LISTERIA REGULATIONS
FOR RTE MEAT & POULTRY
PRODUCTS

Skip Seward, Ph.D.
VP – Regulatory Affairs
American Meat Institute
WHAT YOU WILL HEAR

Philosophy behind Regulations
Historical & Current Regulations
Impact of Regulations
Testing for *Listeria*
Problems with Regulations
State of the Industry
MEAT & POULTRY INSPECTION
FSIS BUDGETS – ACTUAL & ESTIMATES

YEAR

$ MM

2001 2002 2003 2004 2005 2006
RECALLS - *L. monocytogenes*

... over 65 MM pounds
LISTERIA MONOCYTOGENES PERFORMANCE STANDARD

ZERO TOLERANCE
BASIS FOR PERFORMANCE STANDARDS

IMPACT ON PUBLIC HEALTH

… the linkages need work
DESIGN OF PERFORMANCE STANDARDS

BALANCING RISK REDUCTION WITH BUSINESS NEEDS

NACMCF, ICMSF, NAS COMMITTEE
DESIGN OF PERFORMANCE STANDARDS

CODEX PRINCIPLES

PRACTICAL & TECHNICALLY ACHIEVABLE

NACMCF, ICMSF, NAS COMMITTEE
REGULATORY INITIATIVES FOR PERFORMANCE STANDARDS

• PR/HACCP RULE

• NON-TRANSPARENT PROCESS
REGULATORY INITIATIVES FOR PERFORMANCE STANDARDS

• INSPECTOR JUDGEMENT

• MEASURES FOR INSPECTION

% NRs Appealed Successfully

- 27% in '02 4th Q
- 45% in '04 3rd Q
9 CFR 416

SANITATION

... the beginning
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 NOTICE - 1999

HACCP REASSESSMENT – CRITICAL FACTORS

1. Pathogen levels in raw materials
   *(we still don’t know)*
2. Validation of lethality treatments
3. Post-lethality exposure
   *(we need more data)*
4. History of product contamination
PRESIDENTIAL PROCLAMATION

Clinton Presidential Address – May, 2000

... reduce listeriosis by 50 percent in 5 years

Food Safety Makes Good Politics

– Who Can Afford to be Against Safe Food?
2001 PROPOSED RULE – PERFORMANCE STANDARD

Lethality & stabilization requirements
Mandatory testing for *Listeria* spp.
Elimination of trichina treatments
Streamlined canning regulations

… the kitchen sink

… led to the 2003 interim final rule on *L. monocytogenes*
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
This interim final rule took effect on October 6, 2003.
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

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
RTE product?

Exposed to the post-lethality environment?

Handled at deli or frozen, then slacked for an extended time before use?

Subject to rule

Not subject to rule

* 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

Alternative 3 > Alternative 2 > Alternative 1

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
INCENTIVE

“products that receive a post lethality treatment achieving at least 2.0 log reduction of \textit{L. monocytogenes} may likely be sampled less frequently than products that receive a post-lethality treatment achieving <2.0 log reduction”

... a limp carrot
IMPACT OF REGULATIONS

• PETITIONS & COMMENTS

• RESEARCH
PETITION TO FDA

Requesting FDA to set a regulatory limit (100/g) for *L. monocytogenes* for certain food categories that do not support the growth of *L. monocytogenes*, and that contain the bacterium at low, but unavoidable, levels that present minimal risk to public health

12/17/03
PETITION TO FDA

FDA Action: Priority A issue for 2005

Petition to FSIS is next
COMMENTS ON THE RULE

Support risk-based sampling of post-lethality exposed RTE products to verify the efficacy of environmental controls

Thus, certain foods that pose virtually no risk should be excluded
COMMENTS ON THE RULE

The fact that there is product exposure during a repackaging operation after the initial cook should not subject a product to the Rule, …

particularly when there is a second lethality step, or when the product is hot-filled
COMMENTS ON THE RULE

Products destined for further processing are not subject to the Rule, and …

… the documentation required should not be a lot-by-lot expectation, but rather periodic verification (e.g., visit or report from the processor)
COMMENTS ON THE RULE

RTE products destined for a non-RTE food should be excluded from the Rule, ...

... as should products such as lard, popped pork skins, pork rinds, dried soup bases, & pickled pig’s feet that will not support the growth of *L. monocytogenes* to infectious levels
The Alternative category for a product should take into account processing at multiple federally-inspected establishments, …, for example,

… an Alt 3 product shipped to another establishment for freezing (now Alt 2)
Assumption that sanitation is only 85% effective is inaccurate ...

>99% more accurate....
COMMENTS ON THE RULE

(+) *Listeria* results do not necessarily mean the plant is operating under insanitary conditions, ...

