March 16, 2007

Risk Control Measure (RCM) in Processing Establishments in 30 Prototype Locations

Introduction

FSIS is introducing a more robust risk-based inspection system in processing plants to better protect public health. By better utilizing information regularly collected by inspection program personnel at processing establishments, the Agency can more effectively allocation inspection resources to those plants needing it the most, while continuing daily inspection at processing facilities. Background information on this initiative is available at www.fsis.usda.gov.

FSIS is using an algorithm, or mathematical formula, to determine the level of inspection that needs to be performed in processing plants. The algorithm combines two measures. The first is the inherent risk measure associated with different types of processed products and the volume of the processed produces produced by the establishment. The second is the processing establishment risk control measure, which represents how each plant is controlling risk in its operations.

For phase 1, FSIS will test the algorithm in 30 prototype locations beginning in spring 2007. This paper provides additional information on how the algorithm will be determined in these prototype locations. This paper provides additional detail on the establishment risk control measure, including the factors to be considered and how these factors are used to determine the numerical measure. A companion paper provides additional detail on the inherent risk measure (IRM). A third paper describes how the Inherent Risk Measure and the Risk Control Measure will be used to determine the level of inspection in processing plants during phase 1.

The Risk Control Measure considers the following seven factors:

1. Public Health significant NRs
2. Enforcement actions
3. Ready-to-Eat (RTE) *Lm* Alternative
4. *Salmonella* Verification Category
5. Microbiological testing program results
6. Food safety recalls
7. Verified food safety consumer complaints.

These seven components are each assigned a certain number of points and these are mathematically combined to derive an establishment Risk Control Measure between 0 and 100.

Phase I Risk Control Measure

(0) More Effective Controls ←==========→ Less Effective Controls (100)

Factors considered and how points are determined

RBI Risk Control Measures can be computed using this algorithm for all (approximately 5,244) Active Federal and Talmadge-Aiken Part 417 (HACCP) meat and poultry processing establishments[1] with at least one sanitation and/or HACCP inspection procedure performed during a specified six-month window.[2] Additional detail for each of the seven components follows below.

1. Public Health Significant NRs

When inspectors document non-compliances, they cite one or more pertinent regulatory requirements from a list of over 500 in the Performance Based Inspection System (PBIS). Each of these regulatory requirements is categorized in terms of how strongly they indicate a loss of an establishment's food safety system process control.

Category 3 regulations are those that, if not met, indicate a *definite loss of the control of the food safety system.* Such conditions include an establishment failing to implement documented features of its HACCP or prerequisite system or failing to meet explicit regulatory requirements, including corrective action requirements. Examples: 416.15(a) "Appropriate corrective actions" and 417.3(a) "Corrective action after deviation from CCP." Category 2 regulations are those that, if not met, indicate a *reasonable probability that there is a loss of the control of the food safety system.* Examples: 416.13(a) "Conduct pre-op procedures" and 416.14 "Evaluate effectiveness of SSOP's & maintain plan."

Category 1 regulations are those in 9 CFR that, if not met, there is only a *remote probability of a loss of the control of the food safety system.* Examples: 416.2 (a) "Establishment Grounds and Facilities" and 416.2 (b) (1) "Sound construction, good repair & sufficient size." Category Zero (0) are *non-food safety* regulatory requirements that do not indicate a loss of food safety system process control. Examples include violations of *other consumer protection* (OCP) regulations, such as the product standard of identity requirements in 319.15(a) "Chopped beef, ground beef" and 319.307 "Spaghetti sauce with meat."

Each Noncompliance Record (NR) can thus be evaluated in terms of its public health significance by examining which regulatory requirement(s) are not being met. NRs themselves are weighted with 0, 1, 2, or 3 points according to the category weighting of the highest individual noncompliance they cite. Once done, a public health "weighted" NR rate for each establishment can be computed that is mathematically analogous to a traditional NR rate (total NRs divided by the total number of inspection procedures performed) except that, in RBI, not all NRs are treated the same. For example, an establishment with 500 food safety inspection procedures in a six-month window and 5 NRs has a traditional NR rate of (5/500) x 100 =1.0% because each of the 5 NRs is weighted the same. If however, 3 of those NRs cite only Category

[1] Egg products establishments will be considered at a future date.

[2] The exception is the "zero-tolerance" RTE *Salmonella*, *Lm*, and O157:H7 data, and raw *E. coli* O157:H7 data, which are from a *12*-month window. Data presented in this paper were collected from a 6-month window between April1, 2006, though September 30, 2006 and from a 12-month window between October 1, 2005, and September 30, 2006.

