FSIS Updates of the *Listeria monocytogenes* Risk-Based Verification Sampling Algorithm

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FSIS Updates of the *Listeria monocytogenes* Risk Ranking Algorithm

Summary of Content

This document reviews the previously used versions of the Listeria monocytogenes risk ranking algorithm and provides information on two updates of the algorithm for establishments producing RTE products under the Interim Final Listeria Rule (9 CFR 430). The information provided here complements and expands on the data and results of the 2007 FSIS Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*. That document used FSIS *Listeria monocytogenes* sampling verification data from calendar years 2005 and 2006 to evaluate and update the original 2005 risk ranking algorithm. This document uses FSIS *Listeria monocytogenes* sampling verification data from calendar year 2008 for two additional updates of the risk ranking algorithm. Data from calendar year 2008 was selected for analysis because it provided the largest sampling frame among calendar years 2005 through 2011. The 2011 risk ranking algorithm version is presently being evaluated for performance in the FSIS Public Health Information System (PHIS). PHIS was fully implemented as the replacement for the previous Performance Based Inspection System (PBIS) in January 2012 which managed the monthly *Listeria monocytogenes* risk ranking algorithm establishment sampling schedule prior to converting over to PHIS. The algorithm is now fully implemented in PHIS. A document regarding the changes made to the algorithm to conform with PHIS will be forthcoming in an additional algorithm update.

The reasons for the updates in this document are given in Appendix I, which outlines regulatory changes made since the 2007 risk assessment that have impacted the design of the algorithm. The inclusion of regulatory food contact surface sampling results and informative FSIS environmental area sampling results in the 2008 algorithm for estimating *Listeria monocytogenes* risk was made possible by implementation of the RLm and IVT sampling programs documented in Appendix II.

Appendix III outlines further improvements that were made possible by completion of the 2010 FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats, which updated the original 2003 model basis of the risk ranking algorithm. The FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats model was then modified to include *Listeria monocytogenes* contamination at retail, which could be extended to portend consumer cases of listeriosis. The importance of using antimicrobial agents in product formulation was underlined by this risk assessment and the new emphasis on risk modification using these agents was implemented in the risk ranking algorithm; this particularly affected establishments claiming alternatives 1 and 2 that use antimicrobial agents. Most importantly this new information provided the bridge necessary to modify the algorithm in the 2011 version to base the risk calculation on the probability of causing

listeriosis in the susceptible consumer population rather than on the probability of contamination of RTE products with *Listeria monocytogenes* at retail.

Appendix IV transparently provides the SAS computer code and example dataset for the 2008 and 2011 algorithms. The algorithms and example dataset are also found in Excel spreadsheet attachments to this document.

Establishment *Listeria monocytogenes* Risk Ranking Algorithm and Modifications

This sections provides additional information for the establishment *Listeria monocytogenes* (*Lm*) risk ranking algorithm modifications (2005 and 2006 versions) and two subsequent updates: the establishment *Lm* risk ranking algorithm (2008 version) and the establishment *Lm* risk ranking algorithm (2011 version). The 2006 version made minor changes in the Risk3 variable constants compared to the baseline 2005 version. The 2008 version update includes additional food contact surface and environmental FSIS regulatory *Lm* sample results for adjusting the baseline Risk2 ranks. The 2011 version updates the algorithm such that the establishment *Lm* risk ranking is based on the expected probability of illness per serving for the most susceptible population of consumers rather than the expected number of pathogens per serving at retail as in the 2005, 2006, and 2008 versions. The 2011 version also suggests sampling quotas for each alternative to ensure that there will be no oversampling of low risk establishments.

In the 2005 algorithm baseline dataset (Table 1), there were 1,820 total establishments, of these 1,409 are in Alternative 3; this is 71% of all establishments in the RTE001 program. About 23% of all establishments, or 454 establishments, claim Alternative 2. Of these establishments, 397 of those, or 20%, are in Alternative 2b, using a growth inhibitor or process. Fifty-seven, or 3% of establishments, apply a post-processing lethality and so are in Alternative 2a. Exactly 118 establishments claim Alternative 1; this is about 6% of all establishments. There are 1,675 establishments (92%) that claim only one alternative and 161 (8%) that claim multiple alternatives.

Table 1. 2005 Dataset Summary Statistics

	Alternatives		One Alternative	
Variable	Number	Percent	Number	Percent
Establishments	1,820	91.9	1675	100.0
Alternative1	118	6.0	82	4.9
Alternative2a	57	2.9	34	2.0
Alternative2b	397	20.0	293	17.5
Alternative3	1,409	71.1	1,266	75.6
Total Alternatives	1,981	100.0	1,675	100.0
Multiple Alternatives	161	8.1	145	8.7

The 2006 dataset (Table 2) included 2,067 establishments in RTE001, of which 1,401 are in Alternative 3; this is about 56% of the total. About 39% of all establishments, or 967 establishments, claim Alternative 2. Of this number, 654, or 26%, are in Alternative 2b, using a growth inhibitor or process. And 313, or 13% of establishments, apply a post-processing lethality step and so are in Alternative 2a. Alternative 1 includes 125 establishments; this is about 5% of all establishments with post-lethality exposed RTE products.

Table 2. 2006 Dataset Summary Statistics

	Alternatives		One Alternative	
Variable	Number	Percent	Number	Percent
Establishments	2,067	82.9	1,724	100.0
Alternative1	125	5.0	78	4.5
Alternative2a	313	12.6	57	3.3
Alternative2b	654	26.2	343	19.9
Alternative3	1,401	56.2	1,246	72.3
Total Alternatives	2,493	100.0	1,724	100.0
Multiple Alternatives	426	17.1	343	19.9

The 2008/2011 dataset (Table 3) includes 2,315 total establishments of which 1,650 are in Alternative 3; this is about 55%. About 39% of all establishments, or 1,182 establishments, claim Alternative 2. Of these establishments, 904, or 30%, are in Alternative 2b, using a growth inhibitor or post-processing process. Alternative 2a included 278, or 9% of establishments, which apply a post-processing lethality step. The remaining 170 establishments belong to Alternative 1, about 6% of all establishments. About 1,781 of the 2,315 establishments claim only one alternative. These numbers are presented as approximations due to the fluctuation of these self-reported and voluntary classifications.

Table 3. 2008/2011 Dataset Summary Statistics

	Alternatives		One Alternative	
Variable	Number	Percent	Number	Percent
Establishments	2,315	77.1	1,781	100.0
Alternative1	170	5.7	59	3.3
Alternative2a	278	9.3	16	0.9
Alternative2b	904	30.1	386	21.7
Alternative3	1,650	55.0	1,320	74.1
Total Alternatives	3002	100.0	1,781	100.0
Multiple Alternatives	687	22.9	534	30.0

DATA SOURCES

Self-reported Compliance with the Interim Final Rule to Control *Listeria monocytogenes* and Type of Product Processed and Volume of Production

The 2005 algorithm used 7 RTE product classes from FSIS form 10,240-1 (ver. 2004) that report the annual production volume for each class in pounds. The product classes are deli meat sliced, deli meat unsliced, hot dogs, cooked products, fermented products, dried products, and salt-cured products.

The 2006 algorithm used 7 RTE product classes from FSIS form 10,240-1 (ver. 2004 and some ver. 2006) that report the annual production volume for each class in pounds. The product classes are deli meat sliced, deli meat unsliced, hot dogs, cooked products, fermented products, dried products, salt-cured products. A few establishment's data using the 2006 form included categories for pate/meat spreads/deli salads and frozen products that were excluded from the analysis.

The 2008 algorithm used the 9 RTE product classes and annual production volume categories from FSIS form 10,240-1 (ver. 2006). The product classes are deli meat sliced, deli meat unsliced, hot dogs, cooked products, fermented products, dried products, salt-cured products, frozen products, and pate/meat spreads/deli salads.

The 2011 algorithm uses the same 9 RTE product classes and annual production volume categories from FSIS form 10,240-1 (ver. 2006) as the 2008 version.

Past History of Laboratory Results for *Listeria monocytogenes* Testing

The analysis of the 2005 and 2006 algorithms used the product testing results reported for the RTE001 risk-based sampling program taken from the FSIS Pathogen Reduction Enforcement Program (PREP) database. Results were reported by product type based on whether results are positive or negative by establishment number with collection and analysis dates.

The analysis of the 2008 algorithm uses the monthly single product testing results reported for the RTE001 risk-based *Lm* sampling verification program, the ALLRTE random *Lm* sampling verification program, the RLM random *Lm* sampling verification program for *Listeria* Rule establishments, and the IVT intensive verification testing program for multiple pathogens where only the *Lm* sample results are used. The ALLRTE program only takes RTE product samples that are not post-lethality exposed whereas the RTE001 samples are post-lethality exposed. The RLM and IVT programs provide multiple samples from RTE products, food contact surfaces, and environmental swabs.

The 2011 algorithm analysis uses the same historical data sources as the 2008 version.

Establishment *Listeria monocytogenes* Risk Ranking Algorithm

Establishment *Listeria monocytogenes* Risk Ranking Algorithm Equations

The basic form of the algorithm equations is in a two-part analysis. The first part estimates the establishment baseline risk score obtained from form data describing each establishment's alternative(s) and annual production volume for RTE product categories. There are seven categories for the 2005 and 2006 algorithm versions and nine categories for the 2008 and 2011 algorithm versions based on the RTE categories in original FSIS Form 10240-1 (ver. 2004) and its major revision (ver. 2006). The establishment baseline risk scores (Risk2) are ranked (Rank Risk2). Part 2 analysis adjusts the establishment baseline risk rank with historical laboratory results. Risk3 increases the risk ranking with past positive *Lm* results while Risk1 increases establishment risk to the very top risk ranks. Risk4 decreases establishment risk rank when there are no positive *Lm* results. Establishment risk rank is not changed if there are no reported laboratory results. The general form of the risk ranking equation is:

Risk Rank = Risk1 + Rank Risk2 + Risk3 – Risk4

Raw Baseline Risk Score Calculation

The 2005 and 2006 algorithms use a three mass component equation to calculate the equivalent deli meat volume (EDMV) component of the baseline risk score for each alternative. The final sum is taken over all establishment alternatives. The baseline risk score is equal to the product of the EDMV and the establishment alternative Q80 (the 80th quantile of the expected *Lm* contamination distribution). This means there are four equations with three possible mass components for every establishment alternative and level of production. The values are taken as high, medium, or low based on the EDMV distribution over all establishments. The basic equation for each alternative yielding the EDMV is:

$$\sum\left[\left(mass_{deli} + \frac{\text{frankpergramrisk}}{\text{delipergramrisk}} * mass_{frank} + \frac{\text{otherpergramrisk}}{\text{delipergramrisk}} * mass_{other}\right) * \text{delipergramrisk}\right]_{alt}$$

The risk ratios relative to deli meat in this equation are calculated using values taken from the FSIS/FDA quantitative risk assessment shown in Table 4.

The 2008 and 2011 algorithms use a six mass component equation to calculate the baseline risk score for each alternative. This means there are four equations with six possible mass components each for every establishment alternative and level of production. Again, the values were taken as high, medium, or low based on the EDMV distribution over all establishments. The basic equation for each alternative yielding the EDMV is:

$$\sum\Big[\Big(mass_{delius} + \frac{\text{delispergramrisk}}{\text{deliuspergramrisk}} * mass_{delis} + \frac{\text{frankpergramrisk}}{\text{deliuspergramrisk}} * mass_{frank} + \frac{\text{patepergramrisk}}{\text{deliuspergramrisk}} * mass_{pate} + \frac{\text{otherpergramrisk}}{\text{deliuspergramrisk}} * mass_{other} + \frac{\text{frozenpergramrisk}}{\text{deliuspergramrisk}} * mass_{frozen}\Big) * \text{deliuspergramrisk}\Big]_{alt}$$

The risk ratios relative to unsliced deli meat in this equation are calculated using values taken from the FSIS/FDA quantitative risk assessment shown in Table 5.

Table 4. Product risk factors used for the 2005 and 2006 Algorithms from the 2003 FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of RTE Foods.

Product Category	Median number of illnesses per serving	Median Serving Size (grams)	Number of illnesses per gram	Risk ratio relative to deli (dimensionless)
Deli	7.70×10^{-8}	56	1.38×10^{-9}	1
Frankfurter	4.56×10^{-9} (7% @ 6.5×10^{-8} and 93% @ 6.3×10^{-11})	57	8.00×10^{-11}	5.82×10^{-2}
Other	1.70×10^{-11} (value for fermented RTE product)	57	2.98×10^{-13}	2.17×10^{-4}

Table 5. Product risk factors used for the 2008 and 2011 Algorithms from the 2003 FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of RTE Foods.

Product Category	Median number of illnesses per serving	Median Serving Size (grams)	Number of illnesses per gram	Risk ratio relative to deli (dimensionless)
delius	7.70×10^{-8}	56	1.38×10^{-9}	1.0
delis	3.14×10^{-8}	56	5.63×10^{-10}	0.41
pate	3.20×10^{-8}	56	4.74×10^{-10}	0.34
hot dog	4.56×10^{-9}	57	8.00×10^{-11}	5.82×10^{-2}
other	1.70×10^{-11}	57	2.98×10^{-13}	2.17×10^{-4}
frozen	4.81×10^{-14}	57	8.63×10^{-16}	6.25×10^{-7}

The establishment EDMV (pounds/year obtained from form data, converted to grams) is multiplied by the respective alternative expected component *Lm* contamination Q80 (cfu/g) for high, medium, and low volume production shown in Table 6. The division between each production volume is at the 50^{th} and 75^{th} percentiles of the EDMV distribution. The baseline score for the 2005 algorithm is calculated from the equations below with the specific masses substituted for each establishment alternative. The risk scores represent total annual *Lm* colony forming unit (cfu) production by individual establishments available at retail.

The establishment risk scores are the baseline risks that are adjusted by the other component risk factors after converting to ranks in order to obtain the adjusted baseline risk rank for each establishment. The establishments with the largest adjusted baseline risk ranks are chosen for sampling.

Table 6. Quantiles (Q80), Retail Prevalence, and Relative Risk of the *Listeria monocytogenes* distribution at retail by alternative

Alternative	Q80	Retail Prevalence	Relative Risk
1-H	1.40E-08	0.00711	1.097591
1-M	1.25E-08	0.00684	1.056208
1-L	1.10E-08	0.00648	1.000000
2-PP-H	8.20E-08	0.01232	1.902718
2-PP-M	6.74E-08	0.01219	1.881717
2-PP-L	6.10E-08	0.01172	1.808987
2-GI-H	1.53E-06	0.03105	4.794365
2-GI-M	1.29E-06	0.02973	4.590511
2-GI-L	1.16E-06	0.02824	4.361056
3-H	7.24E-06	0.04488	7.011566
3-M	7.08E-06	0.04541	6.929975
3-L	5.65E-06	0.04401	6.795457

For high volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\left[\left(mass_{deli,1-H} + 5.82x10^{-2} * mass_{frank,1-H} + 2.17x10^{-4} * mass_{other.1-H}\right) * 1.40x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP-H} + 5.82x10^{-2} * mass_{frank,2-PP-H} + 2.17x10^{-4} * mass_{other.2PP-H}\right) * 8.20x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-H} + 5.82x10^{-2} * mass_{frank,2-GI-H} + 2.17x10^{-4} * mass_{other\ 2GI-H}\right) * 1.53x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-H} + 5.82x10^{-2} * mass_{frank,3-H} + 2.17x10^{-4} * mass_{other.3H}\right) * 7.24x10^{-6}\right]$$

For medium volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\left[\left(mass_{deli,1-M} + 5.82x10^{-2} * mass_{frank,1-M} + 2.17x10^{-4} * mass_{other.1-M}\right) * 1.25x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP-M} + 5.82x10^{-2} * mass_{frank,2-PP-M} + 2.17x10^{-4} * mass_{other.2PP-M}\right) * 6.74x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-M} + 5.82x10^{-2} * mass_{frank,2-GI-M} + 2.17x10^{-4} * mass_{other\ 2GI-M}\right) * 1.29x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-M} + 5.82x10^{-2} * mass_{frank,3-M} + 2.17x10^{-4} * mass_{other3-M}\right) * 7.08x10^{-6}\right]$$

Finally, for low volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\left[\left(mass_{deli,1-L} + 5.82x10^{-2} * mass_{frank,1-L} + 2.17x10^{-4} * mass_{other.1-L}\right) * 1.10x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP-L} + 5.82x10^{-2} * mass_{frank,2-PP-L} + 2.17x10^{-4} * mass_{other.2PP-L}\right) * 6.10x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-L} + 5.82x10^{-2} * mass_{frank,2-GI-L} + 2.17x10^{-4} * mass_{other\ 2GI-L}\right) * 1.16x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-L} + 5.82x10^{-2} * mass_{frank,3-L} + 2.17x10^{-4} * mass_{other.3-L}\right) * 5.65x10^{-6}\right]$$

The 2008 algorithm uses the extended list of risk ratios in each of the three volume groups for calculating the baseline risk scores. The three sets of equations are presented with the appropriate masses substituted in order to calculate the baseline risk for each establishment across all alternatives that may apply.

For high volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\left[\left(mass_{delius1-H} + 0.41 * mass_{delis1-H} + 0.34 * mass_{pate1-H} + 5.82x10^{-2} * mass_{hotdog1-H} + \right.\right.$$
$$\left.\left. 2.17x10^{-4} * mass_{other1-H} + 6.25x10^{-7} * mass_{frozen1-H}\right) * 1.40x10^{-8}\right] +$$

$$\left[\left(mass_{delius2-PP-H} + 0.41 * mass_{delis2-PP-H} + 0.34 * mass_{pate2-PP-H} + 5.82x10^{-2} * mass_{hotdog2-PP-H} + \right.\right.$$
$$\left.\left. 2.17x10^{-4} * mass_{other2-PP-H} + 6.25x10^{-7} * mass_{frozen2-PP-H}\right) * 8.20x10^{-8}\right] +$$
$$\left[\left(mass_{delius2-GI-H} + 0.41 * mass_{delis2-GI-H} + 0.34 * mass_{pate2-GI-H} + 5.82x10^{-2} * mass_{hotdog2-GI-H} + \right.\right.$$
$$\left.\left. 2.17x10^{-4} * mass_{other2-GI-H} + 6.25x10^{-7} * mass_{frozen2-GI-H}\right) * 1.53x10^{-8}\right] +$$
$$\left[\left(mass_{delius3-H} + 0.41 * mass_{delis3-H} + 0.34 * mass_{pate3-H} + 5.82x10^{-2} * mass_{hotdog3-H} + \right.\right.$$
$$\left.\left. 2.17x10^{-4} * mass_{other3-H} + 6.25x10^{-7} * mass_{frozen3-H}\right) * 7.24x10^{-8}\right]$$

For medium volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\Big[\Big(mass_{delius1\text{-}M} + 0.41*mass_{delis1\text{-}M} + 0.34*mass_{pate1\text{-}M} + 5.82\text{x}10^{-2}*mass_{hotdog1\text{-}M} +$$

$$2.17\text{x}10^{-4}*mass_{other1\text{-}M} + 6.25\text{x}10^{-7}*mass_{frozen1\text{-}M}\Big)*1.25\text{x}10^{-8}\Big] +$$

$$\Big[\Big(mass_{delius2\text{-}PP\text{-}M} + 0.41*mass_{delis2\text{-}PP\text{-}M} + 0.34*mass_{pate2\text{-}PP\text{-}M} + 5.82\text{x}10^{-2}*mass_{hotdog2\text{-}PP\text{-}M} +$$

$$2.17\text{x}10^{-4}*mass_{other2\text{-}PP\text{-}M} + 6.25\text{x}10^{-7}*mass_{frozen2\text{-}PP\text{-}M}\Big)*6.74\text{x}10^{-8}\Big] +$$

$$\Big[\Big(mass_{delius2\text{-}GI\text{-}M} + 0.41*mass_{delis2\text{-}GI\text{-}M} + 0.34*mass_{pate2\text{-}GI\text{-}M} + 5.82\text{x}10^{-2}*mass_{hotdog2\text{-}GI\text{-}M} +$$

$$2.17\text{x}10^{-4}*mass_{other2\text{-}GI\text{-}M} + 6.25\text{x}10^{-7}*mass_{frozen2\text{-}GI\text{-}M}\Big)*1.29\text{x}10^{-6}\Big] +$$

$$\Big[\Big(mass_{delius3\text{-}M} + 0.41*mass_{delis3\text{-}M} + 0.34*mass_{pate3\text{-}M} + 5.82\text{x}10^{-2}*mass_{hotdog3\text{-}M} +$$

$$2.17\text{x}10^{-4}*mass_{other3\text{-}M} + 6.25\text{x}10^{-7}*mass_{frozen3\text{-}M}\Big)*7.08\text{x}10^{-6}\Big]$$

For low volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\Big[\Big(mass_{delius1\text{-}L} + 0.41*mass_{delis1\text{-}L} + 0.34*mass_{pate1\text{-}L} + 5.82\text{x}10^{-2}*mass_{hotdog1\text{-}L} +$$

$$2.17\text{x}10^{-4}*mass_{other1\text{-}L} + 6.25\text{x}10^{-7}*mass_{frozen1\text{-}L}\Big)*1.10\text{x}10^{-8}\Big] +$$

$$\Big[\Big(mass_{delius2\text{-}PP\text{-}L} + 0.41*mass_{delis2\text{-}PP\text{-}L} + 0.34*mass_{pate2\text{-}PP\text{-}L} + 5.82\text{x}10^{-2}*mass_{hotdog2\text{-}PP\text{-}L} +$$

$$2.17\text{x}10^{-4}*mass_{other2\text{-}PP\text{-}L} + 6.25\text{x}10^{-7}*mass_{frozen2\text{-}PP\text{-}L}\Big)*6.10\text{x}10^{-8}\Big] +$$

$$\Big[\Big(mass_{delius2\text{-}GI\text{-}L} + 0.41*mass_{delis2\text{-}GI\text{-}L} + 0.34*mass_{pate2\text{-}GI\text{-}L} + 5.82\text{x}10^{-2}*mass_{hotdog2\text{-}GI\text{-}L} +$$

$$2.17\text{x}10^{-4}*mass_{other2\text{-}GI\text{-}L} + 6.25\text{x}10^{-7}*mass_{frozen2\text{-}GI\text{-}L}\Big)*1.16\text{x}10^{-6}\Big] +$$

$$\Big[\Big(mass_{delius3\text{-}L} + 0.41*mass_{delis3\text{-}L} + 0.34*mass_{pate3\text{-}L} + 5.82\text{x}10^{-2}*mass_{hotdog3\text{-}L} +$$

$$2.17\text{x}10^{-4}*mass_{other3\text{-}L} + 6.25\text{x}10^{-7}*mass_{frozen3\text{-}L}\Big)*5.65\text{x}10^{-6}\Big]$$

The 2011 algorithm also uses the same extended list of risk ratios in each of the three volume groups for calculating the baseline risk scores. The three sets of equations are the same as those detailed above for the 2008 algorithm.

2011 Version Update for Baseline Risk Score Calculation

This version updates the establishment *Lm* risk at retail to consumer risk at the point of consumption. FSIS determines the consumer risk of the susceptible population by estimating the probability of illness given fixed time, temperature, and *Lm* population density for the susceptible consumer population (pregnant women, immunocompromised, and elderly). The risk is based on one deli meat equivalent serving that contains the six sigma estimated *Lm* dose for each establishment given the individual establishment average deli meat equivalent *Lm* contamination in *Lm* colony forming units per gram. The probability is calculated from the one-hit exponential model with an r-value corresponding to the susceptible population (5.85E-12, WHO/FAO). The equation used is the cumulative density of the exponential distribution:

Probability of illness = 1 – exp (-r x Dose)

The Dose in this equation is estimated from six components that correspond to input variables: deli meat sliced (delis) at the establishment; deli meat unsliced (delius) at the establishment; hot dogs; other RTE products (cooked, fermented, dried, and salt-cured); frozen RTE products; and pate/meat spreads/deli salads.