... & other microbiological data should be considered
COMMENTS ON THE EFFECTIVENESS REPORT

“multiple contact or product positives” should not automatically trigger intensified verification testing …

… should consider the company’s Listeria control plan, how it is working, & the corrective actions taken, …
• Food Safety is a Non-Competitive Issue
• Pathogen Intervention Technologies
• Operational Controls and Monitoring of Processing Environment
• Closing Data Gaps to Enhance Risk Assessments

Research to Reduce Risks
FOOD SAFETY RESEARCH FUNDING – ALL SOURCES 1999-2005

* As of November 22, 2004
IMPACT OF REGULATIONS

• FORMULATION CHANGES

• INTERVENTION TECHNOLOGIES
FORMULATION TO INHIBIT GROWTH

ORGANIC ACIDS

lactic, diacetic, sorbic, benzoic, propionic

OTHER INGREDIENTS

rosmarinic acid, pediocin, cetyl pyridium chloride, acidified calcium sulfate, protamine, hydronium ion

SMOKE

approval takes time …
POST LETHALITY TREATMENTS

- Steam Pasteurization
- Hot Water Pasteurization
- Pre-package Radiant Heating
- High Hydrostatic Pressure Processing
VALIDATION OF LETHALITY

• Meat product type and composition
  – Size and shape
  – Whole muscle vs. restructured product
  – Product surface characteristics
  – Thermal properties

• Product packaging
  – Packaged vs. non-packaged
  – Film thickness and material

• Product orientation & package design
  – Single vs. double layer – hot dogs
  – Sliced product – deli type products

• Treatment characteristics
  – Relative humidity
  – Heat transfer rate
QUESTIONS ON VALIDATION

The post lethality treatment must be sufficient to eliminate the levels of contamination that MAY occur

... what are these levels?

Specific product validation vs. use of default criteria ...

... what can we afford?
IMPACT OF REGULATIONS

- EQUIPMENT & FACILITY DESIGN

- ENVIRONMENTAL & PRODUCT MICROBIOLOGICAL TESTING
HARBORAGE SITE/NICHE

A site within the food processing environment wherein microorganisms become established and multiply
Uncleanable plastic-metal interface
Hollow roller on conveyor
Makeshift equipment adjustments
AMI TASK FORCES

10 PRINCIPLES OF SANITARY DESIGN FOR RTE PROCESSING EQUIPMENT

11 PRINCIPLES FOR SANITARY DESIGN OF FACILITIES
SEPARATE LOCKER ROOMS FOR HIGH RISK & LOWER RISK PERSONNEL
ROOF IS SLOPED TO PROVIDE DRAINAGE
SYSTEMS ARE IN PLACE FOR SANITARY TRANSPORTATION OF REWORK INTO RTE/HIGH RISK ZONES
EQUIPMENT IS ACCESSIBLE FOR CLEANING
WELDED NAME PLATE
– FRAMEWORK NOT PENETRATED

RIVETED NAME PLATE PENETRATES FRAME
CONSTRUCTION – A RED FLAG

FSIS - construction increases risk

Need a construction policy ...

Need construction GMPs ...
TESTING FOR
Listeria monocytogenes

Repeat after me:

“I will not release product from my direct control until the results of any pathogen testing are reported!”
TESTING FOR
*Listeria monocytogenes*

Carefully consider:

“I will not do business with customers that insist on conducting pathogen testing once the product leaves my control!”
SEEK POSITIVES

Positives must be treated as a “success” because they enable corrections that can protect consumers!
MANAGEMENT DECISIONS

At what time is the line shut down?

When does corrective action lead to product sampling?

... the best time to prepare for decisions is not during a crisis
PROBLEMS WITH REGULATIONS

• VOLUME BASED
• VERIFICATION TESTING
• ZERO TOLERANCE
• LACK OF PARTNERSHIP

beyond those described in comments on the Rule...
PROBLEMS WITH REGULATIONS – PRODUCTION VOLUME

No data to support FSIS statement that

“prevalence based on relative production volume is more likely to correlate with incidence of illness”

In fact …
The assessment report states “volume is not a risk factor” and cites the Risk Assessment Division conclusion that plant size “is not a significant factor in concentration of contamination, and use of production volume as a significant variable is limited by the non-homogeneity of contamination”
PROBLEMS WITH REGULATIONS

END-PRODUCT VERIFICATION TESTING
MICROBIOLOGICAL TESTING

ICMSF – ROLE OF TESTING

... concern over the “continued indiscriminate use of microbiological testing of the end product.”
### PROBABILITY OF ACCEPTING A DEFECTIVE LOT

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<td>0.46</td>
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<td>0.05</td>
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HIGH NUMBERS OF SAMPLES REQUIRED AT LOW INCIDENCE RATE

