSA and food contact surface sampling
 - “Step down” sampling will occur if results support a reduction

FSIS Risk-based Verification Pilot Program

- Plant visits were “not-for-cause” but rather based on criteria such as production volume and types of products produced
- Agency was concerned with a lack of validation for plants producing Alternative 2 products
- One plant per district was visited

Assessment Components

- Evaluation of Establishment Control Programs for *Listeria monocytogenes*
- SSOP verification
- HACCP verification
- Microbiological testing for *L. monocytogenes*
 - Intact Product
 - Product contact surfaces
 - Pre-op
 - Operational
 - Non-product contact surfaces

Evaluation of Establishment Control Programs for *Listeria* *monocytogenes*

- Antimicrobial Agent Employed to Prevent Growth
- Sanitation
- Ongoing Verification System
- Scored on a system of 30 maximum points
- Scores classified as:
 - Conclusive
 - Substantiated
 - Inconclusive

Factors That May Impact Risk-based Verification Sampling for *L. monocytogenes*

Verification Sampling Assessment - Measures

- Type of intervention selected
- Site testing frequency
- Number of consecutive positives triggering product testing (test and hold)
- Sample size
- Validation support data
- Past regulatory sampling results
- Compliance history

USDA will make refinements to the survey documents and the validation checklist instrument based on feedback they receive during the on-going implementation "shakedown" stage.

Risk Assessment Model

- Assessment findings will be incorporated into the model
- Verification data will support discrimination among Alternatives and products
- Transparent for all stakeholders
- Improved allocation of sampling resources
- Thoroughly evaluates the impact of *Listeria* control measures including;
 - Process lethality
 - Antimicrobial agents
 - Sanitation procedures

Next steps

- As noted the pilot study within each USDA district has been completed
- FSIS plans to perform “intensified verification testing” for LM over the next year
- 200 plants to be visited
- Testing will be “not for cause” and will include a food safety assessment
- Sampling will include products, contact and non-contact surfaces and conducting an in depth process control evaluation
- Plants will be given two weeks notice

Next steps

- Several documents describing the program will be published “soon” in the federal register
- USDA plans to incorporate Ann Draughon’s retail deli study they funded in LM risk assessment methodology
- USDA stated they plan to conduct retail sampling for LM
- “We need to know what is going with our products, if something is going on at retail, then we need to address it”. Phil Derfler, FSIS