FSIS calculated the six components by multiplying the annual production volume by the respective risk ratio from Table 5 and the respective Q80 value from Table 6. The latter value was modified according to the expected *Lm* exponential growth rate (EGR) at 5 degrees Celsius for 7 days. The product of these multiplications yields units of total annual establishment *Lm* colony forming units that provides an estimate of the average *Lm* cfu/g of RTE product when divided by the total annual RTE volume. The representative establishment average Dose is calculated by multiplying the establishment average *Lm* cfu/g by 35 grams per serving. FSIS estimated the Poisson distributed establishment average dose per serving by multiplying the establishment calculated average by 5.997807 (6 sigma critical value for a standard normal distribution) to account for the extreme deviation from the mean, which is then added to the mean to achieve the six sigma limit.

The exponential growth rate function, EGR, is given by:

EGR = 10^ Min(log10 (Q80) x Time x (AMA x 6.24 / loge (10)) x ((Temp + 2.86) / (25 + 2.86))^2 , MPD)

In this formula, Q80 is from Table 6. The antimicrobial agent effect (AMA) is 0.507 for alternatives 1, 2a, and 2b, while for alternative 3 it is 1.128. The antimicrobial agent modification is from Endrikat et al. (2010). The time and temperature formula is taken from Ratkowsky (1982) with the standard temperature being 5 degrees Celsius and the standard time being 7 days. The MPD (Maximum Population Density) is taken for *Lm* to be 7.27 from Pouillot (2011).

Adjustment for Historical Laboratory Results

2006 Version Update for Adjusting Historical Risk

The baseline risk score for each establishment is converted to a risk rank and then adjusted by one of three risk factors. Although the composition of the risk factors differs among the 2005, 2006, and 2008 algorithms, the procedure is the same that adjusts the baseline risk rank with historical laboratory results at retail. The 2011 version of the algorithm makes a similar retail adjustment but carries the contamination risk through to the final point of consumption. This algorithm estimates the rank of risk of illness. The 2011 algorithm bases its ranking on estimates of illness at consumption while the previous algorithm versions based their rankings on contamination at retail. The general equation used for adjusting the baseline risk score is as follows:

$$\text{Adjusted Baseline Risk} = w_1\,\text{Risk1} + w_2\,\text{Baseline Risk2 Score}_{\text{rank}} + w_3\,\text{Risk3} - w_4\,\text{Risk4}$$

The three risks are: Risk1- the risk of a current positive result; Risk2 is the baseline risk of a positive result; Risk3- the risk of a positive result within the past six months; and Risk4- the (negative) risk of having a negative result within the past six months. Each of the risks carries its own weight. Most of the risk is associated with the baseline Risk2 where w_2 equals 1.0, but the weight of Risk1, w_1, equal to the number of ranks, is more important since any input requires an immediate sample while Risk3 and Risk4 have much smaller contributions due to comparatively smaller weights than Risk1 similarly having an affect only when the risks are not equal to zero.
The derivation of the historical weighting factors is given in Appendix IX of the 2007 Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*. The 2005 algorithm weights for Risk3 are shown in Table 7.

Table 7. 2005 Algorithm Weights for Positive *Listeria monocytogenes* Results in Previous Six Months

Lagged Month	Weight
1	--
2	0.231
3	0.205
4	0.191
5	0.186
6	0.186

Both food contact surface testing and retail product testing show higher degrees of correlation than product testing at the establishment, especially at shorter time differences. This is especially true of food contact surfaces.

Risk 3 is the risk associated with past positive cultures in individual establishments with a six-month inclusion window. Additional theoretical research on the Risk 3 weights was done using an intensive simulation of the alternative 3 establishment contamination scenarios that updated the values of these weights used in the 2005 algorithm.

2006 Algorithm Risk3 Weights

Table 8 shows the 2005 version and 2006 version weights side by side. The difference is that more weight is given to months 2 and 3 than to 4, 5, and 6 and additionally giving less weight than for establishments having positive culture results in months 4, 5, and 6 than the 2005 algorithm. The 2007 Risk Assessment for Risk-Based Verification Sampling of Listeria monocytogenes Appendix IX provides the analysis for the 2006 algorithm Risk3 weights.

Table 8. 2006 Algorithm Weights that increase establishment baseline risk score rank based on previous positives

Lagged Month	Weighted 2005	Weight 2006
2	0.231	0.4614
3	0.205	0.2446
4	0.191	0.1252
5	0.187	0.0861
6	0.186	0.0826
Sum	1.000	1.000

2008 Version Update for Adjusting Historical Risk

Purpose of Update

This updated version of the establishment *Lm* risk ranking algorithm describes the inclusion of food contact surface (FCS) and environmental test positive and negative culture results as additional risk factors in the algorithm. This was done to utilize all the pertinent culture data available for analysis. Positive *Lm* culture results in product and on food contact surfaces are regarded as regulatory equivalents. Positive environmental cultures are considered important ancillary information on establishment sanitation and *Lm* harborage sites within individual plants. The weighting of environmental culture results is an important consideration in this update because there is no regulatory implication for environmental culture results. We brought the justification for a minimal weighting scheme forward, because the inclusion of environmental culture results was considered an important additional risk factor.

The risk factors for adjusting the baseline risk ranking are updated in the 2008 algorithm to include laboratory results for *Lm* sampled on food contact surfaces (fcs) and environmental areas (env). The Risk1, Risk3, and Risk4 risk factors are all modified to reflect this change. The modified equations for these risk factors are as follows:

Risk1 = $(\text{month1}_{product} + \text{month1}_{fcs} + 0.0826 \times \text{month1}_{env}) / 2.0826$

Risk3 = $\{(0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{product} + (0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{fcs} + 0.08626 \times (0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{env}\}/2.0826$

Risk4 = $\{((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/18)_{product} + ((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/50)_{fcs} + (0.0826 \times (\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/28)_{env}\}$

It can be seen that the modified risk factors are the weighted average for the component product, food contact surface, and environmental laboratory results for each modified risk factor.

Risk Ranking Model Development

The basic model used to assess model fit to the data, sensitivity analysis, and uncertainty analysis is uniformly the same. The model uses a linear system of equations corresponding to the input variable matrix, X, and the output variable column vector, Y. Equation (1) is the linear model and equation (2) is the solution column vector, B, for the linear system.

(1) $Y = X B$

(2) $B = (X' X)^{-1} X' Y$

In order to compare input and output variables on the same unit standard deviation scale, all variables are transformed by subtracting the mean and dividing by the standard deviation (Z transformation). This transformation removes the intercept from the linear system of equations. To control the error distribution on the linear model, rank regression also is used. Because the error distribution becomes an error distribution on ranks, bootstrapping is used to estimate the non-normal error distribution and approximate t-tests for significance are used. The exact implementation of the linear model is explained in the appendices on sensitivity analysis and uncertainty analysis.

In order to describe the progression of development of the establishment *Lm* risk ranking algorithm, the plan used is to focus on four datasets and their analysis. The four datasets correspond to four phases of the algorithm development. The initial algorithm is described by the 2005 algorithm dataset that is not bootstrapped and provides a baseline model for the risk ranking algorithm. A minor modification with bootstrapped estimates is described by the 2006 algorithm dataset. A major modification with bootstrapped estimates and the addition of risk variables is described by the 2008 algorithm dataset. And the last major modification with bootstrapped estimates using the same 2008 dataset is described by the 2011 algorithm dataset. The datasets were chosen because they bracket the expected extremes of the output establishment risk rank distribution. The 2005 dataset represents the minimum number of alternatives and establishments and the 2008 dataset represents the maximum number of alternatives and establishments observed in the RTE001 program over a six-year period.

Because the risk ranking model is based on the analysis of ranks, the model used for the algorithm is analyzed in two parts. The first part estimates the baseline risk ranking for each establishment and the second part estimates the adjusted baseline risk ranking for each establishment based on historical performance. The model is broken down into baseline establishment risk ranking, adjusted baseline establishment risk ranking, and the evaluation of the combined algorithm parts for the final establishment risk ranking.

Baseline Listeria monocytogenes Establishment Risk Ranking

A model for baseline *Listeria monocytogenes risk* was developed from the FSIS risk assessment for deli meat risk at retail (FSIS, 2003). The original baseline risk model was updated to model post-retail consumer risk based on the FSIS retail risk assessment (FSIS, 2010). Four datasets based on annual FSIS data estimates for 2005, 2006, 2008, and 2011 are used to show the development of the *Listeria monocytogenes* baseline risk ranking algorithm from the deli meat risk assessment model. The input data varies by dataset to show the stepwise development of the baseline risk ranking as part of the adjusted *Listeria monocytogenes* risk ranking algorithm.

2005 Dataset Baseline Risk Ranking

The risk model used for the risk ranking algorithm is a linear and assumes independent risk factors that enter the model as single non-interacting factors. The 2005 baseline risk model has three product volume risk factors: individual establishment deli meat annual production; individual establishment hot dog annual production; and individual establishment other RTE product annual production. Each risk factor is multiplied by the constants (risk ratios) in Table 5 thereby converting the RTE volumes to equivalent deli meat volumes (EDMV); and then each EDMV is multiplied by the Q80, the *Lm* contamination distribution constant for alternative and RTE product subdivided into high, medium, and low production volume for the EDMV of each establishment. The summary statistics for these input distributions are shown in Table 9. The equation used for the baseline risk (Risk2) is:

Risk 2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

The establishment *Lm* risk rank is found by ranking all establishments in ascending order according to their calculated baseline risk. Baseline risk is characterized as Risk2 because Risk1 is the more important regulatory risk defined as a current positive *Lm* result or a regulatory policy decision to sample a particular establishment. Notice that Risk2 is the product of EDMV and Q80 summed for each of an establishment's alternative and production volume.

Table 9a. Summary Statistics for 2005 Dataset Input Variables
Raw Data

Statistic	Deli Meat	HotDog	Other	Q80	EDMV
average	1,667,227	996,984	22,414,534	5.19E-06	1,730,115
stdev	9,515,906	7,900,256	837,248,882	2.75E-06	9,625,318
min	0	0	0	1.10E-08	0
max	267,930,569	175,000,000	37,264,000,000	7.24E-06	268,488,756
median	0	0	78,095	7.08E-06	801
CV%	570.8	792.4	3735.3	52.9	5,56.3
skewness	14.5	12.5	44.5	-0.9	14.2
kurtosis	330.4	198	1,980.10	-1.00	3,19.5
N	1,981	1,981	1,981	1,981	1,981

Table 9b. Summary Statistics for 2005 Dataset Input Variables
Transformed Data

Statistic	Deli Meat*	HotDog*	Other*	Risk 2
average	4.69	0.12	0.01	4.82E+00
stdev	26.99	0.79	0.28	2.71E+01
min	0	0	0	2.72E-10
max	440.41	15.56	12.35	4.40E+02
median	0	0	0	2.73E-03
CV%	575.3	656	3363	563.1
skewness	9.8	10.5	44.5	9.7
kurtosis	114.7	139.5	1,978.3	112.9
N	1,981	1,981	1,981	1,981

*****Distribution has been transformed by multiplying by deli meat risk ratio constants and the Q80 constants.

The transformed distributions for deli meat, hot dogs, and other RTE products are represented in units of annual *Lm* cfu contamination per establishment shown in Table 10. These values are used in a standardized rank regression in order to determine the sensitivity and uncertainty of the risk factors on the *Lm* risk ranking outcome. The rank distributions were used because the input variables deviated significantly from normal distributions as indicated by the skewness and kurtosis statistics shown in Table 10. This is mainly due to many establishments having zero volumes for certain RTE products giving the input distributions a pronounced positive skew and positive kurtosis (skewed to the right and peaked).

The relationship of the output baseline risk rank variable to the three input variables is shown in Table 11. The regression coefficients (b) shown in this table are standardized in order to make comparisons in the same standard deviation units (Sb). The overall regression and the individual regression components are each highly significant. The order of relationship to the output ranked variable is Deli Meat > Other > Hot Dogs. R-squared represents the proportion of the variance in the output rank variable that is accounted for by the linear regression on ranks. In this case this means that 76% of the variance was accounted for by the regression model and 24% was not. Since the variance of the risk ranks is fixed by the bounds set by the number of ranked alternatives the focus of uncertainty is on the 24% of the variance not accounted for by the model.

Table 10. Summary Statistics 2005 Dataset Transformed Variables

Statistic	Deli Meat*	HotDog*	Other*	Risk 2
average	4.69	0.12	0.01	4.82E+00
stdev	26.99	0.79	0.28	2.71E+01
min	0.00	0.00	0.00	2.72E-10
max	440.41	15.56	12.35	4.40E+02
median	0.00	0.00	0.00	2.73E-03
CV%	575.3	656.0	3363.0	563.1
skewness	9.8	10.5	44.5	9.7
kurtosis	114.7	139.5	1,978.3	112.9
N	1,981	1,981	1,981	1,981

*Transformed variable

Table 11. Standardized Regression Coefficients for Full 2005 Algorithm Dataset

Variable	b	Sb
Deli Meat	0.8542*	0.0122
HotDog	0.1473*	0.0117
Other	0.3087*	0.0116
R-Squared	0.7604*	0.2396

*Statistic significant at $p<0.05$

2006 Dataset Baseline Risk Ranking

This dataset was the foundation for developing sensitivity and uncertainty analysis for the risk ranking algorithm. The input variables are all the same except that the dataset is larger (N=2,493) and allows bootstrap estimates based on a sample size of 1,981 the sample size of the 2005 dataset. Table 12 includes the statistics for 2,493 lines of data. Bootstrapped estimates appear in the sections on sensitivity and uncertainty analysis. The estimates are based on the same formula for calculating Risk2 as in the baseline 2005 dataset. Notice that the Q80 and Rank Risk2 distributions are approximately normal based on the skewness and kurtosis statistics. This means that the model error distribution is applicable to t-test significance tests based on ranked data that will have negligible bias. The baseline risk equation used is:

Risk 2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Table 12a. 2006 Dataset with Raw Data and Transformed Baseline Input Variables
Raw Data

statistic	Deli Meat	Hot Dog	Other	Q80
average	2,083,956	53,150	4,218	3.62E-06
stdev	13,051,080	429,068	161,967	2.69E-06
min	0	0	0	1.10E-08
max	301,520,000	10,185,000	8,086,288	7.24E-06
median	0	0	20.2244	4.65E-06
CV%	626.3	807.3	3840.1	74.3
skewness	14.87	13.15	49.9	0.03
kurtosis	298.38	219.23	2490.89	-1.52
N	2,493	2,493	2,493	2,493

Table 12b. 2006 Dataset with Raw Data and Transformed Baseline Input Variables
Transformed Data

statistic	Deli Meat*	Hot Dog*	Other*	Risk2	Rank Risk2
average	4.81	6.23E-03	1.50E-06	4.82	1,247
stdev	31.01	4.43E-02	5.38E-05	31.01	720
min	0	0.00E+00	0.00E+00	0	1
max	564.08	9.07E-01	2.68E-03	564.08	2,493
median	0	0.00E+00	7.76E-09	0	1247
CV%	644	710.3	3591.3	643.4	57.7
skewness	11.18	11.38	49.85	11.18	0
kurtosis	148.38	161.11	2,487.95	148.27	-1.2
N	2,493	2,493	2,493	2,493	2,493

*****Distribution has been transformed by multiplying by deli meat risk ratio constants and the Q80 constants

Table 13 shows the same order of relationship as in the 2005 dataset: Deli Meat > Other > Hot Dog. Each input variable is significant, and the overall regression model is significant. Also, about 20% of the rank variance is not explained by the model.

Table 13. Standardized Baseline Regression Coefficients for Full 2006 Algorithm Dataset

Variable	b	sb
Deli Meat	0.8526*	0.0098
Hot Dog	0.1825*	0.0094
Other	0.2502*	0.0093
R-Squared	0.8011*	0.1989

*Statistic significant at p<0.05

2008 Dataset Baseline Risk Ranking

This algorithm uses an updated equation for Risk2. The equation for the risk transformed data is:

Risk2 = 1.0000 x Delis x Q80 + 0.408293 x Delius x Q80 + 0.058182 x Hot Dog x Q80 + 0.000217 x Other x Q80 + 0.000000625 x Frozen x Q80 + 0.343293 x Pate x Q80

This equation includes input variables for frozen and pate RTE products and splits the deli meat category into sliced and unsliced. Table 14 shows the input data for raw and risk transformed input variables. Table 15 shows the standardized regression coefficients for the full ranked dataset of size 3,002. The regression and input variables are significant.

Table 14a. Raw and Risk Transformed Baseline Input Variables for the 2008 Algorithm Dataset

Statistic	DeliS	DeliUS	HotDog	Other
average	1,076,663	825,757	809,560	6,280,420
stdev	8,302,318	5,128,237	7,757,598	127,659,470
min	0	0	0	0
max	275,000,000	86,667,277	178,291,824	6,948,916,448
median	0	0	0	65,975
CV%	771.1	621	958.2	2,032.70
skewness	16.8	9.5	14.1	53.6
kurtosis	435.1	111.4	230.1	2,917.70
N	3,002	3,002	3,002	3,002

Table 14b. Raw and Risk Transformed Baseline Input Variables for the 2008 Algorithm Dataset

Statistic	Frozen	Pate	Q80	DMCV
average	1,276,139	1,786	3.83E-06	1,314,430
stdev	8,944,261	27,557	2.75E-06	6,559,684
min	0	0	1.10E-08	0
max	152,434,618	694,233	7.24E-06	112,862,449
median	0	0	5.65E-06	402
CV%	700.9	1,542.70	71.6	499.1
skewness	10.8	19.8	-0.2	7.9
kurtosis	140.5	430.2	-1.7	80.1
N	3,002	3,002	3,002	3,002

Table 14c. Raw and Risk Transformed Baseline Input Variables for the 2008 Algorithm Dataset

Statistic	DeliS	DeliUS	HotDog	Other	Frozen	Pate	Risk2	Rank Risk2
average	1.0	2.4	0.1	0.0	1.40E-06	0.0	3.5	1,501
stdev	10.0	22.4	0.9	0.2	1.27E-05	0.0	25.8	867
min	0.0	0.0	0.0	0.0	0.00E+00	0.0	0.0	1
max	260.1	627.5	27.6	10.9	3.56E-04	1.7	627.5	3,002
median	0	0	0	0	0	0	0	1,502
CV%	998.1	933.0	907.2	3,493.2	908.8	1,876.6	732.2	57.7
skewness	18.1	18.2	16.8	54.5	19.1	25.8	14.5	0.0
kurtosis	381.6	407.7	389.8	2,979.7	452.8	750.9	269.6	-1.2
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 15. Standardized Baseline Regression Coefficient Results for the 2008 Algorithm Dataset

Variable	b	sb
DeliS	0.4448*	0.0206
DeliUS	0.4144*	0.0230
HotDog	0.1325*	0.0212
Other	0.3117*	0.0207
Frozen	-0.0443*	0.0144
Pate	0.0472*	0.0224
R-Squared	0.6300*	0.3700

*Statistic significant at p<0.05

The order of importance by coefficient magnitude is: DeliS > DeliUS > Other > Hot Dog > Pate > Frozen. An excess of zeros in the pate variable drives the regression coefficient negative.

2011 Dataset Baseline Risk Ranking

This algorithm uses an updated equation for Risk2. The equation for the risk transformed data is:

Risk2 = (1.0000 x Delis x EGR + 0.408293 x Delius x EGR + 0.058182 x Hot Dog x EGR + 0.000217 x Other x EGR + 0.000000625 x Frozen x EGR + 0.343293 x Pate x EGR)

This transformation of the raw baseline input data provides an estimate of the total annual *Lm* colony forming units in post-lethality exposed product that has been adjusted for the expected increase due to growth between retail and the point of consumption. The input variables in Table 16 are in total *Lm* cfu. We determined an estimate of *Lm* cfu/g by dividing by the total annual RTE volume in grams. Table 17 shows the standardized regression coefficients for the non-bootstrapped dataset. All the input variables are significant with the baseline model accounting for more than 62% of the total variation in 3,002 ranks.

Table 16. Risk Transformed Baseline Input Variables for the 2011 Algorithm Dataset

Statistic	DeliS	DeliUS	HotDog	Other	Frozen	Pate	cfu/g
average	1.16E+04	4.24E+04	1.03E+03	1.16E+02	1.46E-02	5.54E+01	5.52E+04
stdev	1.65E+05	5.00E+05	1.35E+04	4.58E+03	2.44E-01	1.11E+03	5.50E+05
min	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.11E-08
max	5.66E+06	1.44E+07	6.33E+05	2.51E+05	8.17E+00	3.96E+04	1.44E+07
median	0.00E+00	0.00E+00	0.00E+00	2.94E-01	0.00E+00	0.00E+00	7.37E+00
CV%	1,430.8	1,177.9	1,306.1	3,934.6	1,668.0	2,004.0	996.9
skewness	25.4	19.8	36.3	54.5	29.2	26.3	17.2
kurtosis	728.3	461.8	1,626.9	2,981.5	899.9	774.5	356.3
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 17. Standardized Baseline Regression Coefficient Results for the 2011 Algorithm Dataset

Variable	b	sb
DeliS	0.4334*	0.0013
DeliUS	0.4131*	0.0013
HotDog	0.1345*	0.0013
Other	0.3372*	0.0012
Frozen	-0.0550*	0.0012
Pate	0.0356*	0.0012
R-Squared	0.6238*	0.3762

Adjusted *Listeria monocytogenes* Establishment Risk Ranking

The adjusted baseline *Listeria monocytogenes* risk ranking algorithm development is shown through the progression of the same four datasets used for the baseline risk ranking algorithm development. The adjustment is based on historical establishment process control using FSIS regulatory *Listeria monocytogenes* sampling data. The adjustment increases the establishment risk ranking for poor performance and decreases the risk ranking for good performance. FSIS defines poor performance as any positive *Listeria monocytogenes* result within the last six months. The agency defines good performance as no positives and negative *Listeria monocytogenes* results within the last six months.

2005 Dataset Adjusted Baseline Risk Ranking

The equations used for determining the adjusted baseline risk ranking with all the constants are shown below.

Adjusted Risk Rank = 1981x Risk1 + Rank Risk2 + 495.25 x RR x Risk3 / 7.0116 + 495.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.2310 x month2 + 0.2050 x month3 + 0.1910 x month4 + 0.1870 x month5 + 0.1860 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6) / 28

The maximum rank with this dataset is 1,981 so this is set as the limit for Risk1. The maximum change in risk rank is set at 25% of the total number of ranks (495.25). Table 6 lists the variable for prevalence relative risk at retail (RR) with the maximum as 7.011566. The constant coefficients for Risk3 sum to one. The monthly variables contain the total number of positive *Lm* laboratory results for Risk3 by month and the total number of negative *Lm* laboratory results for Risk4 by month. The maximum number of negative laboratory results is set at 28 over six months. Table 18 shows the distribution statistics for adjusted baseline risk as risk transformed variables. Only the rank transformed variables at this stage have near normal distributions. Table 19 shows the standardized rank regression coefficients, which are significant and account for more than 99% of the total output rank variability. The order of the risk rank coefficients for adjusted baseline risk rank is: Rank Risk2 > Risk1 > Risk3 > Risk4. The combined effects of Risk1 and Risk3 are greater than the effect of Risk4.

Table 18. Risk Transformed Adjusted Baseline Input Variables for the 2005 Algorithm Dataset

Statistic	RankRisk2	Risk1	Risk3	Risk4	AdjRankRisk2
average	991	12	3	-21	986
stdev	572	154	23	24	592
min	1	0	0	-311	-248
max	1,981	1,981	246	0	3,673
median	991	0	0	-16	987
CV%	57.7	1281.3	708.1	-114.2	60.1
skewness	0.0	12.7	7.2	-3.3	0.2
kurtosis	-1.2	160.5	50.6	21.1	-0.3
N	1,981	1,981	1,981	1,981	1,981

Table 19. Standardized Adjusted Baseline Regression Coefficient Results for the 2005 Algorithm Dataset

Variable	b	S_b
Rank Risk2	0.9950*	0.0016
Risk1	0.1229*	0.0015
Risk3	0.0462*	0.0015
Risk4	-0.0298*	0.0016
R-Squared	0.9954*	

*Statistic significant at p<0.05

2006 Dataset Adjusted Baseline Risk Ranking

The equations used for the 2006 algorithm are shown below. The maximum rank is 2,493, and it is set as the limit on Risk1. The maximum shift in risk ranking for any establishment is set at 25% of the maximum rank (623.25). As with the 2005 baseline algorithm, the maximum retail prevalence relative risk is set at 7.0116. The major change in this algorithm is the redefinition of the constant coefficients for Risk3 due to new data. The maximum number of negative laboratory results is again set at 28 over six months. Table 20 shows the risk transformed input and output variables for the adjusted baseline risk ranking. Table 21 shows that all the standardized rank regression coefficients and the regression model are significant. The regression coefficient for Risk4 has more of an effect than in the 2005 algorithm because the order of coefficients is now: Rank Risk2 > Risk4 > Risk1 > Risk3. Risk1 and Risk3 compensate for the effect of Risk4.