... about 3000 samples for 95% probability

incidence rate = 0.1%
PARADOX OF REDUCING RISK

Sample size (n)

Probability of finding positives (%)
The government requires –

* a science-based, statistically-defensible sampling and testing plan...*
Yet fails to recognize

the limits to statistical plans,

and fails to define

the science-based limits to
regulatory policies
PROBLEMS WITH REGULATIONS

ZERO TOLERANCE POLICY

Canada, Denmark, UK, Australia & NZ

... a FSO of \( \leq 100/g \) provides a higher level of protection than does a “negative in two 25-g samples”
PROBLEMS WITH ZERO TOLERANCE

• No sampling plan can ensure the absence of a pathogen
• Plans with $c=0$ not always best for public health protection
• Randomness of contamination & sampling unlikely
CURRENT ISSUES

- LABELING
- SAFETY-BASED CONSUME BY DATES
- HOLD AND TEST
- SHARING ISOLATES
- LACK OF RETAIL DATA
LABELING OF RTE PRODUCTS

This product has been treated to reduce the risk from *Listeria monocytogenes*

Conflicts with “Mark of Inspection” & Zero-tolerance Standard
87% of establishments indicated that voluntary labeling was of concern

Inhibits data sharing
Creates good food vs. bad food perception
May mislead consumers about safe handling

62 responses representing 87 establishments
SAFETY-BASED LABELING

NACMCF: 2003-2004

“However, application of a specific SBDL at the manufacturer’s level is a concept that has many practical limitations.”

- number, diversity & complexity of products
- lack of data on initial numbers & growth rates
- lack of FSO tied to a public health goal
What are the implications of a regulatory policy that mandates negative results for pathogen testing before products would be released into commerce?
SHARING ISOLATES

With the company, yes ... 

With the public, academics, lawyers or activists, no, ... there is no well-defined purpose
FOOD SAFETY – RISK VS. REGULATION

Are the regulations placed at the most appropriate location within the farm to table continuum?

authority, not science, often drives regulatory activities…
OUTBREAKS & EATING LOCATION

- Unknown: 5%
- Home: 20%
- Restaurant/Deli: 33%
- School: 4%
- Camp/Picnic/Church: 6%
- Other: 20%

Are regulations appropriately placed?
QUESTIONS AT RETAIL

• WHAT ARE THE RISKS?
• WHAT ARE THE DATA GAPS?
• WHO IS RESPONSIBLE?
• WHAT IS BEING DONE?
STATE OF THE INDUSTRY

Are the *Listeria* regulations working?

Is the industry responding to reduce risks?
FOOD SAFETY – RISK VS. REGULATION

Are the regulations improving public health?

C-
Incidence of Foodborne Illness 1996-2002: Listeria*

*Preliminary FoodNet Data on the Incidence of Foodborne Illnesses --- Selected Sites, United States, 2002
PREVALENCE OF
Listeria monocytogenes
- RTE MEAT & POULTRY PRODUCTS *

*FSIS results of ready-to-eat products analyzed for Listeria monocytogenes
ACKNOWLEDGE SUCCESS

# plants doing both PCS & non-PCS testing increased from 82 to 94%

2004 survey … 62 responses representing 87 establishments
ACKNOWLEDGE SUCCESS

frequency of testing of PCS & non-PCS increased 40 and 24%, respectively

frequency of testing of finished products increased 19%

2004 survey … 62 responses representing 87 establishments
ACKNOWLEDGE SUCCESS

After (+) on PCS, 94% ↑ testing & 55% continue until two (-)

After (+) on non-PCS, 84% ↑ testing & 53% continue until two (-)

2004 survey … 62 responses representing 87 establishments
37% of those using new controls reformulated 20 to 100 products with antimicrobials.

2004 survey … 62 responses representing 87 establishments
Continue to establish the linkage between human health and foods

...this is key to being able to justify regulations & apply resources appropriately
RECOMMENDED
REGULATORY STRATEGY

Use a science-based approach to protecting public health

...this is easy to say, we see it everywhere, but how often is the science acknowledged for its uncertainties, assumptions and lack of information
RECOMMENDED REGULATORY STRATEGY

Implement effective and verifiable environmental *Listeria* control programs

...remains a need for simplified access to, and implementation of, new technology
RECOMMENDED
REGULATORY STRATEGY

Validate *Listeria* control program

... validation requires applied research that needs to be a funding priority for academicians, industry and government laboratories
RECOMMENDED
REGULATORY STRATEGY

Focus on products that support growth of
*L. monocytogenes*

...all of the assessment data indicate that the focus of regulatory and product development activities should be to reduce the risk associated with products that are sold in a state that allows for the growth of potential contamination.
RECOMMENDED REGULATORY STRATEGY

Cooperation

... working together with all stakeholders will allow the best ideas to surface and become best practices
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