



***National Advisory Committee on
Meat and Poultry Inspection
(NACMPI) Public Meeting***

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Selection of Public Health Related Regulations

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Overview

- Background
 - Public Health Decision Criteria and the W3NR criterion
- Approach to updating the public health regulations (PHRs)
- Plan for implementing PHRs



Questions to the Committee

1. What comments does the Committee have regarding the approach used to select the PHR list?
2. Does the Committee have any comments on the four criteria used to select the candidate PHR list?
 1. Establish and maintain HACCP plan and Critical Control Points (CCPs)
 2. Establish and Maintain Sanitary Conditions
 3. Prevent Adulteration
 4. Implement Effective Corrective Actions
3. Does the Committee have any comments on the public health outcomes (pathogen test results) analyzed to select the final list of PHRs?
 1. *Salmonella*
 2. *E. coli* O157:H7
 3. *Listeria monocytogenes*



Public Health Decision Criteria Report*

- In 2008, FSIS developed a data-driven approach for scheduling FSAs
 - Reviewed by NACMPI in 2008
 - Reviewed and endorsed by National Academy of Sciences in 2009
 - Published FSIS website 2010
- Approach uses seven decision criteria

*http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Public_Health_Decision_Criteria_Report.pdf



Public Health Decision Criteria Approach

FSIS Data on
Establishment
Performance



Seven Decision Criteria

1. E. coli O157:H7 or LM positive
2. Salmonella Category 3
3. **High rate of W3NR NCs**
4. Enforcement actions
5. Food safety Recalls
6. Sole supplier to E coli positive
7. Linked to human illness

Any one of these criteria would trigger an FSA



Evaluation for FSA scheduling



One Decision Criterion Was High Rate of W3NRs

- W3NR regulations are also called public health related regulations
- 62 W3NR regulations were selected by a group of FSIS staff
- Selection was based on the potential for non-compliances to have public health consequences



Examples of W3NR Regulations

- Bears or contains poisonous or deleterious substance
- Failure to maintain adequate HACCP Plan
- Failure of keep CCPs under control
- Failure to take appropriate corrective action
- Failure to prevent adulterated product from entering commerce



Need for Updating W3NR Regulations

- With the implementation of PHIS, the W3NR criterion needs to be reevaluated
 - The nature of the data collected has changed
 - The set of regulations to verify is different in PHIS
 - The W3NR rate is computed differently in PHIS
 - The W3NR list needs to be reevaluated
- Therefore the W3NR decision criterion was suspended until the data could be analyzed and an updated list developed



Updating the Public Health Reg List

- Purpose: Make selection of W3NRs more transparent and data-driven
 - ***The new list will be called PHRs to distinguish it from the W3NR list***
- Approach:
 - Define a set of evaluation criteria
 - Develop a list of candidate regulations related to verifying food safety process control
 - Select the subset of regulations whose non-compliance rate is higher in establishments with *Salmonella*, *E. coli* O157:H7, or *Lm* positives



PHR Development Process

Define criteria for Selecting candidate list



Select candidate list of 9 CFR regulations related to HACCP food safety process control



Narrow down list to those with higher NC rates before *Salmonella*, *E coli* O157:H7, *Lm* positives



Develop non-compliance rate Cut Points for use in scheduling FSAs and HAVs



Step 1: Define Selection Criteria

- Four criteria have been identified for selection of public health regs
- Regulations concerning:
 - Establish and maintain HACCP plan and Critical Control Points (CCPs)
 - Establish and Maintain Sanitary Conditions
 - Prevent Adulteration
 - Implement Effective Corrective Actions



Step 2: Select Candidate PHR Regulations

- Assess the set of 9 CFR regulations and select those regulations whose non-compliance provides evidence that establishments are NOT satisfying one of the following four key criteria
 - Could non-compliance be associated with a potential failure to meet the four criteria in step 1



Step 2: Select Candidate PHR Regulations

- A set of 143 9 CFR regulations were selected as being indicators of a potential loss of process control
- The 143 regulations map to 118 regulations in PHIS.
 - Some of the 143 map directly to regulations in PHIS
 - Others are verified under higher order regulations in PHIS.
 - For example, 381.1(i)-381.1(iv) are verified under 381.1



Step 3: Select the Public Health Regulations

- From the list of 118 candidate PHR regulations, select the subset whose non-compliance rate in establishments 3 months before a *Salmonella*, *E. coli* O157:H7, or *Lm* positive is higher than in establishments without any positives
- A two-sided Fisher Exact p value was used to show a statistically higher non-compliance rate



Step 3: Select the Public Health Regulations

- Of the 118 potential PHR Regulations
 - 28 PHR regulations were higher 3 months before a *Salmonella* positive
 - 6 PHR regulations were higher 3 months before a *E. coli* O157:H7 positive
 - 4 PHR regulations were higher 3 months before a *Lm* positive
- The final PHR list has 33 regulations, 21 (64%) of which are on the earlier W3NR list



Examples of PHRs in Common with Earlier W3NR List

- Bears or contains poisonous or deleterious substance
- Failure to maintain adequate HACCP Plan
- Failure of keep CCPs under control
- Failure to take appropriate corrective action
- Failure to prevent adulterated product from entering commerce
- Prevent the use of Specified Risk Materials as human food



Examples of PHRs not in the Earlier W3NR List

- Operate in manner to prevent insanitary conditions
- Evaluate effectiveness of SSOP's
- Product must be protected from adulteration at all times



Where we're at today

- FSIS has
 - Developed a set of candidate regs
 - Analyzed PHIS inspection data to select PHRs
 - Plans to start using the PHR decision criterion in PHIS in 2013
 - Plans to reevaluate the PHR analysis after each year of new PHIS data



Use of the Public Health Regulations

- The PHR regulations are used as one criteria in prioritizing scheduling of FSAs and, when implemented, HAVs
- Noncompliance with a single PHR regulation does not indicate loss of process control
- The aggregate set of PHR regulations is used to identify establishments that significantly deviate from the 3-month rolling average noncompliance rate for all similar establishments (slaughter only, processing only, and slaughter plus processing)



Use of Public Health Regulations

Compute establishment PHR NC rate



Compare to cut point for similar establishments



If selected, include in proposed FSA schedule



District Office selects FSAs to perform



Related Topics

- What about candidate PHRs not selected?
 - FSIS plans to reanalyze data periodically
 - This may result in updates to the PHR list
 - FSIS plans to explore any training or instructions to the field that may drive more informative data
- What about the potential impact of the Poultry Slaughter Rule?
 - Updates will be made as required



Future PHR Updates

- FSIS plans to analyze candidate regs annually and if needed update the set of PHRs
 - Updates would coincide with fiscal years
 - A 90-day period between announcing updates and implementation
- Update cycle:
 - April-May: Reanalyze candidate regulations
 - June: Finalize materials and clear internally
 - July: Announce any PHR updates
 - October: Implement PHR updates



Information For Stakeholders

- FSIS intends to
 - post the list of PHRs
 - post PHR cut points
 - post updated Decision Criteria Document



Conclusion

- A more transparent and data-driven methodology was developed to select public health regulations (PHRs)
- The PHRs have significantly higher noncompliance rates 3 months before a *Salmonella*, *E. coli* O157:H7, or *Lm* positive
- The final PHR list is composed of 33 regulations, 21 (64%) of which are on the earlier W3NR list



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Questions ?