Adjusted Risk Rank = 2493x Risk1 + Rank Risk2 + 623.25 x RR x Risk3 / 7.0116 + 623.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

Table 20. Risk Transformed Adjusted Baseline Input Variables for the 2006 Algorithm Dataset

Statistic	RankR2	R1	R3	R4	AdjRankR2	RiskRank
average	1,247	14	2	-440	832	1,247
stdev	720	221	29	570	807	720
min	1	0	0	-3729.3	-2265	1
max	2493	3498	652.7	0	5873	2493
median	1247	0	0	-241.7	866	1247
CV%	57.7	1576.1	1205.7	-129.5	97	58
skewness	0	15.7	16.6	-2.23	0.19	0
kurtosis	-1.2	244.8	311.2	5.5	3.8	-1.2
N	2,493	2,493	2,493	2,493	2,493	2,493

Table 21. Standardized Adjusted Baseline Regression Coefficient Results for the 2006 Algorithm Dataset

Variable	b	sb
rankRisk2	1.0207*	0.0030
Risk1	0.0850*	0.0028
Risk3	0.0355*	0.0028
Risk4	0.1453*	0.0030
R-Squared	0.9803*	0.0197

*Statistic significant at $p<0.05$

2008 Dataset Adjusted Baseline Risk Ranking

The equations for adjusted baseline risk ranking are shown for the 2008 algorithm. The major change focuses on the incorporation of food contact surface and environmental area laboratory results. The coefficients are repeated for each of the three components in Risk3 and Risk4. The component representing environmental sampling results in Risk3 and Risk4 is down weighted. This value is taken to be 0.0826 representing the tail off in significance at six months (Table 8). Each of the risk factors adjusting the baseline Risk2 is now the weighted average of the three components contributing to each risk factor.

$\text{Risk1} = (\text{month1}_{\text{product}} + \text{month1}_{\text{fcs}} + 0.0826 \text{ x month1}_{\text{env}}) / 2.0826$

$\text{Risk3} = \{(0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{product}} + (0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{fcs}} + 0.08626 \text{ x } (0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{env}} \}/2.0826$

Risk4 = $\{((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/18)_{\text{product}} + ((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/50)_{\text{fcs}} + (0.0826 \times (\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/28)_{\text{env}}$

Table 22 shows the risk transformed risk factors by individual subcomponent. Each individual risk subcomponent was examined to determine if it was necessary to include in the analysis. Table 23 shows that the rank regression on risk subcomponents is significant for all but the environmental variables in Risk3 and Risk4. Because there is no apparent advantage to subcomponent analysis, the subcomponents are aggregated into the original Risk1, Risk3, and Risk4 risk factors. Table 24 proves this point because there is no loss in significance; therefore the conclusions drawn by using the aggregated dataset for analysis are valid.

Table 22a. Risk Transformed Adjusted Baseline Input Variables for the 2008 Algorithm Dataset

Statistic	Risk1	Risk3-P	Risk3-FCS	Risk3-ENV
average	9.2	1.2	0.6	0
stdev	164.3	24.8	17.1	1.1
min	0	0	0	0
max	3,002	742	727	60
median	0	0	0	0
CV%	1,792.30	2,018.60	3,003.10	3,749.00
skewness	18.2	24.9	37.2	48.9
kurtosis	328.1	666.5	1,451.00	2,527.90
N	3,002	3,002	3,002	3,002

Table 22b. Risk Transformed Adjusted Baseline Input Variables for the 2008 Algorithm Dataset

Statistic	Risk4-P	Risk4-FCS	Risk4-ENV	adjRisk2	Risk Rank
average	-9.5	-2.2	-0.1	1,473.60	1,501
stdev	40.4	23.2	1.1	875.8	867
min	-383.1	-424.3	-25.4	-291.6	1
max	98	86	0	5,752	3,002
median	0	0	0	1,479	1,502
CV%	-426.4	-1,059.10	-1,254.50	59.4	57.7
skewness	-2.6	-7	-16.1	0.1	0
kurtosis	11.6	76.1	288.2	-0.8	-1.2
N	3,002	3,002	3,002	3,002	3,002

Table 23. Standardized Adjusted Baseline Regression Risk Subcomponent Coefficient Results for the 2008 Algorithm Dataset

Variable	b	sb
Rank Risk2	0.9973*	0.0026
Risk1	0.1059*	0.0278
Risk3-P	0.0228*	0.0077
Risk3-FCS	0.0053	0.0092
Risk3-ENV	0.0211*	0.0087
Risk4-P	0.0424*	0.0021
Risk4-FCS	0.0437*	0.0048
Risk4-ENV	0.0016	0.0051
R-Squared	0.9945*	0.0055

*Statistic significant at $p<0.05$

Table 24. Standardized Adjusted Baseline Regression Coefficient Results for the 2008 Algorithm Dataset

Variable	b	sb
Rank Risk2	0.9905*	0.0088
Risk1	0.0868*	0.0086
Risk3	0.0614*	0.0087
Risk4	-0.1797*	0.0089
R-Squared	0.9028*	0.0972

*Statistic significant at $p<0.05$

2011 Dataset Adjusted Baseline Risk Ranking

The adjusted baseline establishment risk ranking equations for the 2011 algorithm are shown below. The 2011 algorithm historical adjustment is the same as for the 2008 algorithm. Table 25 shows the risk transformed input and output variable statistics. All variables are non-normal except for the initially ranked variables that approach normal distributions. Table 26 shows the standardized rank regression coefficients for the input variables that shows that the model regression is significant and accounts for more than 95% of the rank variability. All the input variables are significant in the model.

$Risk1 = (month1_{product} + month1_{fcs} + 0.0826 \times month1_{env}) / 2.0826$

$Risk3 = \{(0.4614 \times month2 + 0.2446 \times month3 + 0.1252 \times month4 + 0.0861 \times month5 + 0.0826 \times month6)_{product} + (0.4614 \times month2 + 0.2446 \times month3 + 0.1252 \times month4 + 0.0861 \times month5 + 0.0826 \times month6)_{fcs} + 0.08626 \times (0.4614 \times month2 + 0.2446 \times month3 + 0.1252 \times month4 + 0.0861 \times month5 + 0.0826 \times month6)_{env} \}/2.0826$

Risk4 = {((month1 + month2 + month3 + month4 + month5 + month6)/18)$_{product}$ + ((month1 + month2 + month3 + month4 + month5 + month6)/50)$_{fcs}$ + (0.0826 x (month1 + month2 + month3 + month4 + month5 + month6)/28)$_{env}$

Table 25. Risk Transformed Adjusted Baseline Input Variables for the 2011 Algorithm Dataset

Statistic	Risk2	Base Rank	Risk1	Risk3	Risk4	AdjRank2	Rank
average	2.90E-06	1,501	9	2	-48	1,465	1,507
stdev	2.89E-05	867	164	31	83	886	868
min	0.00E+00	1	0	0	-1,153	-866	1
max	7.56E-04	3,002	3,002	742	0	5,607	3,010
median	3.87E-10	1,502	0	0	-22	1,459	1,507
CV%	996.8	57.8	1,792.3	1,681.6	-171.4	60.5	57.6
skewness	17.2	0.0	18.2	20.5	-4.5	0.1	0.0
kurtosis	356.2	-1.2	328.1	446.0	30.1	-0.8	-1.2
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 26. Standardized Adjusted Baseline Regression Coefficient Results for the 2011 Algorithm Dataset

Variable	b	sb
Risk2	0.9165*	0.0064
Risk1	0.0956*	0.0291
Risk3	0.0361*	0.0120
Risk4	0.1838*	0.0076
R-Squared	0.9693	0.0307

*Statistic significant at p<0.05

Listeria monocytogenes Establishment Risk Ranking Algorithms

The development of four risk ranking algorithms is shown using the same four datasets used in baseline and adjusted baseline establishment risk ranking based on the progression of four *Listeria monocytogenes* risk ranking models. The 2005 and 2006 dataset analysis is repeated for clarity from Appendix IX of the 2007 Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*.

2005 Dataset Risk Ranking Algorithm

Table 27 shows the raw data statistics for the 2005 dataset. Table 28 shows the number of establishments and total number of alternatives in each category. The data indicate that 8.1% of the establishments have more than one alternative. Because the baseline and baseline adjustment input data are not normally distributed, the robust rank regression is justified. This dataset serves as the lower limit for the number of alternatives and the number of establishments to be used for comparison with the following datasets with more establishments and alternatives represented.

Table 27a. Summary of Input and Output Variables for 2005 Dataset

Statistic	Deli Meat	Hot Dogs	Other	Q80	Risk2	RankRisk2
average	1,667,227	996,984	22,414,534	5.19E-06	4.82E+00	991
stdev	9,515,906	7,900,256	837,248,882	2.75E-06	2.71E+01	572
min	0	0	0	1.10E-08	2.72E-10	1
max	267,930,569	175,000,000	37,264,000,000	7.24E-06	4.40E+02	1,981
median	0	0	78,095	7.08E-06	2.73E-03	991
CV%	570.8	792.4	3735.3	52.9	563.1	57.7
skewness	14.5	12.5	44.5	-0.9	9.7	0
kurtosis	330.4	198	1980.1	-1	112.9	-1.2
N	1,981	1,981	1,981	1,981	1,981	1,981

Table 27b. Summary of Input and Output Variables for 2005 Dataset

Statistic	Risk1	Risk3	Risk4	AdjRankRisk2	RiskRank
average	12	3	-21	986	991
stdev	154	23	24	592	572
min	0	0	-311	-248	1
max	1,981	246	0	3,673	1,981
median	0	0	-16	987	991
CV%	1281.3	708.1	-114.2	60.1	57.7
skewness	12.7	7.2	-3.3	0.2	0
kurtosis	160.5	50.6	21.1	-0.3	-1.2
N	1,981	1,981	1,981	1,981	1,981

Table 28. 2005 Dataset Alternatives

Variable	Number
Establishments	1,820
Alternative1	118
Alternative2a	57
Alternative2b	397
Alternative3	1,409
Total Alternatives	1,981
Multiple Alternatives	8.1%

The full risk ranking model used for this version of the establishment *Lm* risk ranking algorithm is as follows. The ranks of the baseline risk2 variable described in the Risk2 equation are taken and then adjusted with Risk1, Risk3, and Risk4. The coefficients making up the weights for each of these risk factors are taken from Appendix IX Tables 1–4. The weight for Risk1 is equal to the number of alternatives. The weight for Risk3 is the product of the RR coefficient for the establishment alternative product volume relative risk divided by the maximum RR and 495.25, which is 25% of the total ranks of 1,981. The weight for Risk4 is 495.25 times the adjusted establishment alternative product volume RR divided by the maximum RR. The adjusted RR is the negative of the maximum RR minus 1. The month1-6 variables are the number of positive *Lm* results in the respective months for Risk3 and the number of negative *Lm* results in the respective months for Risk4.

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 1981x Risk1 + Rank Risk2 + 495.25 x RR x Risk3 / 7.0116 + 495.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.2310 x month2 + 0.2050 x month3 + 0.1910 x month4 + 0.1870 x month5 + 0.1860 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

Table 29 shows the standardized regression coefficients for one-stage and two-stage model for the equations described. The one-stage regression model of seven input variables does not take into account the stepwise nature of the calculation. Additionally, the deli meat, hot dog, and other RTE products variables have insignificant p-values and therefore do not seem important to the final rank output because the correlated nature of the data has not been taken into account. The two-stage model corrects these deficiencies. Table 26 illustrates why the two-part regression is preferred to a single regression model because of the reasons stated.

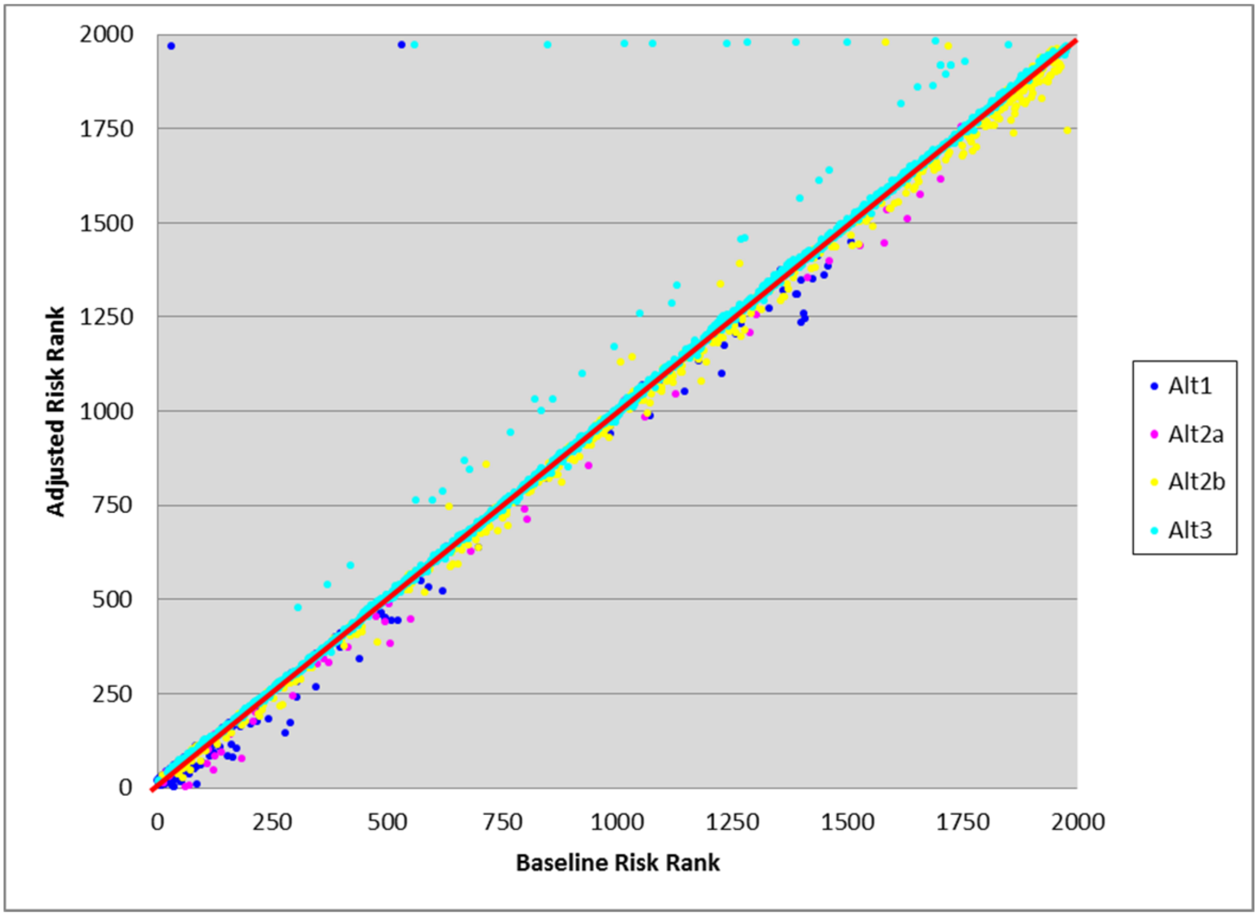
Table 29. Standardized Regression Coefficients for One-Stage and Two-Stage Models with Significance in the 2005 Algorithm

One-Stage Model			Two-Stage Model		
Variable	b	S_b	Variable	b	S_b
Deli Meat	0.0038	0.0032	Deli Meat	0.8542*	0.0122
HotDog	0.0015	0.0017	HotDog	0.1473*	0.0117
Other	0.0023	0.0019	Other	0.3087*	0.0116
-	-	-	R-Squared	0.7604*	
Rank Risk2	0.9912*	0.0032	Rank Risk2	0.9950*	0.0016
Risk1	0.1228*	0.0015	Risk1	0.1229*	0.0015
Risk3	0.0462*	0.0015	Risk3	0.0462*	0.0015
Risk4	0.0298*	0.0016	Risk4	-0.0298*	0.0016
R-Squared	0.9954*	0.0046	R-Squared	0.9954*	

*Statistic significant at p<0.05

Figure 1 plots baseline risk ranks versus adjusted baseline risk ranks. This graph shows the 1,981 establishment baseline risk ranks on the diagonal red line bisecting the figure while the adjusted risk ranks appear off the diagonal line.

Figure 1. 2005 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks



2006 Dataset Risk Ranking Algorithm

Table 30 shows the raw data statistics for the 2006 dataset. Table 31 shows the number of establishments and total number of alternatives in each category. More than 17% of the establishments have more than one alternative. Compared with the baseline 2005 algorithm dataset there are more establishments in each alternative and more total establishments. Because the baseline and baseline adjustment input data are not normally distributed, the robust rank regression is again justified. This dataset serves as the bootstrapped lower limit for the number of alternatives and the number of establishments to be used for comparison with the following datasets with more establishments and alternatives represented.

Figure 2 shows some difference from that shown in Figure 1 for the baseline dataset. This figure shows more dispersion on both sides of the diagonal representing the baseline establishment ranking. Establishments showing deviation from the diagonal have their risk ranking increased when above the line and their risk ranking decreased when below the line. Recall that adjustments increasing risk ranking are due to positive *Lm* sampling results. A decreased risk ranking is due to negative *Lm* sampling results.

Table 30a. Summary of Input and Output Variables for 2006 Dataset

Statistic	Deli Meat	Hot Dogs	Other	Q80	Risk2	RankRisk2
average	2,083,956	53,150	4,218	3.62E-06	4.93E+00	1,247
stdev	13,051,080	429,068	161,967	2.69E-06	3.12E+01	720
min	0	0	0	1.10E-08	2.03E-10	1
max	301,520,000	10,185,000	8,086,288	7.24E-06	5.64E+02	2493
median	0	0	20	4.65E-06	1.21E-03	1247
CV%	626.3	807.3	3,840.1	74.3	632.2	57.7
skewness	14.87	13.15	49.9	0.03	11.1	0
kurtosis	298.38	219.23	2,490.89	-1.52	146.33	-1.2
N	2,493	2,493	2,493	2,493	2,493	2,493

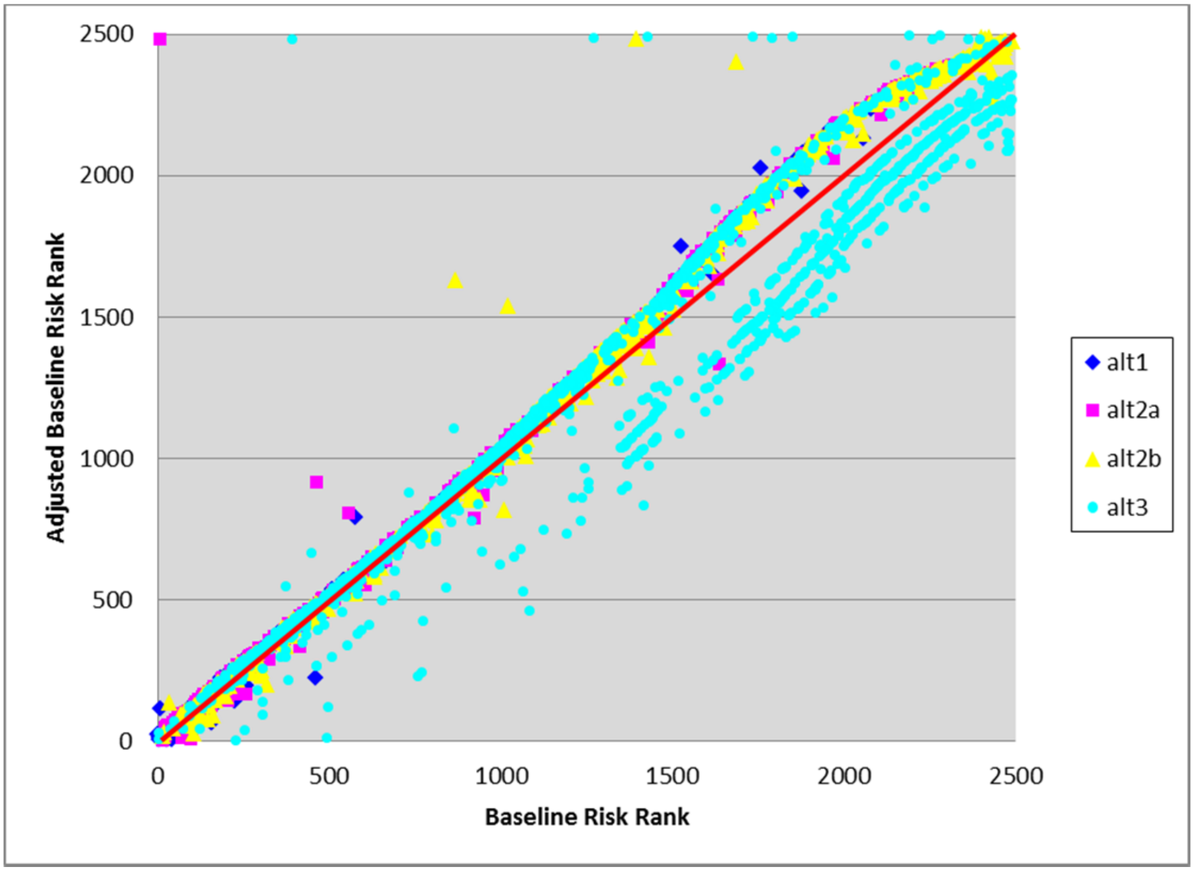
Table 30b. Summary of Input and Output Variables for 2006 Dataset

Statistic	Risk1	Risk3	Risk4	AdjRankR2	RiskRank
average	14	2	-440	832	1,247
stdev	221	29	570	807	720
min	0	0	-3,729.3	-2,265	1
max	3,498	652.7	0	5,873	2,493
median	0	0	-241.7	866	1,247
CV%	1,576.1	1,205.7	-129.5	97	58
skewness	15.7	16.62	-2.23	0.19	0
kurtosis	244.8	311.15	5.45	3.78	-1.2
N	2,493	2,493	2,493	2,493	2,493

Table 31. 2006 Dataset Establishment Alternative Numbers

Variable	Number
Establishments	2,067
Alternative1	125
Alternative2a	313
Alternative2b	654
Alternative3	1,401
Total Alternatives	2,493
Multiple Alternatives	17.1%

Figure 2. 2006 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks



The risk ranking equations used are shown below. In this instance, Table 32 shows that the two-stage model and all input variables are significant. The model accounts for more than 97% of the rank variance, but the regression coefficients feeding into Rank2 are of the same or less magnitude than the baseline risk adjustment factors. Because the signs are negative and not positive for Deli Meat and Other RTE products they do not make sense as negative contributors to the final risk ranking. This is another reason supporting the use of a two-part rank regression model.