1 regulatory requirements and 2 of the NRs cite Category 3 requirements, the weighted public health NR rate = [(3+6)/500] x 100 = 1.8%.

Six equal percentiles of the Public Health NR rate distribution are calculated, the result being an equal number of establishments having between 0 and 5 points. The calculated public health NR ranges that yield 5 groups with approximately the same number of establishments in each are:[3]

Public Health NR Range < 0.35%	= 0 points
Public Health NR Range >/= 0.35% but < 0.89%	= 1 point
Public Health NR Range >/= 0.89% but < 1.57%	= 2 points
Public Health NR Range >/= 1.57% but < 2.55%	= 3 points
Public Health NR Range >/= 2.55% but < 4.60%	= 4 points
Public Health NR Range >/= 4.60	= 5 points

Note that the tabulated ranges will be used for starting calculations and will be maintained for a period of time. Over time, the number of establishments in each of the ranges (0-5 points) will change as each establishment's public health NR rate changes. An establishment with 3 points based on a public health NR rate of 1.7 % using six months of data would improve to 2 points the following month if its public health NR rate fell to 1.5% in the refreshed six-month window.

2. Enforcement Actions

There are a variety of enforcement actions the Agency can take against establishments that fail to sufficiently comply with applicable requirements- both food safety and non food safety. All types of enforcement actions probably indicate a need for closer inspection by the Agency, but some types more so than others. An establishment's Risk Control Measure will increase commensurate with the gravity of any enforcement action taken against it, according to the following formula:

Notice of Intended Enforcement (NOIE)	3 points
NOIE Under Deferral	2 points
Suspension	4 points
Suspension Held in Abeyance	3 points
Reinstatement of Suspension	6 points
Reinstatement Held in Abeyance	3 points
Complaint to Withdraw Inspection	6 points
Inspection under Consent Order	5 points

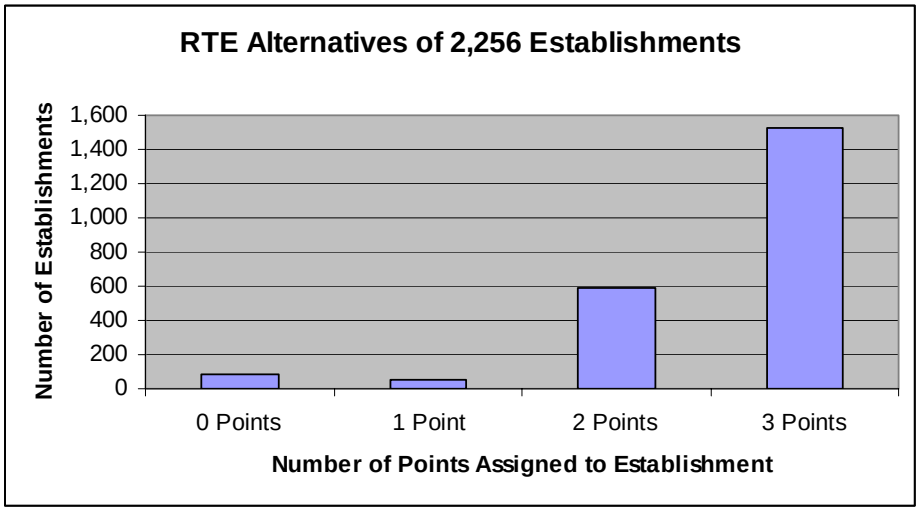
[3] Based on NR data from 5,244 establishments between April 1 and September 30, 2006,

3. RTE Lm Alternative

Establishments that produce RTE products that are exposed to the environment subsequent to the lethality step must comply with the provisions of 9 CFR 430. The Agency maintains that *how* an establishment complies with those provisions indicates how well they control the risk associated with *Listeria monocytogenes* in RTE products. Risk Control Measures of the 2,256 establishments subject to the requirements of 9 CFR 430 will increase commensurate with the RTE Alternative they follow, according to the following formula:

- RTE Regulatory Alternative III-Sanitation Only (3 points)
- RTE Regulatory Alternative II-Anti-Microbial Agent (2 points)
- RTE Regulatory Alternative II- Post-Lethality Treatment (1 point)
- RTE Regulatory Alternative I- Anti-Microbial *and* Post-Lethality (0 points)

The next figure shows approximately how many of the 2,256 affected establishments would receive 0, 1, 2 or 3 points based on their RTE alternative. For Phase I RBI, the RTE Alternative "status" of establishments producing products under more than one alternative is based on the highest of their two or more alternatives.