The equations used for the 2006 algorithm are:

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 2,493x Risk1 + Rank Risk2 + 623.25 x RR x Risk3 / 7.0116 + 623.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

Table 32. Standardized Rank Regression Coefficients for the One-Stage and Two-Stage 2006 Algorithm

One-Stage Model			Two-Stage Model		
Variable	b	sb	Variable	b	sb
Deli Meat	-0.0198*	0.0095	Deli Meat	0.8528*	0.0134
Hot Dog	0.0109*	0.0046	Hot Dog	0.1828*	0.0176
Other	-0.0239*	0.0051	Other	0.2504*	0.0164
-	-	-	R-Squared	0.8014*	
rankRisk2	1.0349*	0.0098	Rank Risk2	1.0079*	0.0036
Risk1	0.0852*	0.0274	Risk1	0.0643*	0.0228
Risk3	0.0443*	0.0101	Risk3	0.0224*	0.0049
Risk4	0.1842*	0.0059	Risk4	0.0384*	0.0030
R-Squared	0.9721*		R-Squared	0.9955*	

*Statistic significant at $p<0.05$

2008 Dataset Risk Ranking Algorithm

The 2008 algorithm represents a departure from the more narrowly focused sampling of RTE products to more inclusive sampling because it examines laboratory results from other sampling verification programs sampling *Lm* on food contact surfaces and environmental areas. The algorithm still relies heavily on industry supplied establishment FSIS form 10,240-1 data for recording annual post-lethality exposed RTE product volumes. The primary method to differentiate *Lm* risk is based on the alternative and annual production volume for high risk products like deli meat. Tables 33 and 34 shows the summary statistics for this dataset broken down into baseline and adjusted baseline model input and output variables. The input variables are non-normal and require robust rank regression in order to make reasonable estimates of risk. Table 35 shows that the total number of establishments has increased, and the numbers of establishments in alternatives 1, 2b, and 3 have also increased. The number in alternative 2a has decreased. This dataset marks the maximum number of alternatives and establishments in the RTE001 sampling program over a six-year period.

Table 33a. Summary of Raw and Risk Transformed Input and Output Variables for 2008 Dataset

Statistic	DeliS	DeliUS	HotDog	Other	Frozen	Pate	Q80	DMCV
average	1,076,663	825,757	809,560	6,280,420	1,276,139	1,786	3.83E-06	1,314,430
stdev	8,302,318	5,128,237	7,757,598	127,659,470	8,944,261	27,557	2.75E-06	6,559,684
min	0	0	0	0	0	0	1.10E-08	0
max	275,000,000	86,667,277	178,291,824	6,948,916,448	152,434,618	694,233	7.24E-06	112,862,449
median	0	0	0	65,975	0	0	5.65E-06	402
CV%	771.1	621.0	958.2	2,032.7	700.9	1,542.7	71.6	499.1
skewness	16.8	9.5	14.1	53.6	10.8	19.8	-0.2	7.9
kurtosis	435.1	111.4	230.1	2,917.7	140.5	430.2	-1.7	80.1
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 33b. Summary of Raw and Risk Transformed Input and Output Variables for 2008 Dataset

Statistic	DeliS	DeliUS	HotDog	Other	Frozen	Pate	Risk2	Rank Risk2
average	1.0	2.4	0.1	0.0	1.40E-06	0.0	3.5	1,501
stdev	10.0	22.4	0.9	0.2	1.27E-05	0.0	25.8	867
min	0.0	0.0	0.0	0.0	0.00E+00	0.0	0.0	1
max	260.1	627.5	27.6	10.9	3.56E-04	1.7	627.5	3,002
median	0	0	0	0	0	0	0	1,502
CV%	998.1	933.0	907.2	3,493.2	908.8	1,876.6	732.2	57.7
skewness	18.1	18.2	16.8	54.5	19.1	25.8	14.5	0.0
kurtosis	381.6	407.7	389.8	2,979.7	452.8	750.9	269.6	-1.2
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 34a. Summary of Input and Output Variables for 2008 Dataset

Statistic	Risk1	Risk3-P	Risk3-FCS	Risk3-ENV
average	9.2	1.2	0.6	0
stdev	164.3	24.8	17.1	1.1
min	0	0	0	0
max	3,002	742	727	60
median	0	0	0	0
CV%	1,792.30	2,018.60	3,003.10	3,749.00
skewness	18.2	24.9	37.2	48.9
kurtosis	328.1	666.5	1,451.00	2,527.90
N	3,002	3,002	3,002	3,002

Table 34b. Summary of Input and Output Variables for 2008 Dataset

Statistic	Risk4-P	Risk4-FCS	Risk4-ENV	adjRisk2	Risk Rank
average	-9.5	-2.2	-0.1	1,473.60	1,501
stdev	40.4	23.2	1.1	875.8	867
min	-383.1	-424.3	-25.4	-291.6	1
max	98	86	0	5,752	3,002
median	0	0	0	1,479	1,502
CV%	-426.4	-1,059.10	-1,254.50	59.4	57.7
skewness	-2.6	-7	-16.1	0.1	0
kurtosis	11.6	76.1	288.2	-0.8	-1.2
N	3,002	3,002	3,002	3,002	3,002

Table 35. Number of Establishments and Alternatives for the 2008 Dataset

Variable	Number
Establishments	2,315
Alternative1	170
Alternative2a	278
Alternative2b	904
Alternative3	1,650
Total Alternatives	3,002
Multiple Alternatives	22.9%

The following equations are used in the risk ranking calculations for the 2008 algorithm. These equations allow for the inclusion of a substantial increase in the amount of *Lm* sampling data available for estimating establishment risk.

Risk2 = 1.0000 x Delis x Q80 + 0.408293 x Delius x Q80 + 0.058182 x Hot Dog x Q80 + 0.000217 x Other x Q80 + 0.000000625 x Frozen x Q80 + 0.343293 x Pate x Q80

Adjusted Risk Rank = 3002 x Risk1 + Rank Risk2 + 750.5 x RR x Risk3 / 7.0116 + 750.5 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk1 = $(\text{month1}_{product} + \text{month1}_{fcs} + 0.0826 \times \text{month1}_{env}) / 2.0826$

Risk3 = $\{(0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{product} + (0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{fcs} + 0.08626 \times (0.4614 \times \text{month2} + 0.2446 \times \text{month3} + 0.1252 \times \text{month4} + 0.0861 \times \text{month5} + 0.0826 \times \text{month6})_{env}\}/2.0826$

Risk4 = {((month1 + month2 + month3 + month4 + month5 + month6)/18)$_{product}$ + ((month1 + month2 + month3 + month4 + month5 + month6)/50)$_{fcs}$ + (0.0826 x (month1 + month2 + month3 + month4 + month5 + month6)/28)$_{env}$ }

Figure 3 shows the plot of baseline risk ranks versus adjusted baseline risk ranks using the two-stage model. Note: The diminished segmentation of the lower risk alternatives. Alternative 1 and 2a now are more evenly dispersed along the bisecting line of the figure. This means that establishments with lower risk alternatives will tend to be sample more frequently compared with the previous algorithm versions. But, the majority of samples will still be from alternative 3.

Table 36 shows that the one-stage model accounts for more than 99% of the rank variance; however, the effect of ranking is more dependent on the baseline rank adjustment than the production volume input variables that are not significant in the non-partitioned model regression. All the regression coefficients are significant in the two-stage model.

Figure 3. 2008 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks

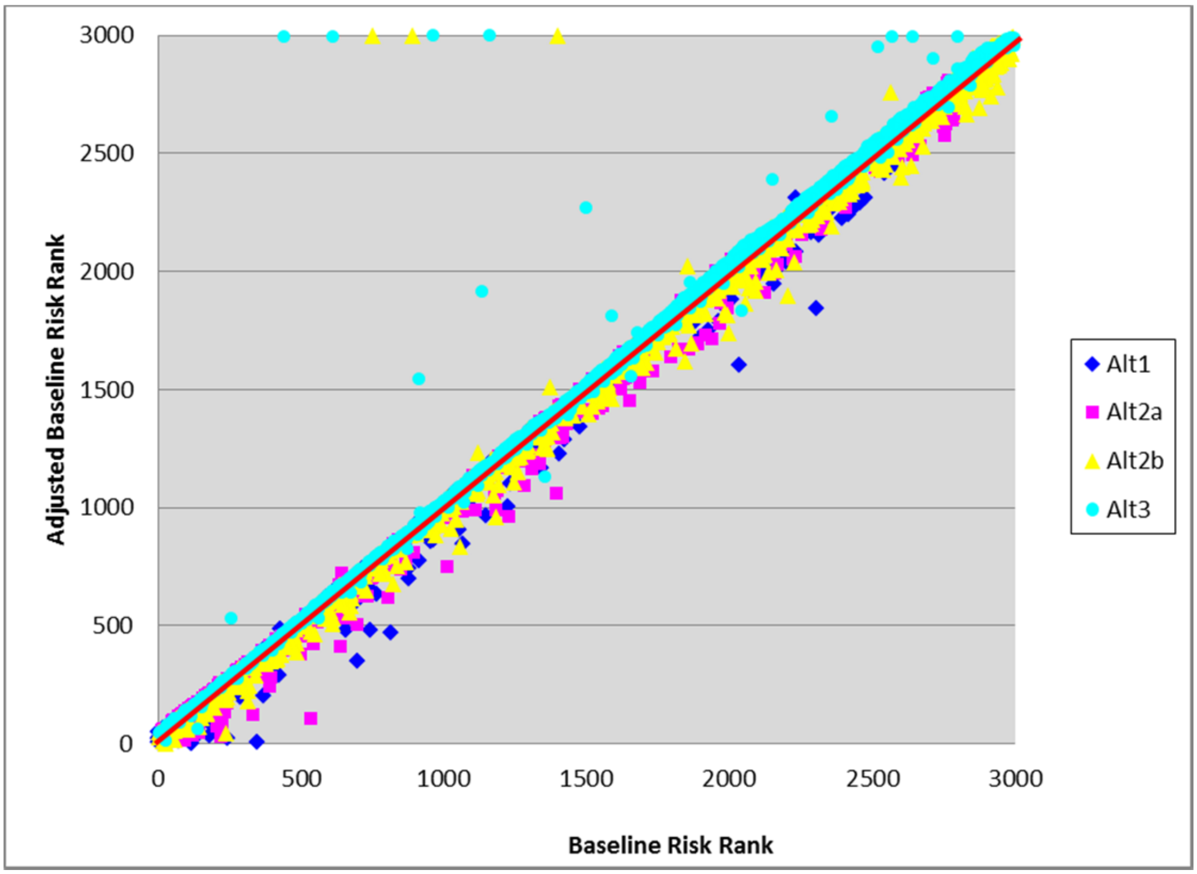


Table 36. Rank Regression Coefficients for One-Stage and Two-Stage Models for the 2008 Dataset

One-Stage			Two-Stage		
Variable	b	sb	Variable	b	sb
DeliS	-0.0007	0.0016	DeliS	0.4448*	0.0206
DeliUS	0.0005	0.0022	DeliUS	0.4144*	0.0230
HotDog	0.0022	0.0014	HotDog	0.1325*	0.0212
Other	0.0024	0.002	Other	0.3117*	0.0207
Frozen	0.0002	0.0019	Frozen	-0.0443*	0.0144
Pate	0.0001	0.0013	Pate	0.0472*	0.0224
-	-	-	R-Squared	0.6300*	
Risk2	1.0013*	0.0039	Rank Risk2	1.0025*	0.0028
Risk1	0.1011*	0.0296	Risk1	0.0999*	0.0289
Risk3	0.0253*	0.008	Risk3	0.0259*	0.0076
Risk4	0.0478*	0.0021	Risk4	-0.0478*	0.0021
R-Squared	0.9950*		R-Squared	0.9950*	

*Statistic significant at p<0.05

2011 Dataset Risk Ranking Algorithm

The most recent establishment *Lm* risk ranking algorithm uses the same 2008 dataset, because this dataset marked the high point of establishment participation in the RTE001 program. However, because the method of estimating the establishment risk is probability based, the risk transformed input variables have a different structure, and their summary statistics are different than seen with the 2008 algorithm. Table 37 shows these differences, but Table 38 shows the same number of establishments and establishments in alternatives as before.

Table 37a. Summary of Input and Output Variables for 2011 Dataset

Statistic	DeliS	DeliUS	HotDog	Other	Frozen	Pate	cfu/g
average	1.16E+04	4.24E+04	1.03E+03	1.16E+02	1.46E-02	5.54E+01	5.52E+04
stdev	1.65E+05	5.00E+05	1.35E+04	4.58E+03	2.44E-01	1.11E+03	5.50E+05
min	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00	9.11E-08
max	5.66E+06	1.44E+07	6.33E+05	2.51E+05	8.17E+00	3.96E+04	1.44E+07
median	0.00E+00	0.00E+00	0.00E+00	2.94E-01	0.00E+00	0.00E+00	7.37E+00
CV%	1,430.8	1,177.9	1,306.1	3,934.6	1,668.0	2,004.0	996.9
skewness	25.4	19.8	36.3	54.5	29.2	26.3	17.2
kurtosis	728.3	461.8	1,626.9	2,981.5	899.9	774.5	356.3
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 37b. Summary of Input and Output Variables for 2011 Dataset

Statistic	Risk2	Base Rank	Risk1	Risk3	Risk4	AdjRank2	Rank
average	2.90E-06	1,501	9	2	-48	1,465	1,507
stdev	2.89E-05	867	164	31	83	886	868
min	0.00E+00	1	0	0	-1,153	-866	1
max	7.56E-04	3,002	3,002	742	0	5,607	3,010
median	3.87E-10	1,502	0	0	-22	1,459	1,507
CV%	996.8	57.8	1,792.3	1,681.6	-171.4	60.5	57.6
skewness	17.2	0.0	18.2	20.5	-4.5	0.1	0.0
kurtosis	356.2	-1.2	328.1	446.0	30.1	-0.8	-1.2
N	3,002	3,002	3,002	3,002	3,002	3,002	3,002

Table 38. Number of Establishments and Alternatives for 2011 Dataset

Variable	Number
Establishments	2,315
Alternative1	170
Alternative2a	278
Alternative2b	904
Alternative3	1,650
Total Alternatives	3,002
Multiple Alternatives	22.9%

The following equations show that the Q80 descriptive of alternative volume and alternative risk has been incorporated into the exponential growth rate (EGR) calculation. The effect of antimicrobial agents in reducing public health risk has also been incorporated. However, to estimate an establishment *Lm* risk, a single probability calculation is used rather than multiple iterations to obtain a Monte Carlo estimate. The main difference is in the calculation of baseline risk because the baseline risk adjustment is the same as in the previous algorithm version.

Risk2 = 1 – exp (-r x {(1.0000 x Delis x EGR + 0.408293 x Delius x EGR + 0.058182 x Hot Dog x EGR + 0.000217 x Other x EGR + 0.000000625 x Frozen x EGR + 0.343293 x Pate x EGR) / Total Volume}x 35 })

EGR = 10^ Min (log10 (Q80) + Time x (AMA x 2.64 / loge (10)) x ((Temp x 2.86 / (25 + 2.86))^2, MPD)

AMA (antimicrobial agent) = 0.507 for Alternatives 1, 2a, and 2b, AMA = 1.182 for Alternative 3

MPD (Maximum Population Density) for *Lm* = 7

Adjusted Risk Rank = 3002 x Risk1 + Rank Risk2 + 750.5 x RR x Risk3 / 7.0116 + 750.5 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = {(0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{product}$ + (0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{fcs}$ + 0.08626 x (0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{env}$ }/2.0826

Risk4 = {((month1 + month2 + month3 + month4 + month5 + month6)/18)$_{product}$ + ((month1 + month2 + month3 + month4 + month5 + month6)/50)$_{fcs}$ + (0.0826 x (month1 + month2 + month3 + month4 + month5 + month6)/28)$_{env}$ }

Table 39 shows the two-stage rank regression analysis for this dataset. The baseline estimate model is significant as are all the input variables. The variable for frozen RTE products seems at first problematic, but the negative coefficient can be rationalized because of the low probability of detecting *Lm* contamination in this product class. The historical adjustment variables and their regression equation are also significant. The baseline adjustment is comparable to the previous algorithm version.

Table 39. Rank Regression Coefficients for the Two-Stage Model 2011 Dataset

Variable	b	S_b
DeliS	0.5217*	0.0180
DeliUS	0.3007*	0.0209
HotDog	0.1542*	0.0196
Other	0.0743*	0.0192
Frozen	-0.1917*	0.0149
Pate	0.0515*	0.0215
R-Squared	0.6143*	
Risk2	0.9165*	0.0064
Risk1	0.0956*	0.0291
Risk3	0.0361*	0.012
Risk4	0.1838*	0.0076
R-Squared	0.9693*	

*Statistic significant at $p<0.05$

Figure 4 shows some similarity between the same plots for the 2005, 2006, and 2008 algorithm datasets. Alternative 1 has the lowest risk ranks and alternative 3 has the highest risk ranks with alternative 2a and 2b being intermediate. There is no apparent difference between the 2011 Algorithm results with this plot and the previous algorithms. Figure 5 shows the rank segmentation plotted against the $\log_{10}$ of the total RTE production volume. The plot is slightly different from that shown in the main text for the 2005 dataset. In this figure, there is more separation of the alternative 3 and alternative 2b *Lm* risk ranks with higher risk plants appearing in separate segmentations for both alternatives. The 2011 algorithm appears to achieve better separation and delineation of high risk plants than the previous algorithms. Figure 6 illustrates the *Lm* risk ranks versus establishment probability of causing illness in the susceptible population during an extreme contamination event. The alternatives are clearly delineated with alternative 3 being more likely to have such extreme contamination events while the other alternatives produce a much lower likelihood of such an occurrence.

Figure 4. 2011 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks

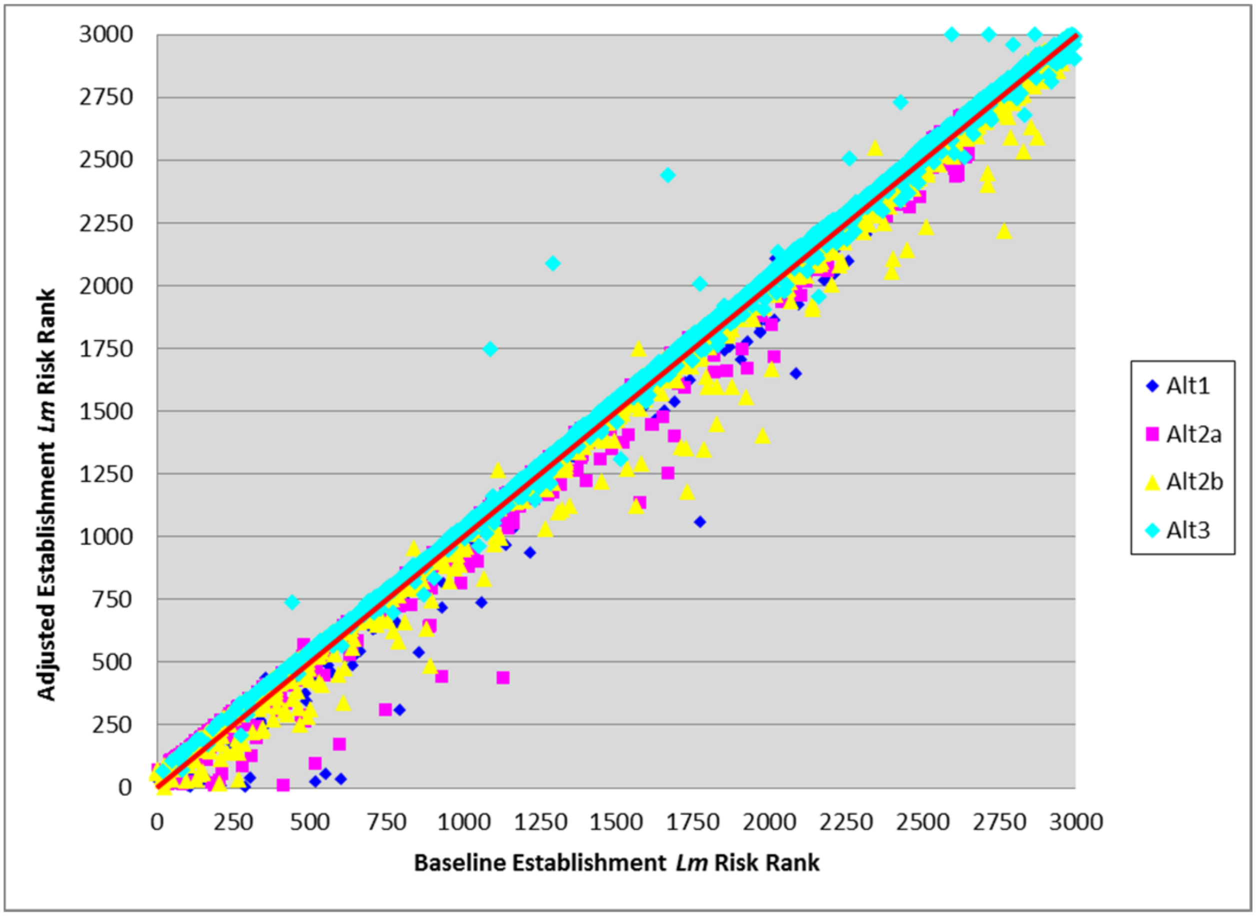


Figure 5. 2011 Algorithm Log10 of EDMV versus Adjusted Baseline Establishment Risk Ranks

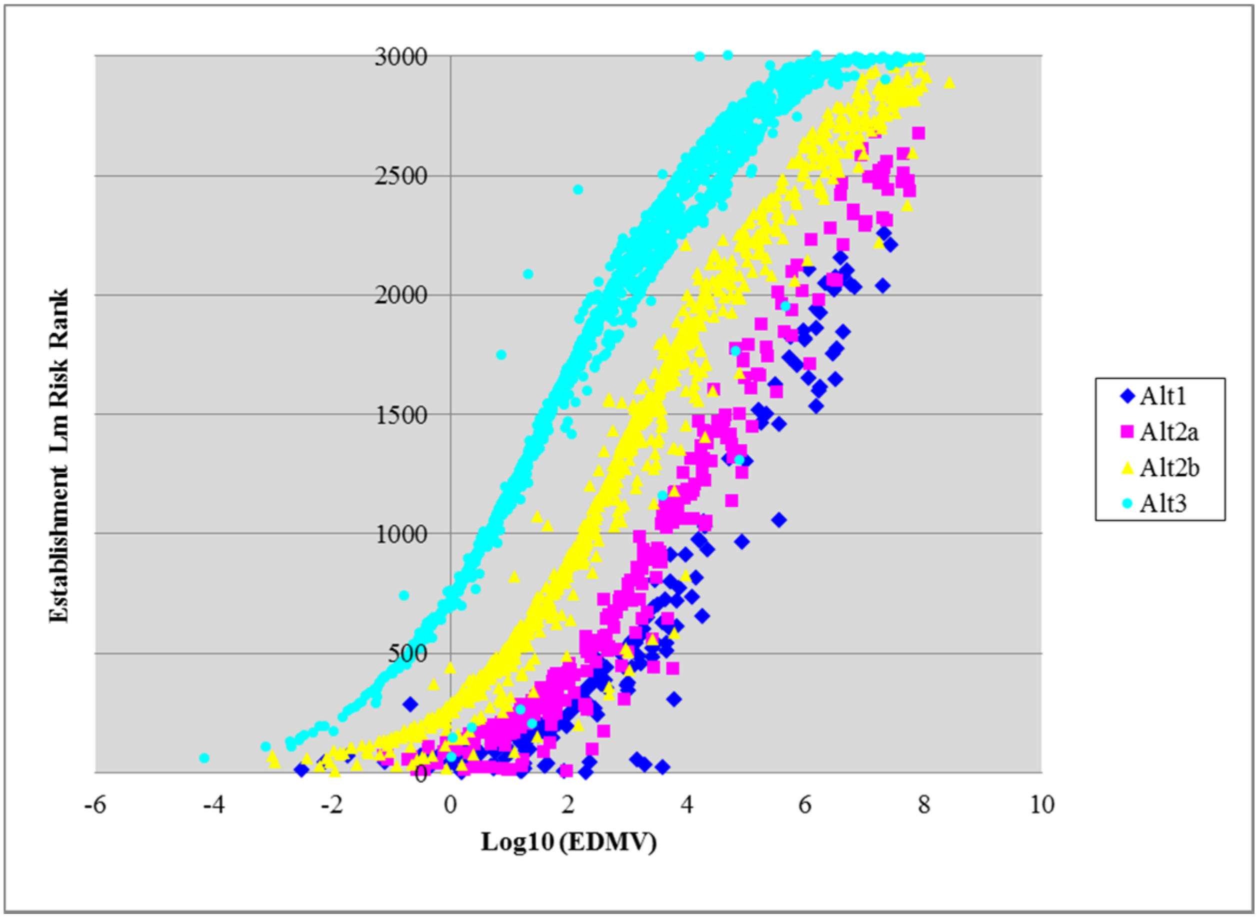


Figure 6 shows the rationale behind the tiered plots. This figure plots probability of illness versus risk rank. Alternative 3 plants are clearly differentiated from the other alternatives based on the probability of illness in the susceptible population. Figure 8 is a comparison plot of the same data using the 2008 algorithm. Figure 7 plots the expected annual *Listeria monocytogenes* cfu/g at retail versus establishment risk rank. In this case, the *Listeria monocytogenes* risk at retail, using the units of annual *Listeria monocytogenes* cfu/g at retail, substitutes for the probability of illness. Notice that there is less separation of establishment ranks on the higher risk end of the risk ranking scale for the 2008 algorithm. Because there is clearly better separation of establishment ranks across most of the high risk ranking scale, the 2011 algorithm appears the better choice among the two.

Figure 6. 2011 Algorithm Adjusted Baseline Establishment Risk Ranks versus Probability of Illness in the Susceptible Population

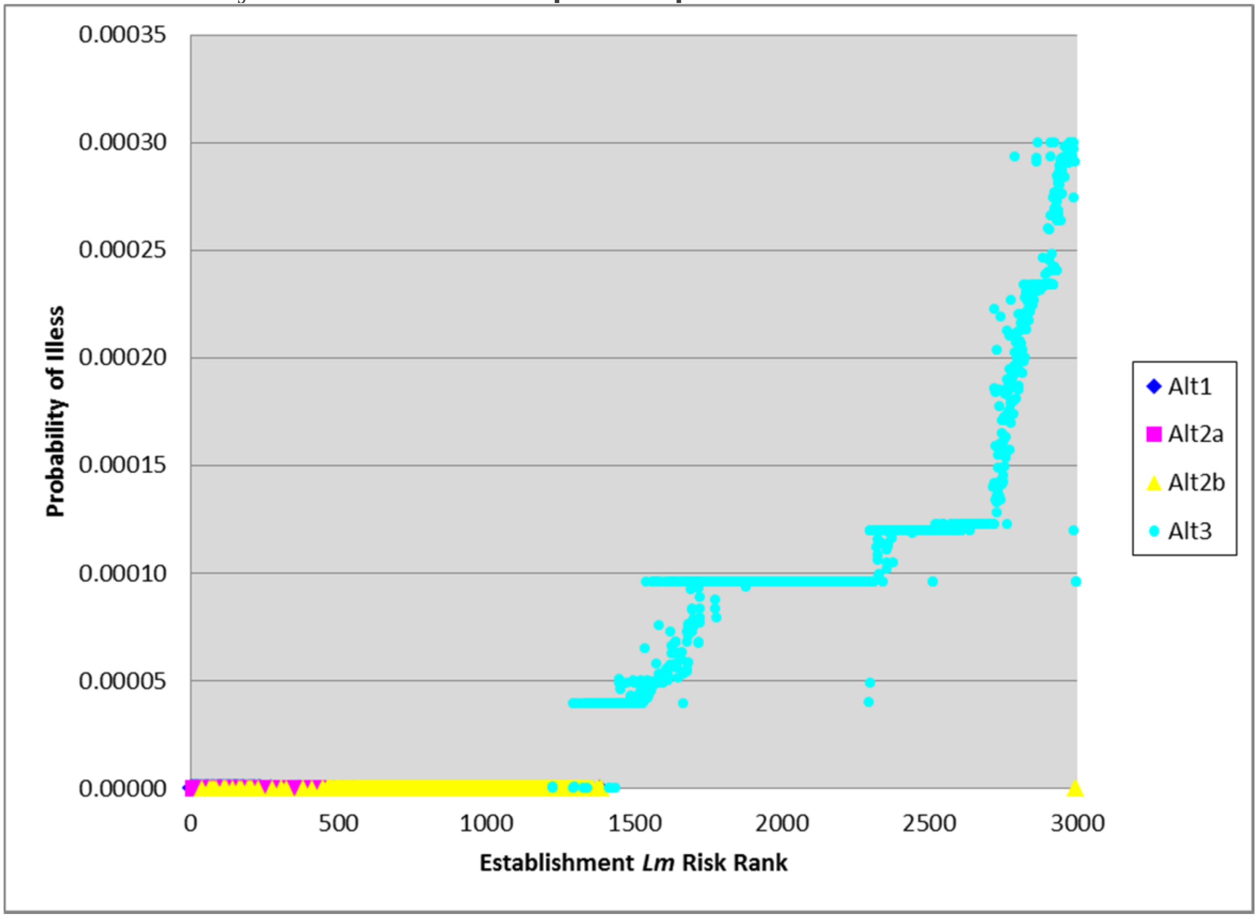
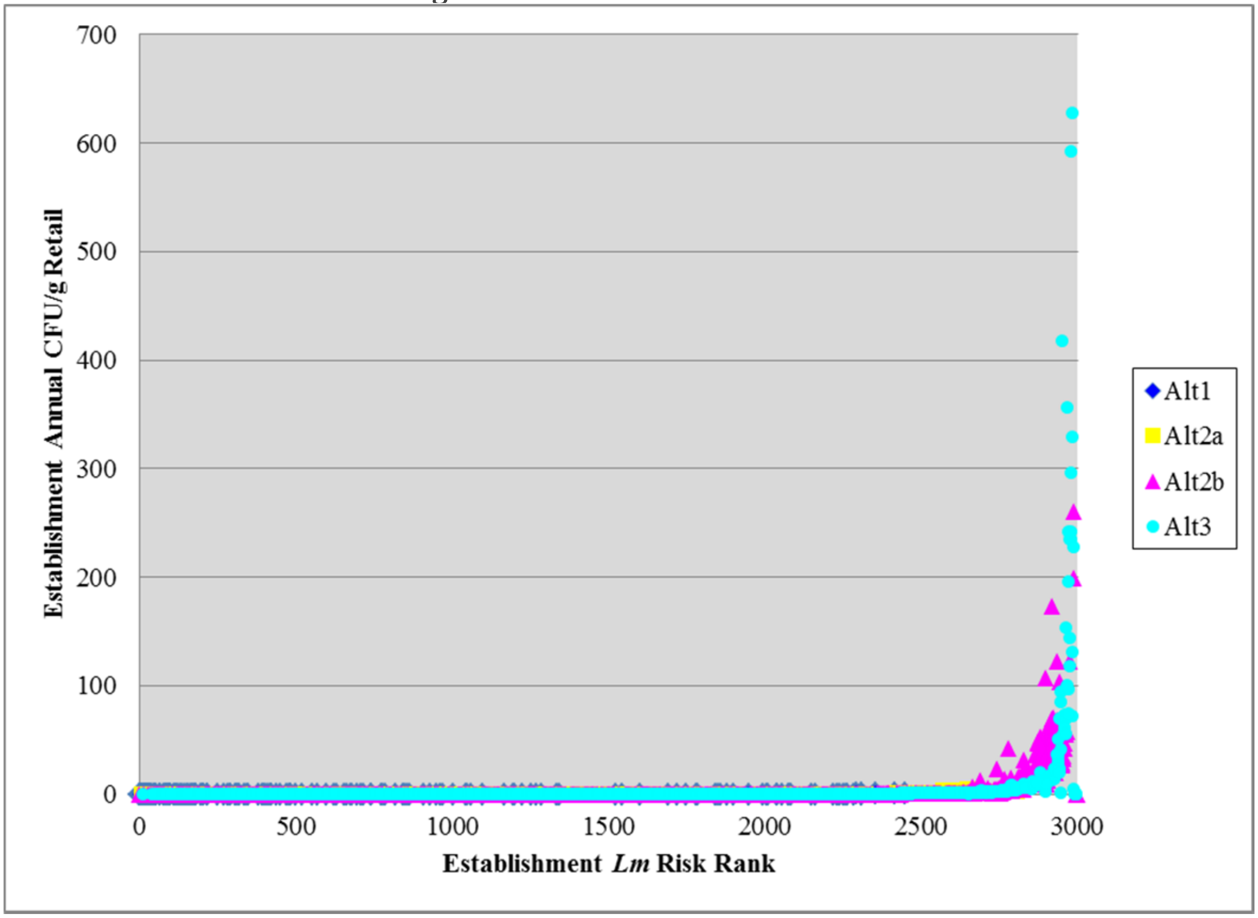


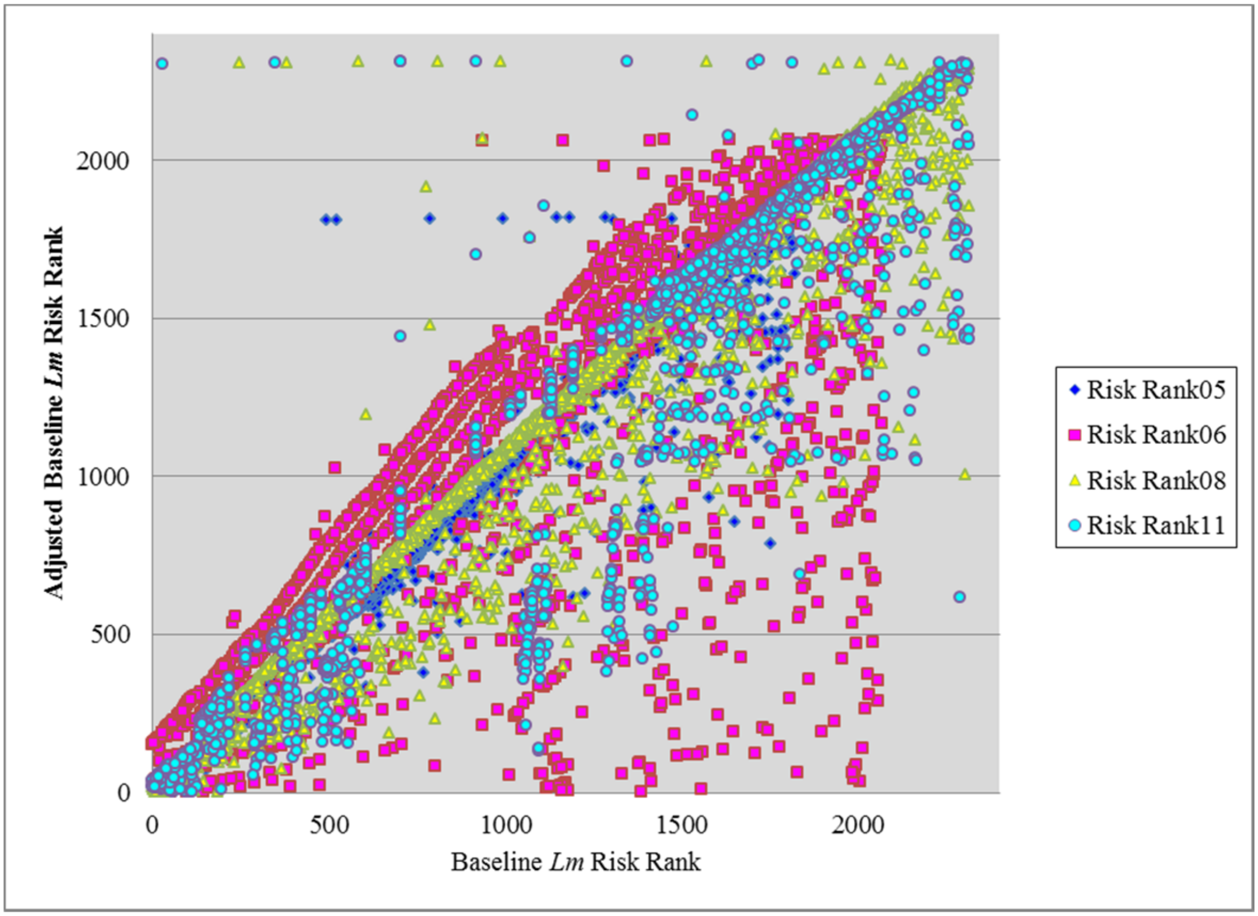
Figure 7. 2008 Algorithm Adjusted Baseline Establishment Risk Ranks versus Risk2- Annual *Lm* CFU/g at Retail



Establishment *Lm* Risk Rank

The *Listeria monocytogenes* establishment risk rank is determined by ranking the establishment adjusted Risk2 ranks that are calculated for each establishment's baseline alternative product volume subset. The adjusted ranks have to be ranked again because they are no longer ordinal integers. This is accomplished by summing the ranks over establishment alternatives before the final establishment ranking and then ranking the summed establishment ranks. By performing the establishment ranking in this way, establishment laboratory results can be collected to perform the Risk2 adjustment by alternative. This achieves the same final establishment risk ranking as when the establishment sum is done on Risk2 or on the sum of Risk2 ranks. The final adjustment can be done either by establishment or by establishment alternative with the same result. Figure 8 shows the four *Lm* risk ranking algorithm version baseline ranks versus adjusted baseline ranks.

Figure 8. Baseline versus Adjusted Baseline for 2005, 2006, 2008, and 2011 Establishment *Lm* Risk Ranking Algorithm Versions



Sensitivity Analysis

Listeria monocytogenes Risk Ranking Model Sensitivity Analysis

Sensitivity analysis is a kind of uncertainty analysis to identify the variables in the risk ranking model that are most important to the outcome variable estimate. The outcome variable is the establishment *Listeria monocytogenes* (*Lm*) risk rank and the input variables are those described in the risk ranking algorithm update section for the four *Listeria monocytogenes* risk ranking algorithm models characterized on four datasets. This section identifies the input variables that are most important to determining the risk outcome for each risk model. Even though a given input variable may show a large effect on the output risk ranking it still may not be significant in the rank regression model analysis (it may not have a significant p-value) due to extreme variability. A test is considered significant with a p-value of less than 0.05. This section only addresses sensitivity of the output risk ranking to individual input variables. The significance of the individual input variable variability in relation to uncertainty is addressed in the uncertainty section. All models are analyzed by selecting components or subcomponents of baseline risk factors and adjusted baseline risk factors. The sensitivity analysis model used in each case is the standardized linear regression model on the transformed input and output variables as ascending ranks.

The method used for finding the standardized regression coefficients (b) and their standard errors (S_b) is as follows. Each one of the input and output variables are transformed into an ascending rank distribution of ordinal risk ranks. The highest risk establishment has the highest rank. The matrix of input and output variables is transformed into a Spearman rank correlation matrix. As shown in equation (1), the inverse of the correlation matrix of the input variables $(R_{xx})^{-1}$ is multiplied by the by the column vector of output correlations with the input variables (R_{yx}). This product equals the column vector of standardized regression coefficients (b).

The standardized regression coefficient variability for b (S_b) is found from taking the square root of the error mean square (EMS) of the standardized regression multiplied by the associated square root of the diagonal element of the inverse input variable correlation matrix $(R_{xx})^{-1}$ (equation 2). In matrix terms the formulas are given below, where the x subscript refers to input variables and the y subscript refers to the output variable and R is the Spearman rank correlation matrix:

(1) $b = (R_{xx})^{-1}R_{yx}$

(2) $S_b = \sqrt{\{EMS\ (R_{xx})^{-1}\}}$

The standardized regression coefficients are adjusted with the correlation matrix. They provide a more accurate description of the effect of individual input risk variables on the output risk ranking than the independently derived rank correlations. The standardized regression coefficients are proportional measures of input risk impact on output risk ranking. The sensitivity of the risk ranking to standard unit change in input risk variable is defined in standardized regression coefficient units.

The sensitivity associated with each input variable is shown graphically in three types of charts. The first chart is a horizontal bar chart. Input variables with greatest sensitivity are at the top of the figures. The second type of graphic is a spider chart showing the unit change in the output rank variable when changing each input variable one at a time in standardized units from the base value of each input variable. In the spider chart, the greater the slope of an input risk variable the greater the sensitivity. The third type of graphic is given as a tornado plot of the magnitude of the effect of each input risk variable on the standardized risk rank output. This graphic shows how wide a range of unit output ranks is affected with a standard unit change in input risk variable. Input risk variables with greatest sensitivity are at the top of the tornado plot.

All the statistics in this appendix and plots are derived from the standardized rank regression analysis that are based on bootstrap estimates. The bootstrap estimates are minimum variance unbiased estimators (MVUE) derived as particular U-statistics specific for this analysis (Hoeffding W, 1948). This is a consequence of the resampling done on each dataset. The base dataset has 1,981 rows of data. This is taken as the standard bootstrap sample size that is applied to the 2006, 2008, and 2011 datasets. The bootstrap resampling only coincides with a standard bootstrap sample equal to the size of the alternative population in the 2005 dataset where resampling can be done with a sample size of 1,981. The resampling rates are 100%, 83%, and 66% for the three datasets respectively.

2005 Dataset Algorithm

Baseline Risk Ranking and Adjusted Listeria monocytogenes Establishment Risk Ranking

The 2005 dataset is the standard of comparison for the other three datasets. This algorithm has been described in the 2007 Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*. Only the sensitivity estimates are shown here for the baseline and adjusted establishment risk rankings.

Table 40 shows that there is no difference between the bootstrapped and not-bootstrapped regression coefficients, but there is a difference between the error estimates. All regression coefficients are significant. The R-squared statistic that represents the proportion of the total variance explained by the regression model is larger for the bootstrapped estimates and the error estimates of the input risk factors are also larger for the bootstrapped estimates. The section on uncertainty analysis will address the issue of these apparent differences in error estimation. The order of sensitivity is: Deli Meat > Other > Hot Dog for bootstrapped and not-bootstrapped estimates.

Table 41 shows the significance of rank regression for adjusted baseline input variables. All input variables also are significant. The bootstrapped estimates have larger error variances and the R-squared values is also larger. The order of sensitivity is: Rank of Risk2 > Risk1 > Risk3 > Risk4.

Table 40. Bootstrapped Baseline and Adjusted Rank Regression Coefficients for 2005 Dataset

First-Stage	Bootstrapped	
Variable	b	sb
Deli Meat	0.8542*	0.0156
HotDog	0.1474*	0.0187
Other	0.3102*	0.0177
R-Squared	0.7611*	0.2389
Second-Stage	Bootstrapped	
Variable	b	S_b
RankRisk2	0.9957*	0.0036
R1	0.1227*	0.0259
R3	0.0460*	0.0041
R4	-0.0297*	0.0019
R-Squared	0.9960*	0.004

*Significant regression coefficient component

Listeria monocytogenes Establishment Risk Ranking Algorithm

2006 Dataset Algorithm

The 2005 dataset is the standard of comparison for the other three datasets. This algorithm has been described in the 2007 Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*. Only the sensitivity estimates are shown here for the baseline and adjusted establishment risk rankings.

Baseline Risk Ranking and Adjusted *Listeria monocytogenes* Establishment Risk Ranking

The baseline rank regression is significant and the three risk factors in the regression are also significant. The order of sensitivity is: Deli Meat > Other RTE products > Hot Dogs. Other RTE products are apparently more sensitive than the higher risk hot dog products because of the greater mass of other RTE products relative to the mass of hot dogs.

The adjusted baseline rank regression is significant and the four risk factors in the regression also are significant. The order of the absolute value of sensitivity (b) is: Rank Risk2 > Risk1 > Risk4 >

Risk3. There is nearly an equivalence of the Risk3 with Risk4 effects. This occurs because Risk3 increases the establishment risk ranking for poor historical performance and Risk4 decreases the establishment risk ranking for good performance.

Table 41. Bootstrapped Baseline and Adjusted Rank Regression Coefficients for 2006 Dataset

First-Stage	Bootstrapped	
Variable	b	sb
Deli Meat	0.8542*	0.0122
HotDog	0.1473*	0.0117
Other	0.3087*	0.0116
R-Squared	0.7604*	0.2396
Second-Stage	Bootstrapped	
Variable	b	sb
Rank Risk2	1.0079*	0.0036
Risk1	0.0643*	0.0228
Risk3	0.0224*	0.0049
Risk4	-0.0384*	0.0030
R-Squared	0.9955*	0.0045

*Significant regression coefficient component

2008 Dataset Algorithm

This dataset provides the opportunity to analyze the new subcomponents for the baseline risk rank adjustment. This dataset adds risk factors for deli meat sliced/unsliced and frozen RTE products, as well as pate/meat spreads/deli salads. Also added are additional risk factors for food contact surface and environmental laboratory *Lm* results. The analysis evaluates the feasibility of adding risk subcomponents to the model or simply adding them as new components to the risk factor aggregates.

Baseline Risk Ranking

There are six components analyzed as baseline risk components in this sensitivity analysis. The baseline rank regression and the six risk factors are significant. Table 42 lists the order of sensitivity as: Deli Meat Sliced (Delis) > Deli Meat Unsliced (Delius) > Other RTE products > Hot Dogs > Pate > Frozen Products . Deli meats sliced in the producing establishment have more impact than deli meats not sliced in the producing establishment. As seen in the previous 2006 model other RTE products are more sensitive than the higher risk hot dog products because of the greater mass of other RTE products relative to the mass of hot dogs. The horizontal bar plot in Figure 9 shows that sliced and unsliced deli meats have the greatest relative magnitude of the rank regression coefficients. The spider plot in Figure 10 shows that sliced and unsliced deli meats have the greatest slope factors (unit rate of change in baseline ranks per unit change in input risk factor) and therefore the greatest impact on baseline risk rank output. The tornado plot in Figure 11 shows that sliced and unsliced deli meats have the greatest absolute effect on the magnitude of the baseline risk rank output. Other RTE products have the third greatest sensitivity followed by hot dogs. Pate and frozen products have the least sensitivity.

The negative effect for frozen products is interesting and not entirely unexpected. This is because it is unlikely that significant *Listeria monocytogenes* growth between point of production and retail will result due to frozen products and cause illness. Temperature abuse and cross-contamination at the point of consumption are likely to cause illness from previously frozen RTE products. Data indicating cross-contamination or temperature abuse at retail do not enter into the risk calculation with the 2008 algorithm. Therefore, it is not surprising that the frozen product risk component decreases the establishment *Lm* risk rank. This result is suggestive that the frozen RTE product component should be dropped from the algorithm. However, it has been a policy decision to include the frozen component up to this point in time.