4. Salmonella Verification Category[4]

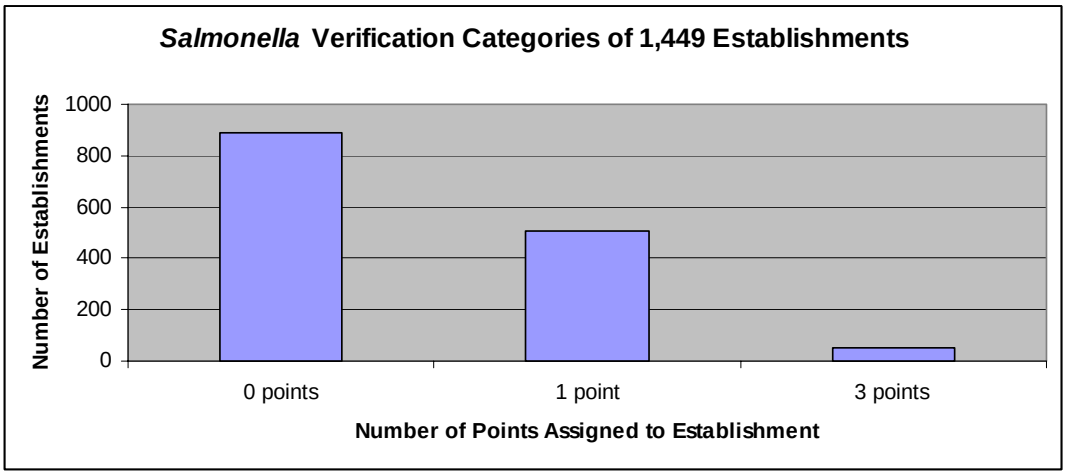
Approximately 1,449 establishments produce one or more types of raw meat or poultry products that are subject to *Salmonella* performance standards. These establishments are classified into one of several *Salmonella* Verification Categories (SVCs) based on the results of recent *Salmonella* sets. The Agency maintains that establishments in "higher" SVCs have less effective *Salmonella* risk controls, and will increase their Risk Control Measures according to the following formula:

- *Salmonella* Category III (3 points)
- *Salmonella* Category II (1 point)
- *Salmonella* Category I (0 points)

[4] Serotype information will be included once available.

Category III establishments are those that *failed* their most recent *Salmonella* set, category I establishments are those that achieved *Salmonella prevalence rates that were less than 50% of the performance standard* in their two most recent sets, and establishments with other combinations of results for their two most recent sets are category II establishments.

The next figure shows approximately how many of the nearly 1,500 affected establishments would receive 0, 1, or 3 points based on their current SVC. The Agency will adjust establishments' Risk Control Measures as the establishments themselves move between SVCs based on *Salmonella* control performance. For Phase I RBI, the SVC "status" of an establishment that produces products subject to more than one performance standard is based on the highest of their two or more SVCs.



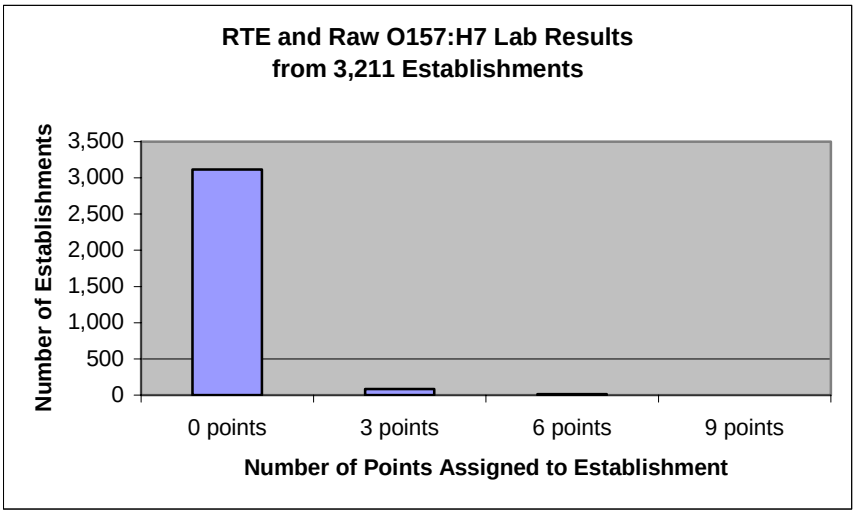
5. Microbiological testing program results