Table 42. Baseline Rank Regression Bootstrapped Coefficients for 2008 Algorithm Dataset

Variable	b	sb
DeliS	0.4448*	0.0206
DeliUS	0.4144*	0.0230
HotDog	0.1325*	0.0212
Other	0.3117*	0.0207
Frozen	-0.0443*	0.0144
Pate	0.0472*	0.0224
R-Squared	0.6300*	0.3700

*Significant regression coefficient component

Figure 9. Sensitivity of Baseline Input Variables—Horizontal Bar Plot, 2008 Dataset

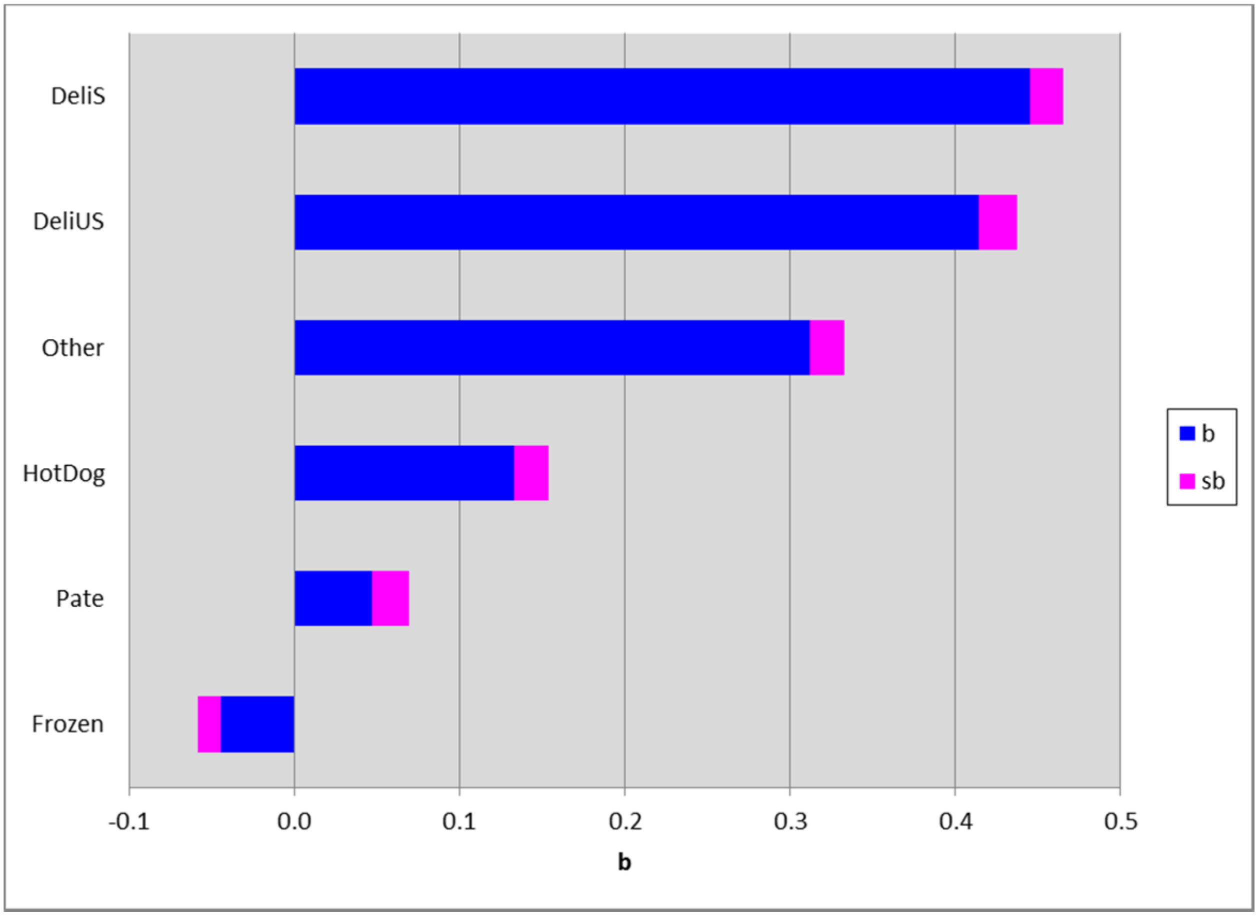


Figure 10. Sensitivity of Baseline Input Variables—Spider Plot, 2008 Dataset

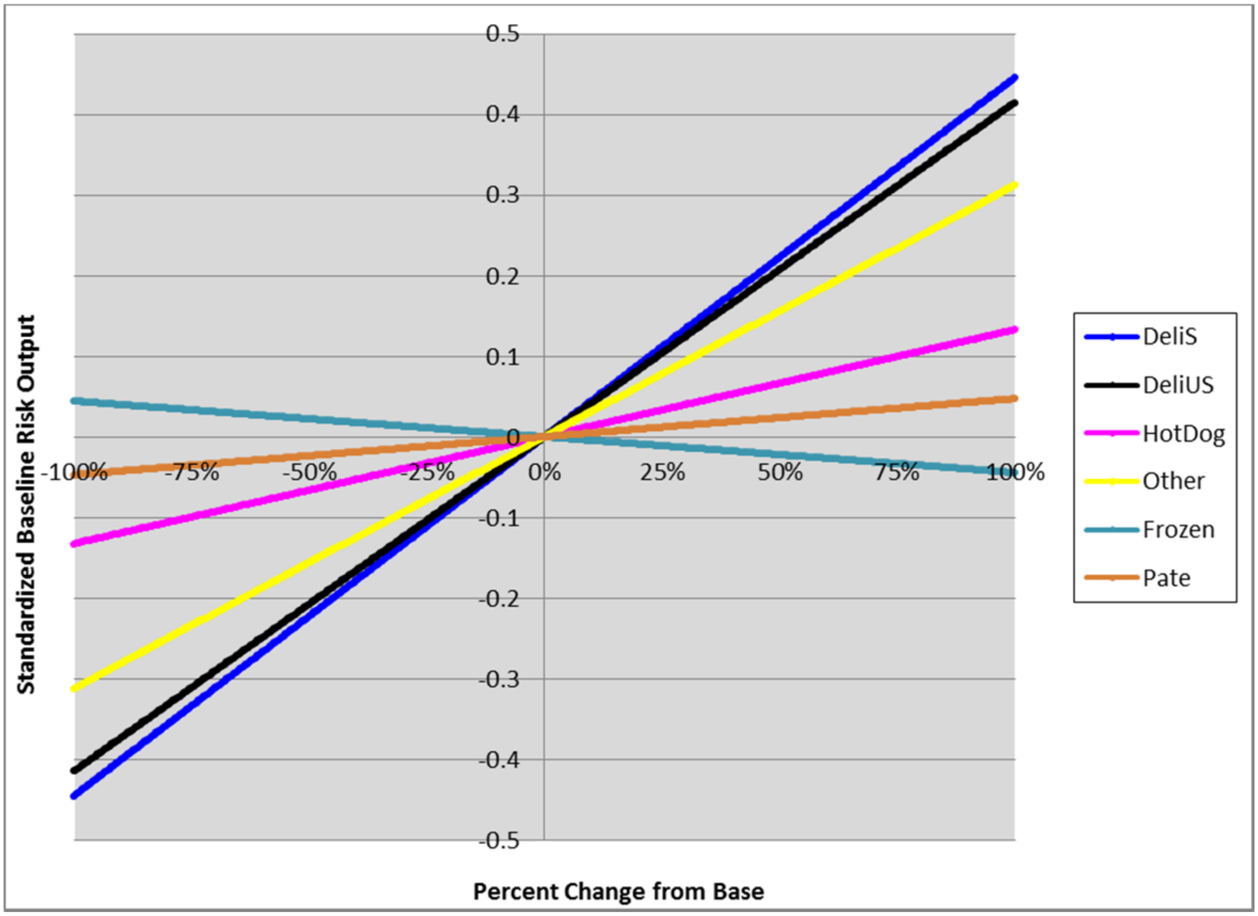
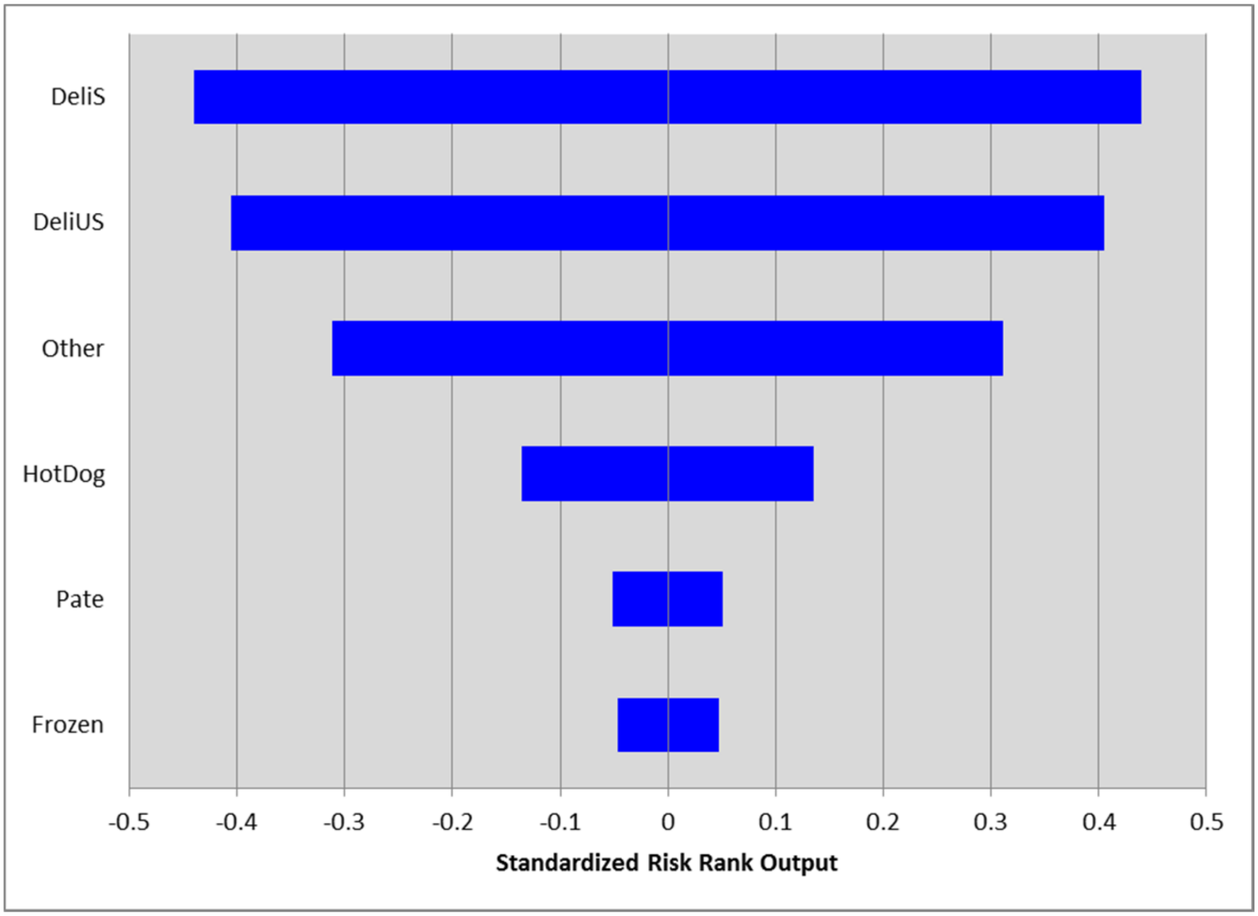


Figure 11. Sensitivity of Baseline Input Variables—Tornado Plot, 2008 Dataset



Adjusted Listeria monocytogenes Establishment Risk Ranking

Risk Subcomponent Analysis

The adjusted baseline rank regression for nine subcomponent risk variables is significant. Seven of the eight risk factors in the regression also are significant. The order of the absolute value of sensitivity (b) is: Rank Risk2 > Risk1 > Risk4-fcs > Risk4-p > Risk3-p > Risk3-env > Risk3-fcs > Risk4-env as shown in Table 43. The horizontal bar plot in Figure 12 shows the same relative ordering of risk component magnitudes of the rank regression coefficients. The spider plot in Figure 13 shows the same ordering of risk components by slope factors (unit rate of change in baseline ranks per unit change in input risk factor) therefore showing the ordering of greatest impact on adjusted baseline risk rank output. The tornado plot in Figure 14 shows the same relative ordering by greatest absolute effect on the magnitude of the baseline risk rank output. In each of these figures the Rank of baseline Risk2 has the most important effect on baseline risk output while the Risk1, Risk3, and Risk4 components provide adjustment of lesser magnitude.

Table 43. Adjusted Baseline Rank Regression Bootstrapped Component Coefficients for 2008 Algorithm Dataset

Variable	b	sb
Rank Risk2	0.9973*	0.0026
Risk1	0.1059*	0.0278
Risk3-P	0.0228*	0.0077
Risk3-FCS	0.0053	0.0092
Risk3-ENV	0.0211*	0.0087
Risk4-P	-0.0424*	0.0021
Risk4-FCS	-0.0437*	0.0048
Risk4-ENV	-0.0016	0.0051
R-Squared	0.9945*	0.0055

*Significant regression coefficient component

Figure 12. Sensitivity of Adjusted Baseline Subcomponent Input Variables—Horizontal Bar Plot, 2008 Dataset

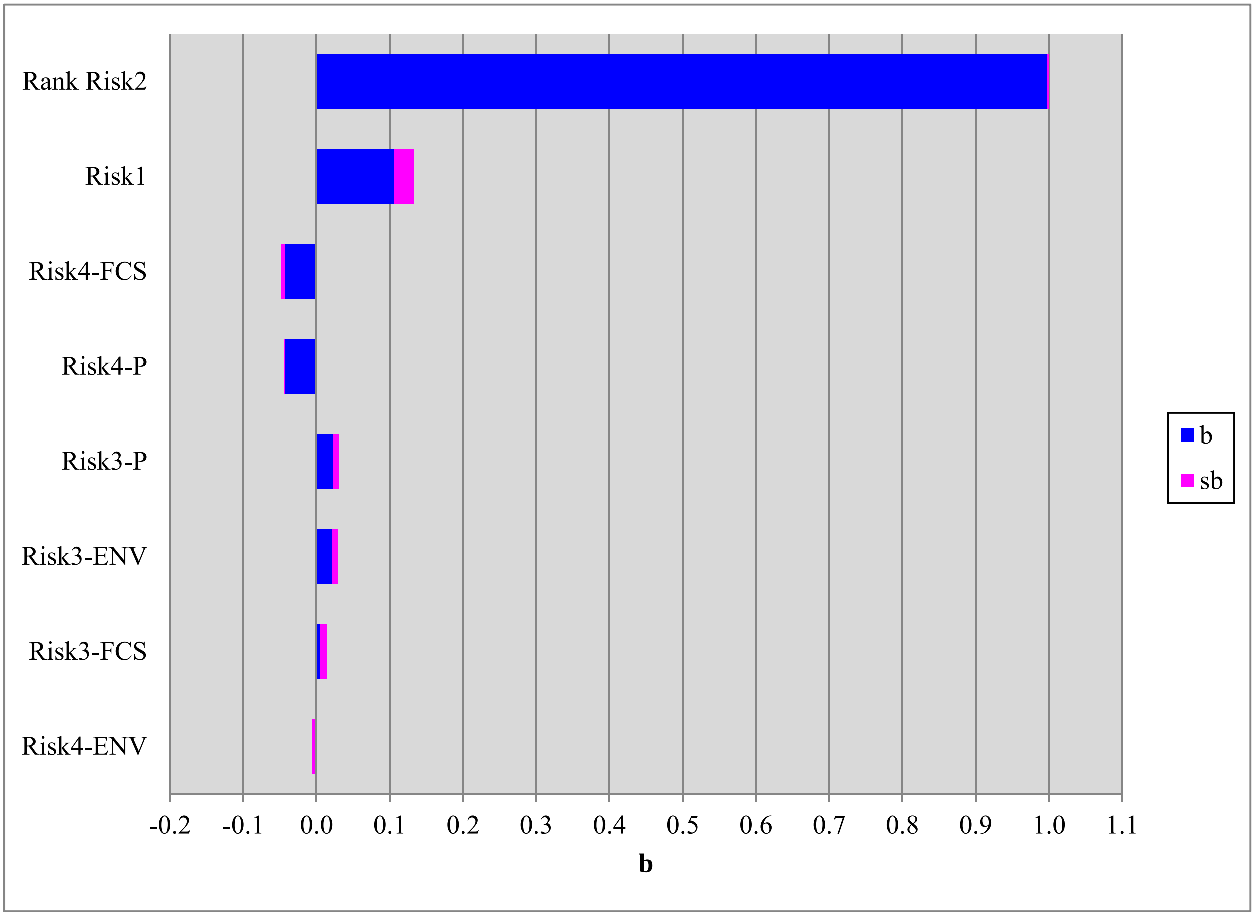


Figure 13. Sensitivity of Adjusted Baseline Component Input Variables—Spider Plot, 2008 Dataset

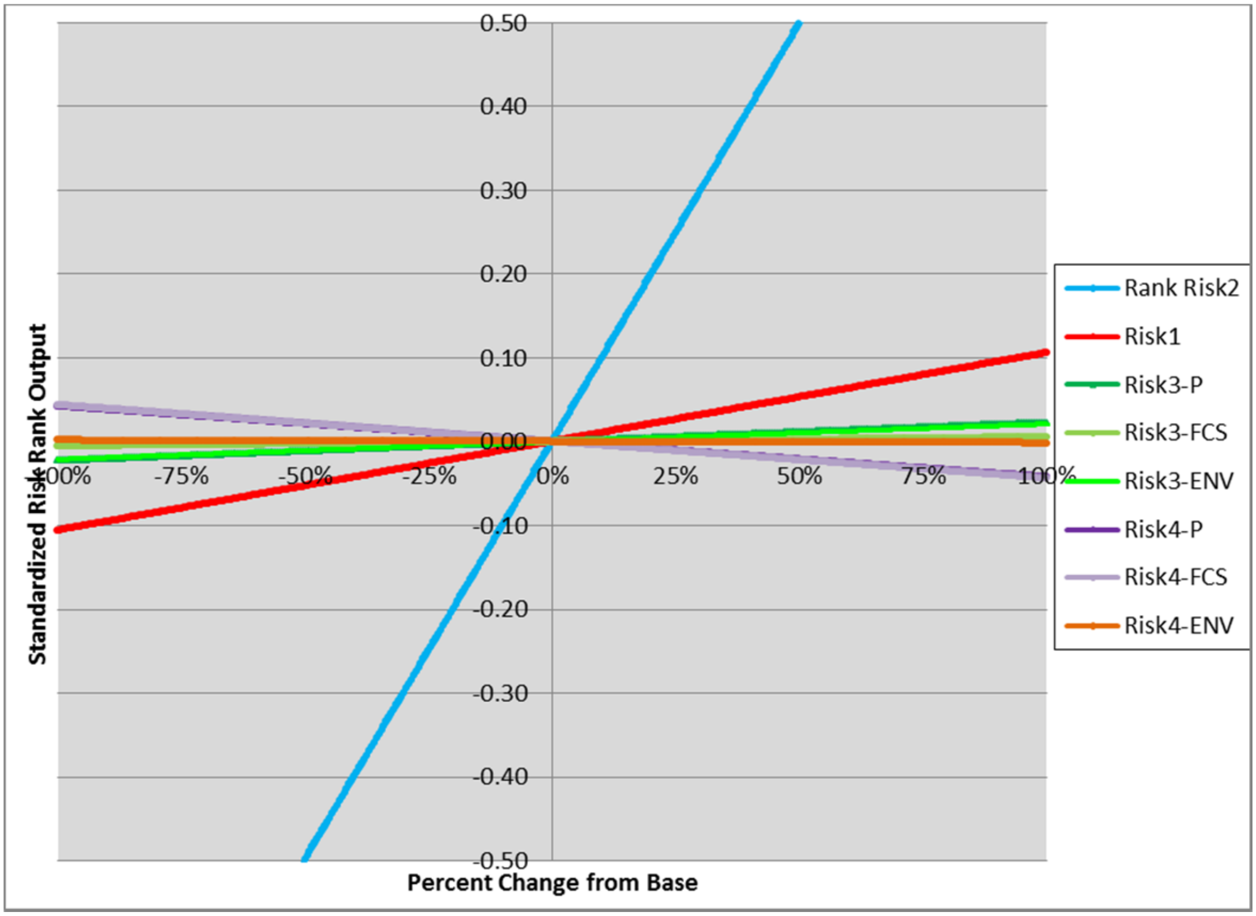
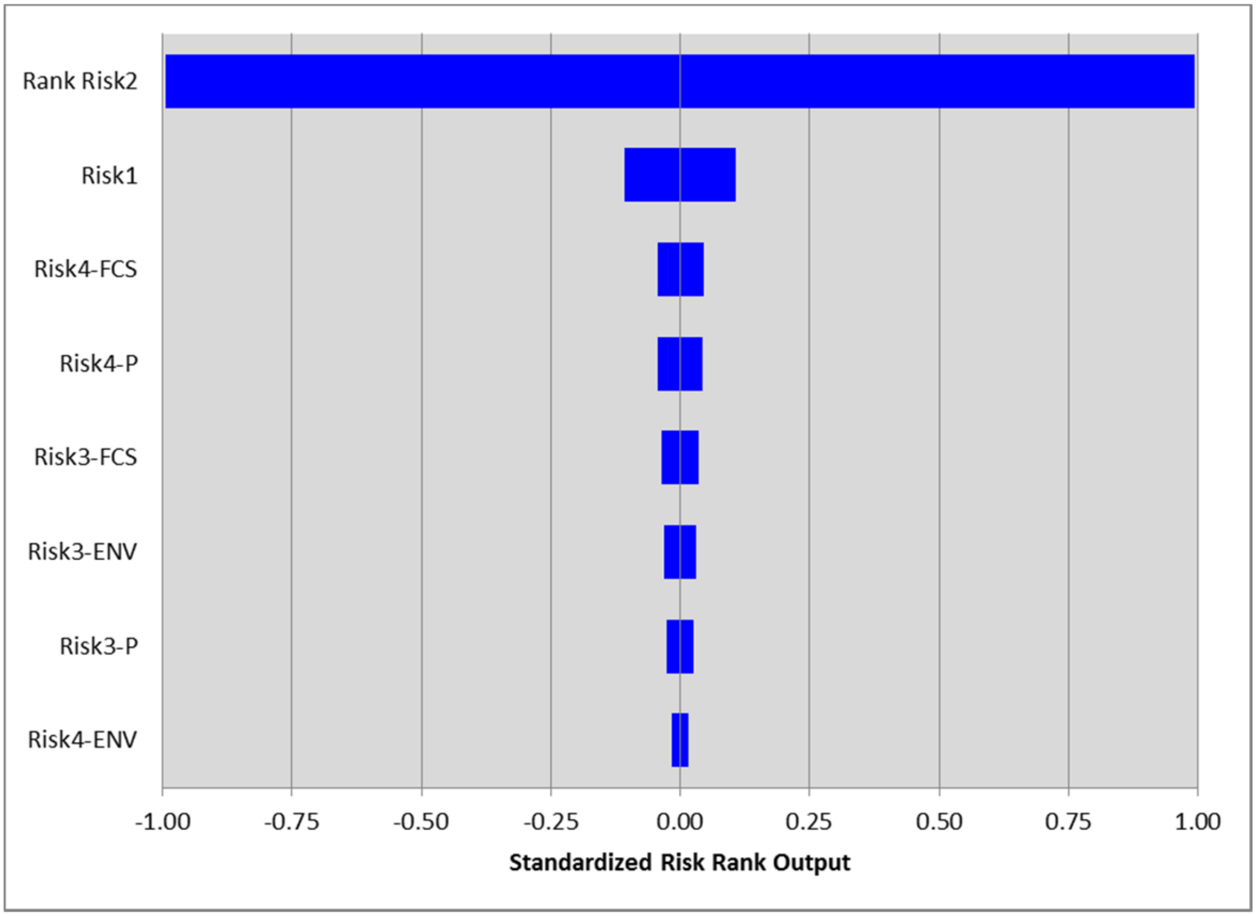


Figure 14. Sensitivity of Adjusted Baseline Component Input Variables—Tornado Plot, 2008 Dataset



Aggregated Risk Component Analysis

The adjusted baseline rank regression for four component risk variables and the four risk factors are significant. The order of the absolute value of sensitivity (b) is: Rank Risk2 > Risk1 > Risk4 > Risk3 as shown in Table 44. The horizontal bar plots in Figure 15 shows the same ordering of relative magnitudes of the rank regression coefficients. The spider plot in Figure 16 shows the same ordering of slope factors (unit rate of change in baseline ranks per unit change in input risk factor) indicating the ordering of impact on baseline risk rank output. Figure 17 shows the same ordering of absolute effects on the magnitude of the baseline risk rank output. In each of the figures the baseline Rank Risk2 component has the greatest effect while the other risk subcomponents provide minor sensitivity adjustment.

Because the aggregated risk component analysis proved better than the subcomponent analysis due to all risk components showing significance, the simpler aggregated model is preferred. The adjusted baseline part of the establishment *Listeria monocytogenes* risk ranking algorithm used for the 2006, 2008, and 2011 algorithms are the same as described here.