Approximately 3,211 establishments that produce RTE[5] and/or raw ground beef products are subject to pathogen testing programs. RTE products are tested for *Lm*, *Salmonella* and *E. coli* O157:H7 and raw ground beef products are subject to *E. coli* O157:H7 testing. Establishments that "test positive" for these "zero tolerance" pathogens demonstrate a loss of food safety system process control, and their risk control measures rise based on the following formula:

- positive samples on 3 or more separate days[6] (9 points)
- positive samples on 2 separate days (6 points)
- positive sample(s) on one day (3 points)
- no positive samples (0 points)

The next figure shows approximately how many of the approximately 3,211 affected establishments would receive 0, 3, 6, or 9 points based on their recent laboratory test results.

[5] Algorithm counts only product and product contact surface samples.
[6] Date is used as a proxy for production lot.



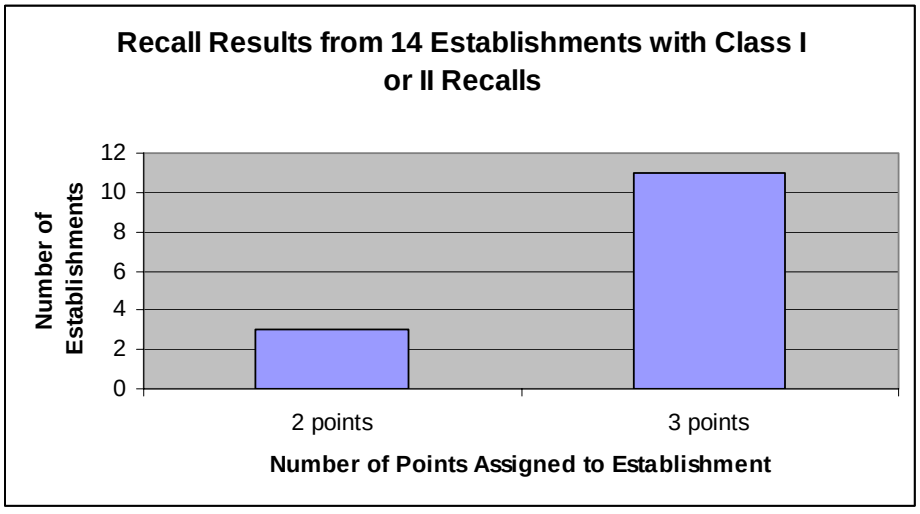
6. Food Safety Recalls

Establishments that have to recall products from commerce for food safety reasons demonstrate a loss of food safety system process control, and their risk control measures rise based on the following formula:

- Class I recalls (3 points)
- Class II recalls (2 points)

Recall results are cumulative for the six-month window, with a maximum of 6 points. For example, if an establishment experienced a Class I recall on January 1 and a Class II recall on April 1, the establishment would have 3 points from January 1 through March 31, 5 points from April 1 through June 30, 2 points from July 1 through September 30, and 0 points thereafter.

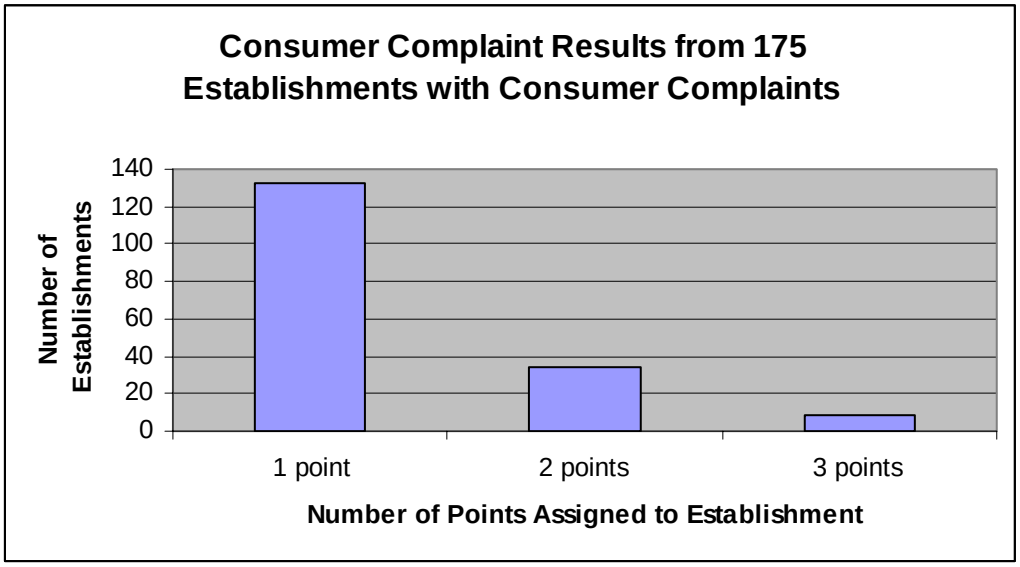
Class I and Class II recalls initiated in a recent six-month period would affect the risk control measures of fourteen establishments as illustrated below.