Table 44. Adjusted Baseline Rank Regression Bootstrapped Coefficients for 2008 Algorithm Dataset

Variable	b	sb
Rank Risk2	1.0025*	0.0028
Risk1	0.0999*	0.0289
Risk3	0.0259*	0.0076
Risk4	-0.0478*	0.0021
R-Squared	0.9950*	0.0050

*Significant regression coefficient component

Figure 15. Sensitivity of Adjusted Baseline Input Variables—Horizontal Bar Plot, 2008 Dataset

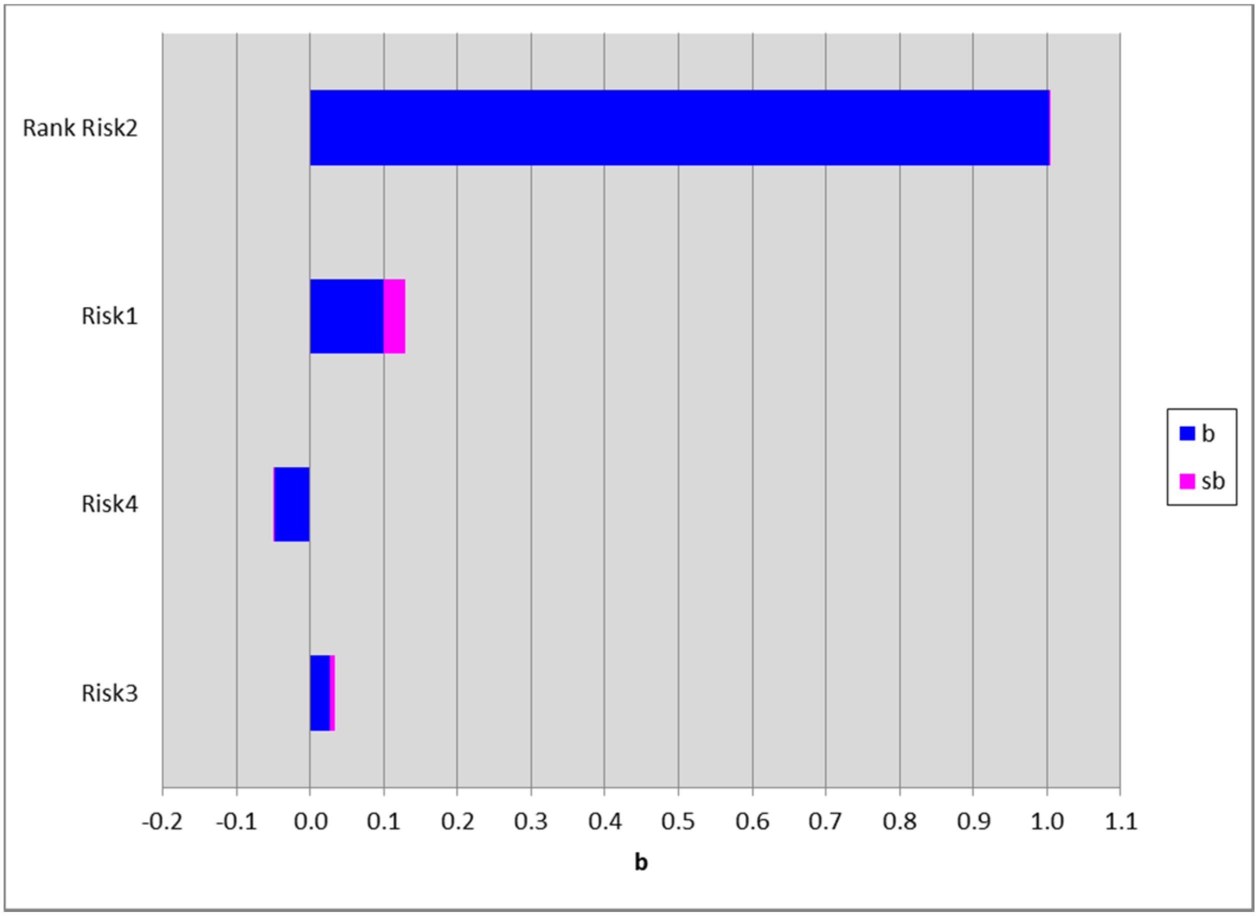


Figure 16. Sensitivity of Adjusted Baseline Input Variables—Spider Plot, 2008 Dataset

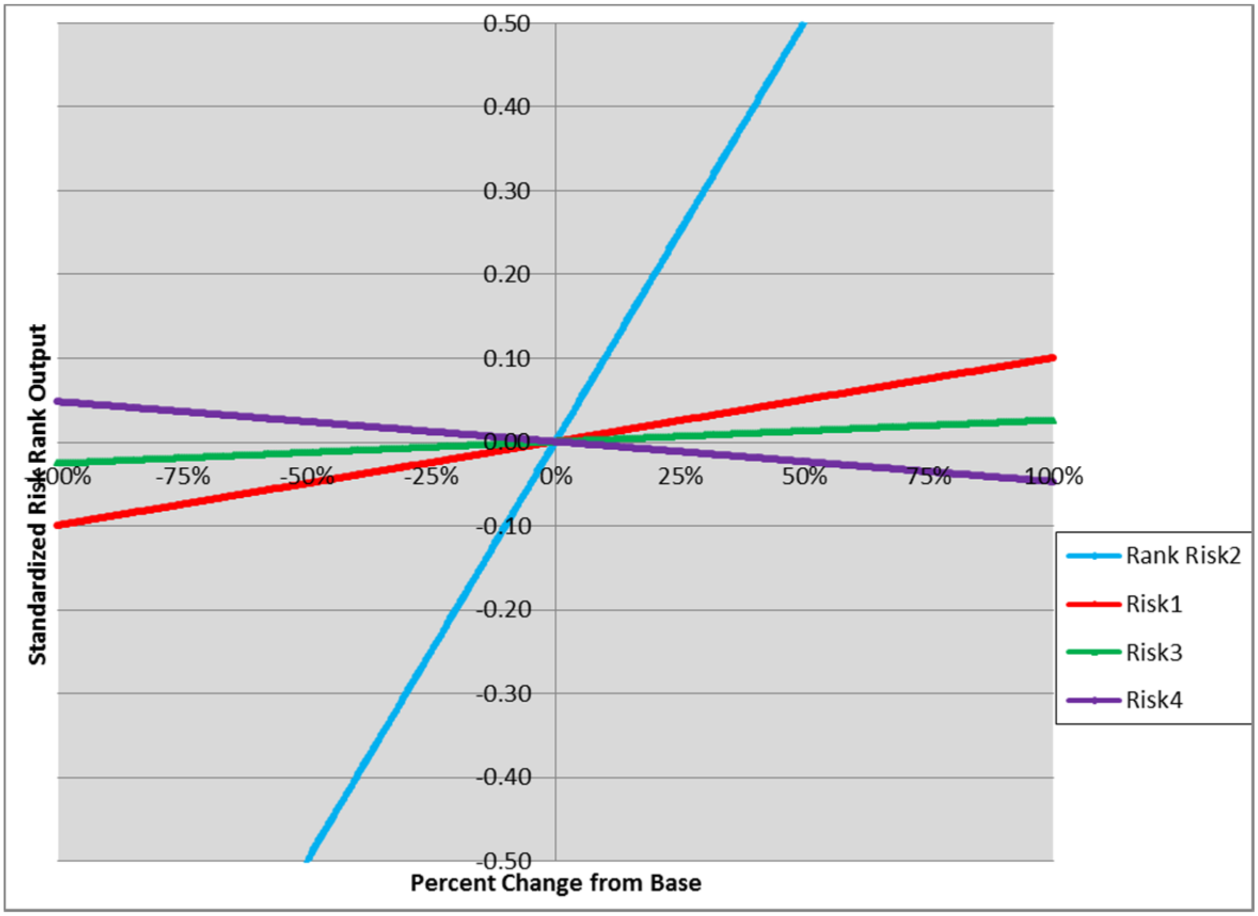
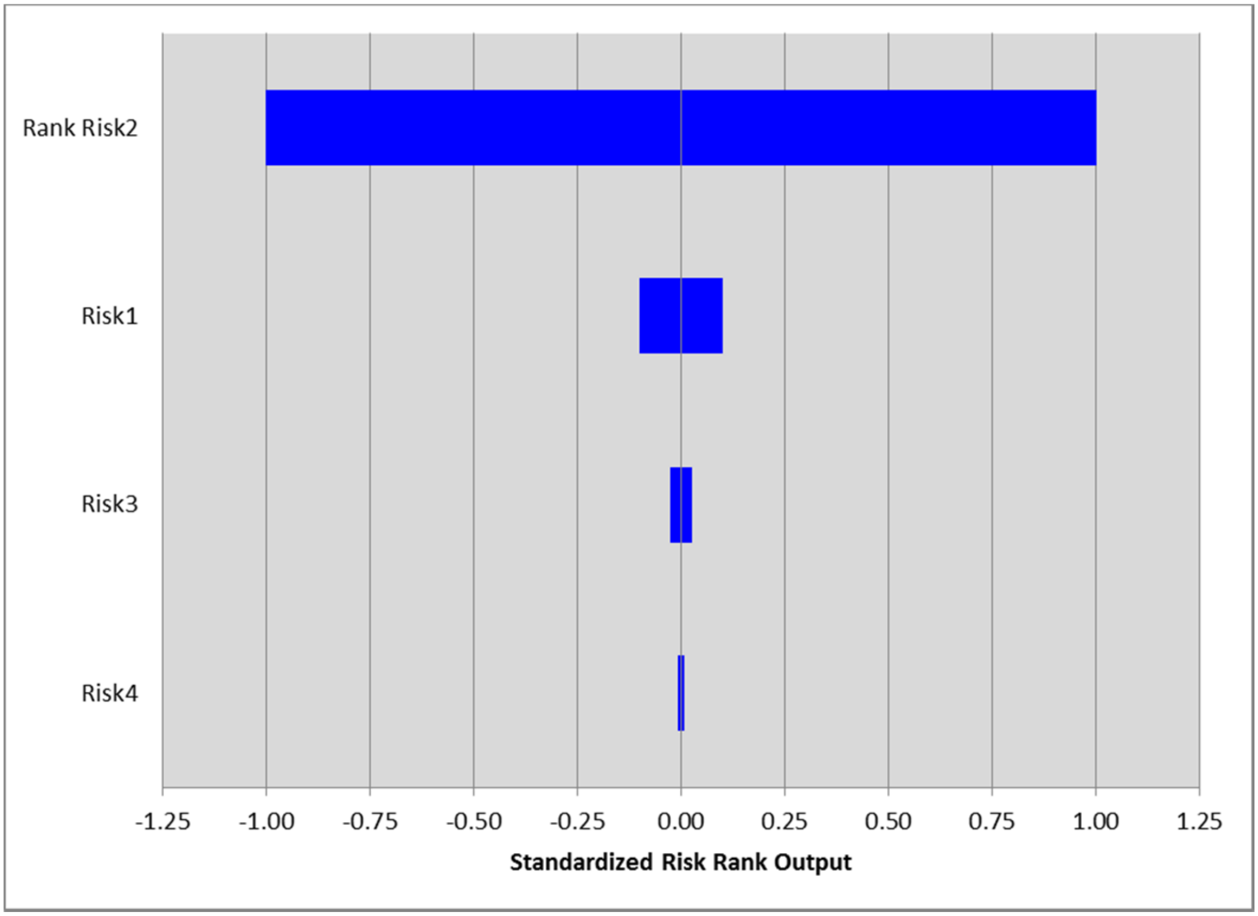


Figure 17. Sensitivity of Adjusted Baseline Input Variables—Tornado Plot, 2008 Dataset



2011 Dataset Algorithm

The sensitivity analysis is the same as the 2008 establishment *Lm* risk ranking algorithm. The 2011 algorithm incorporates new baseline risk equations updating the algorithm to achieve the original goal of basing the risk calculation on consumer risk at the point of consumption. Previous algorithms were based the risk calculation of the total annual *Lm* contamination of post-lethality exposed RTE products at retail. New risk assessment data became available (FSIS, 2010) providing the information to update the baseline risk equations.

Baseline Risk Ranking

There are six components analyzed as baseline risk components in this sensitivity analysis with the same component names as in the 2008 algorithm. However, the risk calculation estimates *Listeria monocytogenes* contamination at the point of consumption rather than estimating the average *Listeria monocytogenes* dose per serving at retail contributed by individual establishments. An extreme limit of *Listeria monocytogenes* contamination is estimated per serving. The probability of illness for the serving for one person out of the susceptible population is estimated for all establishments. The risk rank of each establishment is based on the probability rankings that provide the establishment baseline *Lm* risk ranks.

The baseline rank regression and the six risk factors are significant. The order of sensitivity is: Deli Meat Sliced (Delis) > Deli Meat Unsliced (Delius) > Frozen Products > Hot Dogs > Other RTE products > Pate as shown in Table 45. Deli meats sliced in the producing establishment have more impact than deli meats not sliced in the producing establishment. It is not entirely unexpected that frozen products have the third most important impact on the baseline risk ranking. The negative effect of this risk component reduces the establishment risk ranking. The sensitivity is a result of relatively very few establishments producing frozen products. Those few establishments producing these products account for more average annual pounds production than all the other RTE product categories except the ‘other’ RTE Products category. The sensitivity is large but in the opposite direction to deli meat sliced and unsliced and all the other RTE product categories. Hot dogs now as expected have a greater sensitivity impact than the ‘other’ RTE product category. The horizontal bar plot in Figure 18 shows that sliced and unsliced deli meats have the greatest relative magnitude of the rank regression coefficients. The spider plot in Figure 19 shows that sliced and unsliced deli meats have the greatest slope factors (unit rate of change in baseline ranks per unit change in input risk factor) therefore these components greatest impact on baseline risk rank output. The tornado plot in Figure 20 shows that sliced and unsliced deli meats have the greatest absolute effect on the magnitude of the baseline risk rank output. In all of these plots, frozen products have the third greatest (negative) sensitivity followed by hot dogs, other RTE products, and pate. The low relative sensitivity of pate even though it has high *L.monocytogenes* growth potential is due to low annual production.

Table 45. Baseline Rank Regression Bootstrapped Coefficients for 2011 Algorithm Dataset

Variable	b	sb
DeliS	0.5217*	0.0180
DeliUS	0.3007*	0.0209
HotDog	0.1542*	0.0196
Other	0.0743*	0.0192
Frozen	-0.1917*	0.0149
Pate	0.0515*	0.0215
R-Squared	0.6143*	0.3857

*Significant regression coefficient component

Figure 18. Sensitivity of Adjusted Baseline Input Variables—Horizontal Bar Plot, 2011 Dataset

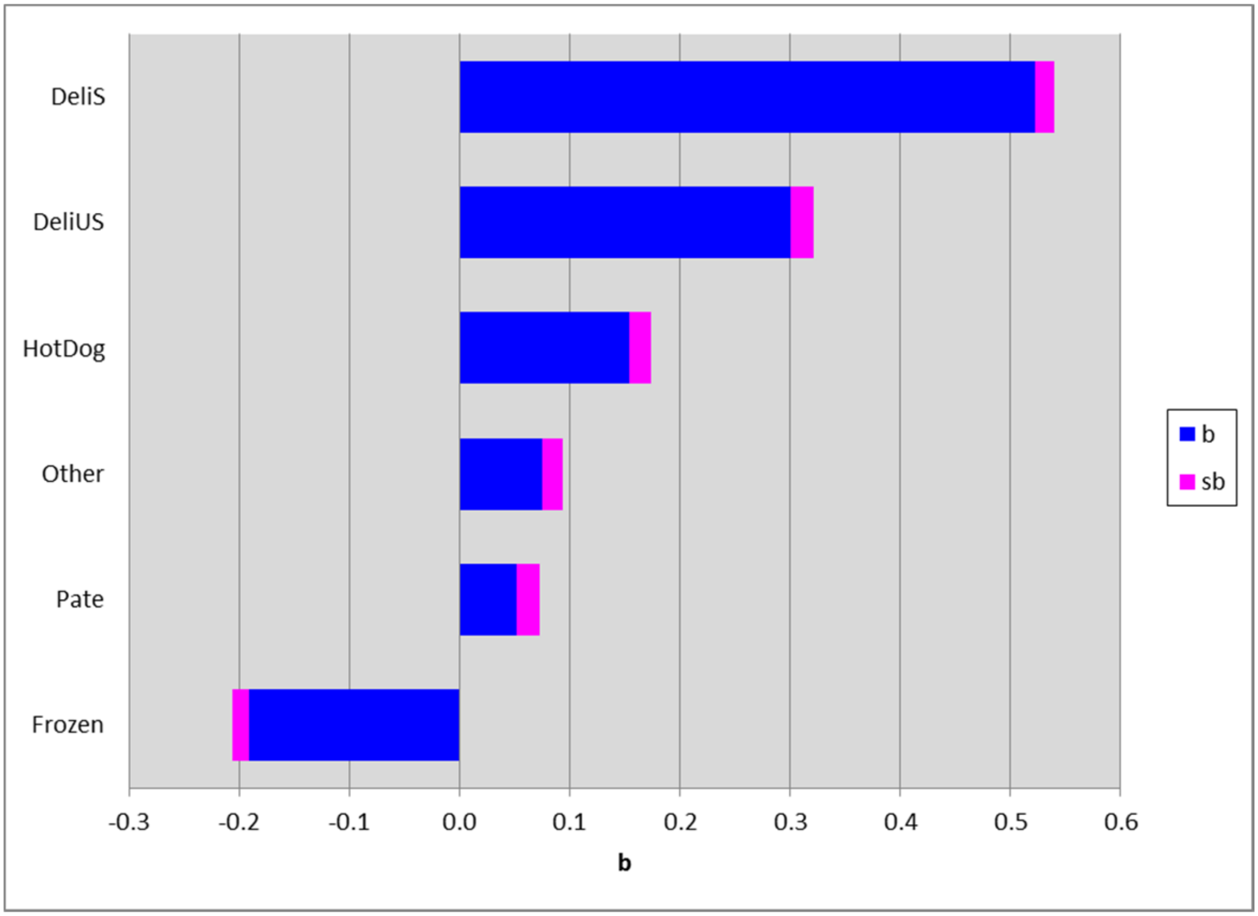


Figure 19. Sensitivity of Baseline Input Variables—Spider Plot, 2011 Dataset

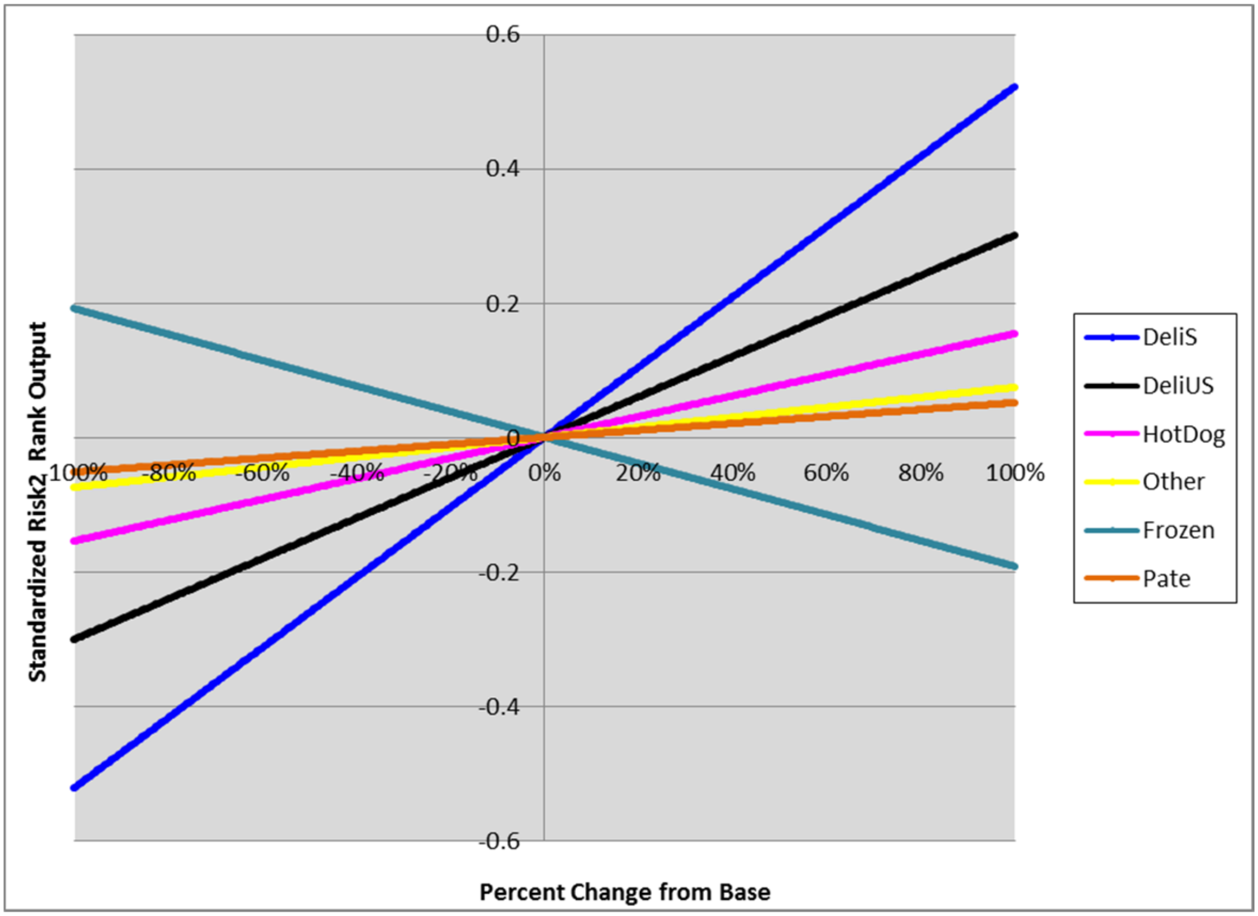
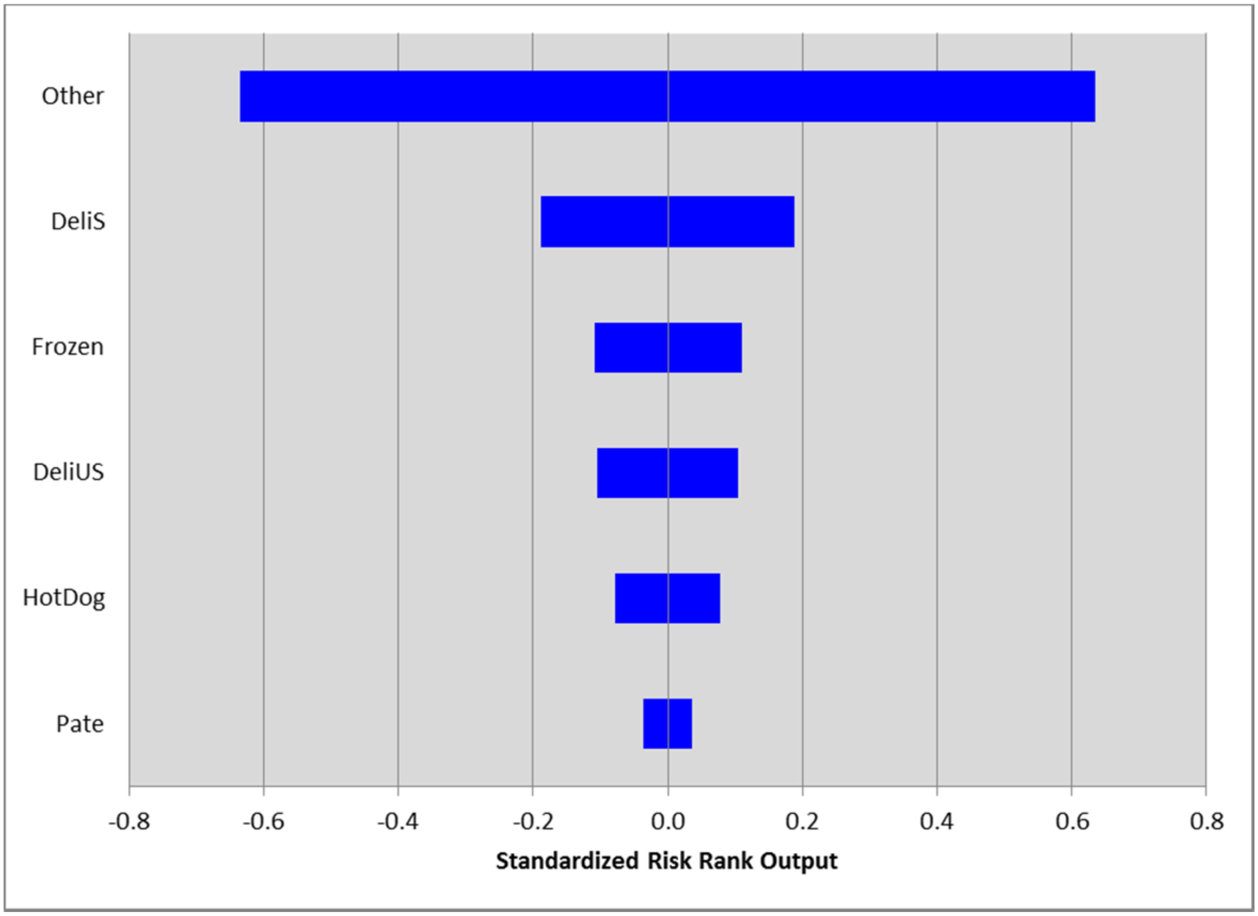


Figure 20. Sensitivity of Baseline Input Variables—Tornado Plot, 2011 Dataset



Adjusted Listeria monocytogenes *Establishment Risk Ranking*

The adjusted baseline rank regression for four component risk variables and the four risk factors are significant. The order of the absolute value of sensitivity (b) is: Rank Risk2 > Risk4 > Risk1 > Risk3 as shown in Table 46. The sum of Risk1 and Risk3 is less than that of Risk4 with Risk4 having more of an overall average effect. The horizontal bar plot in Figure 21 shows the rank of baseline Risk2 has the greatest relative magnitude of the rank regression coefficients. The spider plot in Figure 22 shows that the ranks of baseline Risk2 has the greatest slope factors (unit rate of change in baseline ranks per unit change in input risk factor) therefore the greatest impact on baseline risk rank output. Risk4 is the most sensitive adjustment risk factor. The tornado plot in Figure 23 shows that rank Risk2 has the greatest absolute effect on the magnitude of the baseline risk rank output. The other risk subcomponents provide baseline risk adjustment with less sensitivity.