Food Safety Consumer Complaints

Verified food safety consumer complaints are also evidence of establishment loss of food safety system process control. In a recent six month period, 175 establishments were connected to verified food safety consumer complaints in the Agency's Consumer Complaint Monitoring System. These incidents will enter establishments' Risk Control Measures according to the following formula:

- 3 or more complaints (3 points) (about 5% of establishments with food safety complaints in CCMS)
- 2 complaints (2 points) (about 20% of establishments with food safety complaints in CCMS)
- 1 complaint (1 point) (about 75% of establishments with food safety complaints in CCMS)



Risk Control Measure Computation and Examples

An establishment's Risk Control Measure is computed as the sum of the "points" it accumulates according to the seven factors above divided by the *maximum* number of "points" it *could* accumulate given its operational and inspection/verification status. The quotient of this calculation is then multiplied times 100 to convert the measure to a 0-100 point scale.

Risk control measure = (number of points ÷maximum possible points) X 100

This method of calculation allows establishments with different risk control factors to have comparable scores. That is, although all establishments have "NR data" (even though they may have no NRs), are "exposed" to consumer complaints, *could* experience recalls, and *could* be the subject of enforcement actions, some will be subject to FSIS testing requirements that will factor into the risk control calculation while others will not.

In cases where an establishment is subject to FSIS testing but has not been tested, the lack of test results will not improve the establishment's score as would a negative test result. For such an establishment, FSIS would not include the possibility of testing as a value in the denominator of the Risk Control Measure calculation. Doing so would inappropriately equate not being testing with having a negative test result.

The four establishments in the Figure below illustrate how Risk Control Measures are computed. Establishment A produces a single product: raw ground pork. The product is not ready-to-eat, is not subject to *E. coli* O157:H7 testing, and has no *Salmonella* performance standard. The establishment has a total of 20 possible points (for NRs, consumer complaints, recalls, and enforcement) and has accumulated 4 actual points. Its computed Risk Control Measure is (4/20) x 100 = 20.0.

Establishment B instead produces raw ground chicken, for which the Agency *does* have a *Salmonella* performance standard. This establishment's *Salmonella* Verification Category is 1, which means recent testing results in the establishment showed that the *Salmonella* prevalence rate was less than ½ of the performance standard. Its Risk Control Measure (17.4) is lower than establishment A's because there is *more* data on food safety system process control in Establishment B, and the evidence is *favorable*.

Establishment C produces raw ground beef, for which there is both a *Salmonella* performance standard and *E. coli* O157:H7 testing. Its score is lower still (12.5) because there is even *more* information on its food safety system process control (laboratory results for *E. coli* O157:H7) and *all* of its samples were negative for the pathogen.

Finally, establishment D produces the same product as establishment C, but there are indications of a *loss* of process control (relative to Establishment C) in several areas. As a result, its Risk Control Measure—40.6—is the highest of the four example establishments.

	Establishment A		Establishment B		Establishment C		Establishment D	
	Actual	Possible	Actual	Possible	Actual	Possible	Actual	Possible
NR Data	3	5	3	5	3	5	3	5
Verified Food Safety Consumer Complaint Data	1	3	1	3	1	3	2	3
Food Safety Recall Data	0	6	0	6	0	6	2	6
Enforcement Data	0	6	0	6	0	6	2	6
Salmonella Verification Category	NA	NA	0	3	0	3	1	3
E. coli O157:H7 and/or RTE Pathogen Testing	NA	NA	NA	NA	0	9	3	9
RTE Alternative	NA	NA	NA	NA	NA	NA	NA	NA
Total	**4**	**20**	**4**	**23**	**4**	**32**	**13**	**32**
Risk Control Measure	**20.0**		**17.4**		**12.5**		**40.6**	