Table 46. Adjusted Baseline Rank Regression Bootstrapped Coefficients for 2011 Algorithm Dataset

Variable	b	sb
Risk2	0.9165*	0.0064
Risk1	0.0956*	0.0291
Risk3	0.0361*	0.0120
Risk4	-0.1838*	0.0076
R-Squared	0.9693*	0.0307

*Significant regression coefficient component

Figure 21. Sensitivity of Adjusted Baseline Input Variables—Horizontal Bar Plot, 2011 Dataset

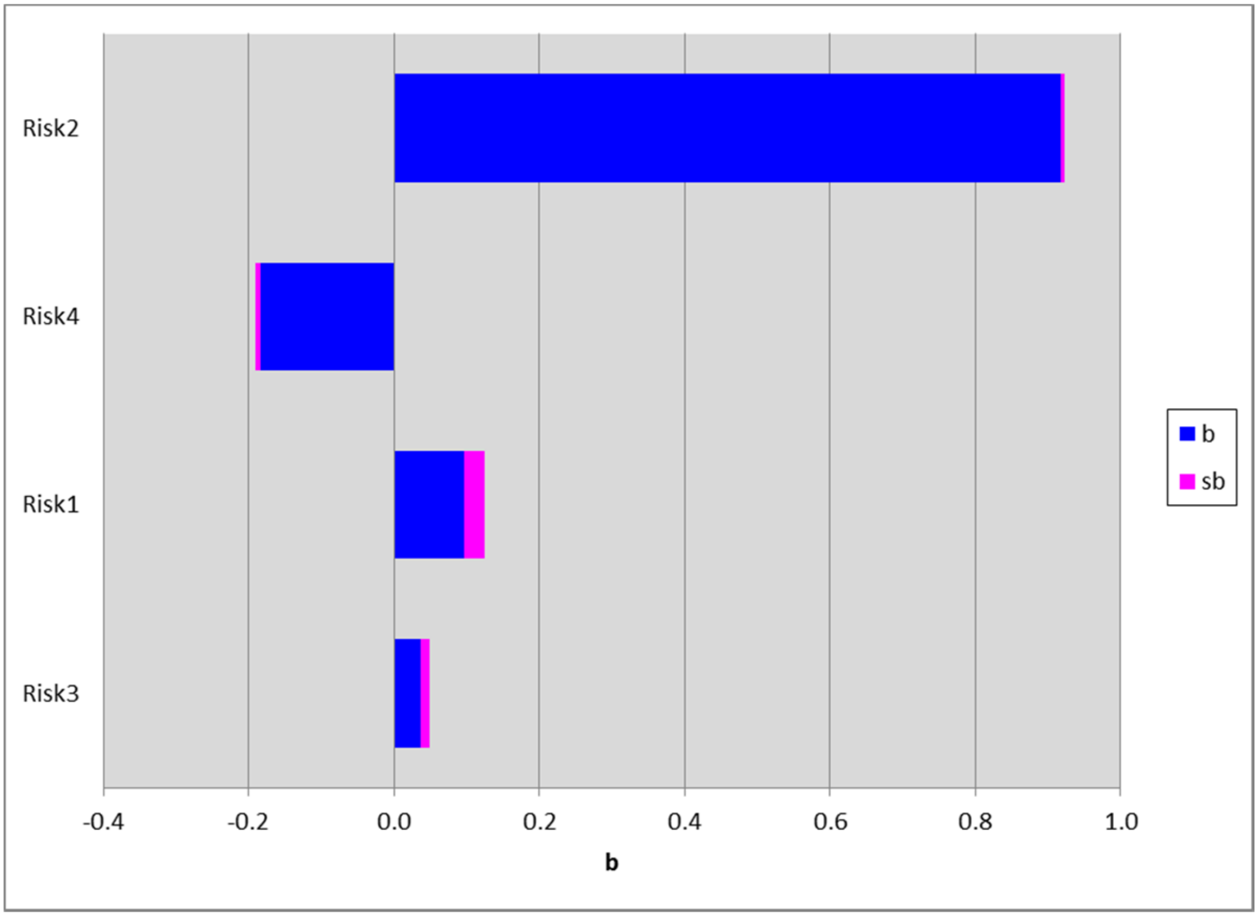


Figure 22. Sensitivity of Adjusted Baseline Input Variables—Spider Plot, 2011 Dataset

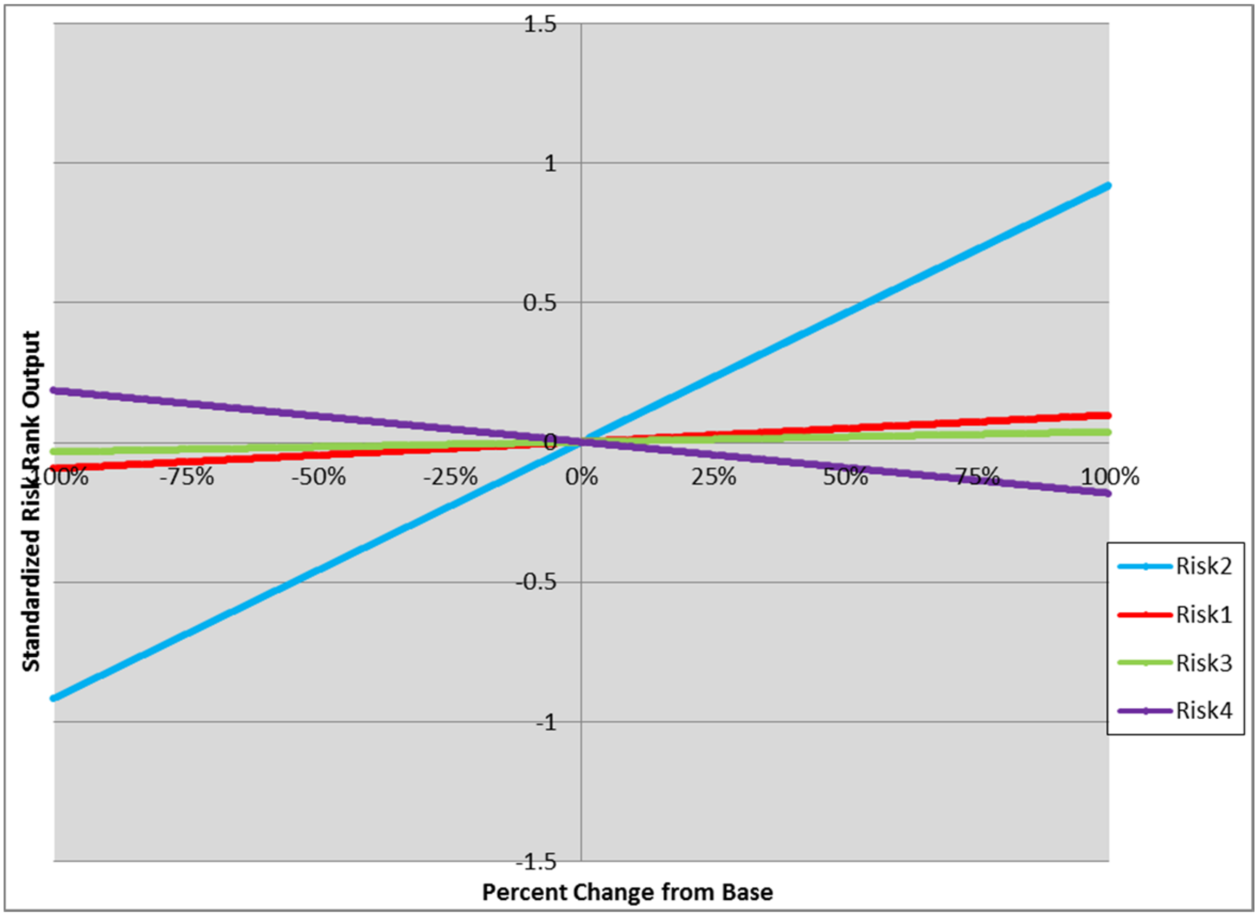
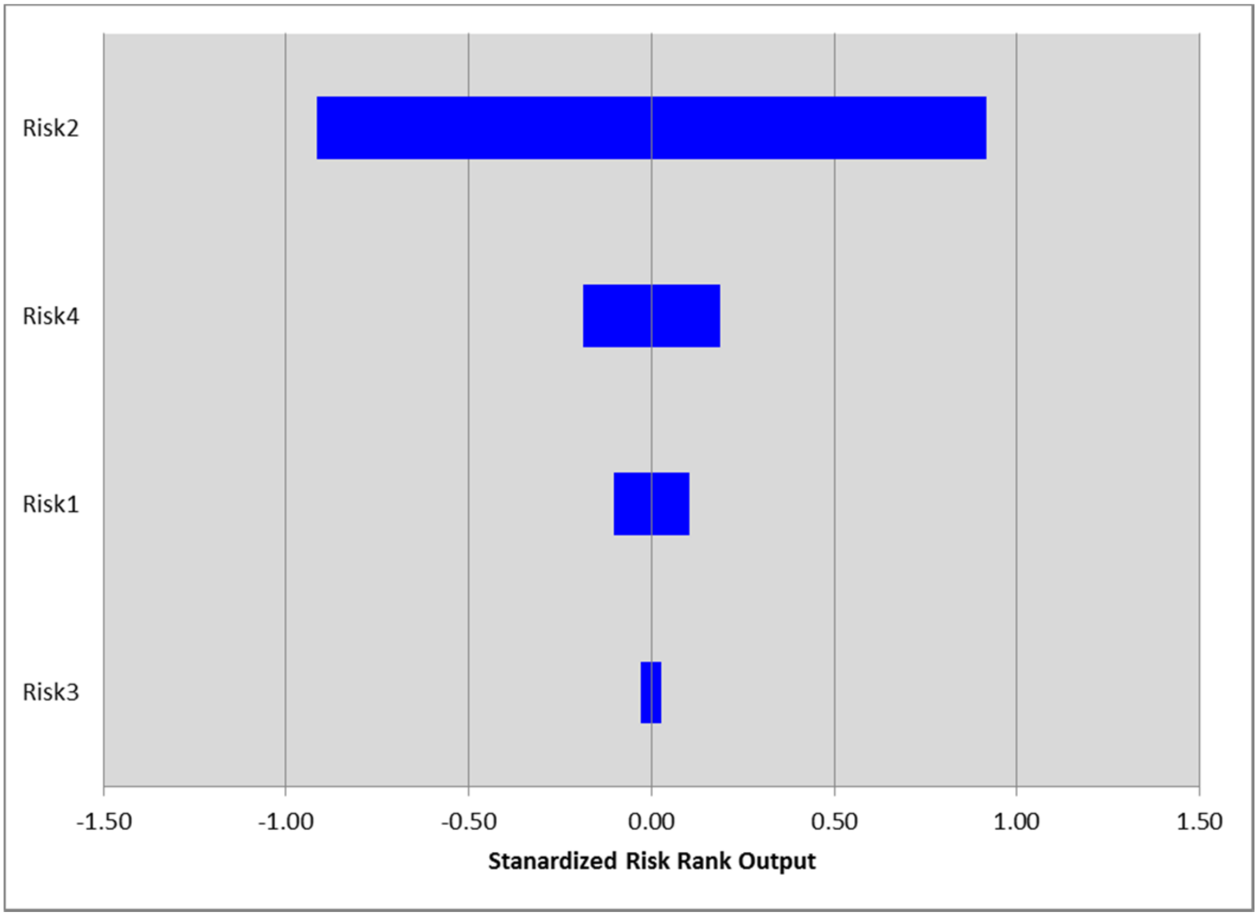


Figure 23. Sensitivity of Adjusted Baseline Input Variables—Tornado Plot, 2011 Dataset



Listeria monocytogenes Establishment Risk Ranking Algorithm

Summary of Results

Table 47 summarizes the algorithm's stage 1 input variable effect on the baseline Risk2 rank output variable for the 2005 and 2006 algorithms. The algorithm's stage 2 adjusted baseline input variable effect on the establishment *Listeria monocytogenes* risk ranking variable is also shown for all four algorithms. The baseline input variables for the 2005 and 2006 versions can be directly compared but the later versions use a different set of baseline input variables. The table shows that the order of sensitivity is the same for these versions: Deli Meat > Other RTE products > Hot

Dogs. Because there are more data points in the 2006 version, the R-squared statistic increases. Table 48 shows the algorithm's stage 1 baseline comparisons for the 2008 and 2011 algorithms. The R-squared values are similar explaining more than 60% of the rank variability. The 2011 algorithm, however, does better at predicting the RTE risk because the order of relative sensitivity (negative values less than positive values) is: Delis > Delius > Hot Dog > Other > Pate > Frozen. The 2008 version has 'other' RTE products that are more sensitive than Hot Dogs. The negative sensitivity effect of frozen products is consistent between the two algorithms. The negative sensitivity effect of Risk4 is also consistent across all algorithms.

Table 47. Bootstrapped Rank Regression Coefficients Representing Stage 1 Baseline Output Rank Variable Sensitivity and Stage 2 Adjusted Baseline Input Variables Sensitivity by Algorithm

Variable	2005	2006	2008	2011
Deli Meat	0.8542	0.8528	-	-
HotDog	0.1473	0.1828	-	-
Other	0.3087	0.2504	-	-
R-Squared	0.7604	0.8014	-	-
Rank Risk2	0.9950	1.0079	1.0025	0.9165
Risk1	0.1229	0.0643	0.0999	0.0956
Risk3	0.0462	0.0224	0.0259	0.0361
Risk4	-0.0298	-0.0384	-0.0478	-0.1838
R-Squared	0.9954	0.9955	0.9950	0.9693

Table 48. Bootstrapped Rank Regression Coefficients Representing Stage 1 Baseline Output Rank Variable Sensitivity to Input Variables by Algorithm

Variable	2008	2011
DeliS	0.4448	0.5217
DeliUS	0.4144	0.3007
HotDog	0.1325	0.1542
Other	0.3117	0.0743
Frozen	-0.0443	-0.1917
Pate	0.0472	0.0515
R-Squared	0.6300	0.6143

Uncertainty Analysis

Uncertainty in the *Listeria monocytogenes* risk ranking algorithm is characterized by an orthonormal set of input variables that partition the total uncertainty variability. The uncertainty distribution is determined by the bounded variability of the establishment *Listeria monocytogenes* risk rank output variable. The 2005 dataset provides a baseline variability of 1,981 alternatives for 1,820 establishments. The baseline rank distribution is for 1,981 ranks. The larger dataset of 2,493 alternatives from the 2006 dataset are used for the intermediate estimate and the 3,002 alternatives representing 2,315 establishments from the 2008/2011 datasets are used for the final uncertainty bound estimate. The bootstrap risk ranking model parameter estimates for 1,981 randomly selected alternatives bounded at the upper and lower limits of 1,981 and 3,002 alternatives and 1,820 and 2,315 establishments provide an estimate of the feasible uncertainty distribution for the *Listeria monocytogenes* risk rank variable. Intermediate uncertainty bounds for the output rank variable of 1,981 and 2,493 alternatives are obtained for the 2006 dataset and final uncertainty bounds of 1,981 and 3,002 alternatives are obtained for the 2008/2011 datasets. This is because 1,981 is the smallest number of alternatives observed and 3,002 is the maximum number of alternatives observed over a six-year period. The uncertainty distribution modeled captures the maximum feasible uncertainty in the number of establishments and the similar uncertainty in the percentage of alternatives. The uncertainty in the total percentage of alternatives is captured by uncertainty iterations over the feasible range of alternative percentages.

The formulas used to partition the uncertainty distribution of establishment *Listeria monocytogenes* risk ranks are as follows. The linear equations for rank regression are given in matrix form (Hettmansperger and McKean, 1998). The matrix X corresponds to the matrix of ranked input variables and the column vector Y corresponds to the establishment risk rank output variable. The column vector B corresponds to the regression coefficients for the ranked variables in equation (1) and the column vector b corresponds to the standardized regression coefficients (b) for the Z transformed X and Y variables in equation (2). The column vector b* (equation 4) is the solution set of regression coefficients for the orthogonal matrix Ux (equations 3 and 4) of input variables that partitions both the Z transformed output variable Zy (equations 2 and 3) and the untransformed rank output variable Y (equation 4). The matrix Ux is obtained using the modified Gram-Schmidt orthonormalization procedure. Because Ux and its inverse are identical, multiplying Ux and Y in equation (4) provides the coefficients (b*) that when squared sum to R-squared, the proportion of the variability in Y that is accounted for by the regression of X on Y. The column vector V of variance components of Y in equation (5) represents the solution for each input risk component.

(1) $Y = X B$

(2) $Zy = Zx\ b$

(3) $Zy = Ux\ b^*$

(4) $b^* = Ux\ Y$

(5) $V = (b^*)^2$

The uncertainty distributions are obtained by bootstrapping 1,981 to 2,493 alternatives over the solution space of the rank regressions for 1,000 iterations at each alternative using the 2,493 input vectors for the 2006 dataset. For the 2008/2011 datasets, 1,981 to 3,002 alternatives are bootstrapped over the 3,002 input vectors.

Similar to the Sensitivity section, all the statistics in this section and plots are derived from the standardized rank regression analysis that is based on bootstrap estimates. The bootstrap estimates are minimum variance unbiased estimators (MVUE) derived as particular U-statistics specific for this analysis (Hoeffding, 1948). The main assumption is that the sampling is done independently and randomly on identically distributed variables. This criterion is satisfied because the population distributions are bootstrapped rank distributions. The U-statistics are the bootstrapped means, and the N-weighted variances of the bootstrapped rank regressions resampled at the standard size of 1,981. Only the 2008 and 2011 estimates can be compared without bias because the 2005 and 2006 datasets have different sampling frequencies due to different total populations. The bootstrap resampling only coincides with a standard bootstrap sample equal to the size of the alternative population in the 2005 dataset where resampling can be done with a sample size of 1,981. The resampling rates are 100%, 83%, and 66% for the three datasets respectively. The most efficient number of bootstrap iterations was found to be greater than 2,000 because the extreme values of the statistics rapidly converged with iterations less than 1,000. The standard number of bootstrap iterations was held at 10,000.

Significance tests on parameters use a modified t-test under the assumption that the bootstrapped variances asymptotically approach normal distributions. The standard t-test formula for a two-sided test for a critical value at $p<0.05$ is used with the bootstrapped mean and variance substituted at the regression degrees of freedom.

It is important to realize that the vector V is the solution vector being bootstrapped. V represents the component variances that sum to R-squared in proportion to the amount of variance explained by the rank regression model. The independent regression coefficient components of V each represent the uncertainty explained by the model in standardized units. The variance of these components is the square of the component regression coefficients. The standard deviation of the model variances is found from the bootstrapped component regression coefficients. The uncertainty not explained by the bootstrapped statistics is equal to the percent of 1 minus R-squared minus the sum of the uncertainty component variances of the bootstrapped statistics. The total uncertainty is the sum of the model coefficient uncertainties, the bootstrapped uncertainties explained by the bootstrapped estimates and the uncertainties not explained by these estimates in standardized units. The assumption is made that the component uncertainties not explained by the bootstrapped estimates are proportional to the uncertainties explained by the bootstrapped estimates.

2005 Dataset Algorithm

The 2005 dataset estimates uncertainty by bootstrapping the population at the size of the population. It fixes the uncertainty analysis at 1,981 data points per input variable rank distribution.

Baseline Risk Ranking

The baseline risk rank uncertainty with this dataset involves characterizing the input variable variability with respect to percentage attribution of the total output error variability. The uncertainty for each input variable component is determined by the model estimated regression coefficients and the attendant coefficient uncertainty associated with the bootstrap statistics. Table 49 shows that without bootstrapping, 24% of the error variance is not explained by the rank regression model because the R^2 statistic indicates that 76% of the output variability is accounted for by the model. The percentage error components of the input variables in order of explained variability are: Deli Meat > Other RTE products > Hot Dogs. Deli Meat is the most important and significant explanatory variable contributor. Table49 shows that the division of 76% of the error explained by the model is allocated exactly among the three input variable components. The model uncertainty is indicated by the output error not explained by the model. The bootstrap statistics partition the unexplained model error. The U-statistics estimate that 5% of the previously unexplained model error is due to rank coefficient estimation variability (SVar%) and the remaining 19% of the unexplained model error is portioned into uncertainty for each component (UVar%). The order of uncertainty in this case is: Other RTE products > hot dogs > deli meat.

Table 49 shows how the partitioning occurs in the first-stage analysis. The non-bootstrapped components partition the total variance explained by the risk ranking model to equal the value of R-squared (Var % column) and similarly the bootstrapped dataset closely provided the same partition (Var% in the bootstrapped column). The partition is exact and the error variance calculated from the residuals of each component is equal to the other components (SVar% columns). The component uncertainty estimates for the not-bootstrapped model are all equal to the percent of 1 minus R-squared because no component distinction is possible. The significance test for the component variances is calculated from the ratio of the component Var% divided by the standard error of Var%. The standard error of Var% is equal to the square root of 1 minus R-squared divided by the degrees of freedom (1,981-3) which is the same for each component. The bootstrap uncertainty estimates come from portioning the remainder of the variance not explained by the regression, which is 24%. The sum of the not-bootstrapped uncertainty Svar% is 24%. The bootstrapped data provides another estimate of the component error variance Svar% that is smaller in this particular resampling problem (5.15% versus 24%). Uncertainty not explained by bootstrapping (Uvar% equal to 18.79%) is estimated as the difference between the total bootstrapped S%var and the total unexplained variance (24%-5.15%). This uncertainty is then partitioned among the input risk components in proportion to the component bootstrapped uncertainty estimate. This analysis determines the significance of the variance component (Var%) due to each orthogonal regression coefficient and partitions the variance remaining after determining these component variances and their bootstrapped error variances. The significance of the partitioned component uncertainty is inferred by magnitude of the component uncertainty partition accompanied by the non-significance of the variance component. If the variance component is significant then the associated uncertainty can be considered negligible.

Table 49. 2005 Dataset Input Component Percent Variability

First-Stage	Bootstrapped		
Variable	Var%	SVar%	UVar%
Deli Meat	65.02%*	1.51%	5.50%
HotDog	2.39%*	1.81%	6.61%
Other	8.65%*	1.83%	6.68%
R-Squared	76.06%*	5.15%	18.79%
Second-Stage	Bootstrapped		
Variable	Var%	SVar%	UVar%
Rank Risk2	97.69%*	0.01%	0.20%
Risk1	1.62%*	0.01%	0.17%
Risk3	0.21%*	0.00%	0.01%
Risk4	0.08%*	0.00%	0.00%
R-Squared	99.60%*	0.03%	0.37%

*Significant percent variability component

Adjusted **Listeria monocytogenes** *Establishment Risk Ranking*

The adjusted baseline risk rank component variability is shown in the second-stage analysis of Table 49. The regression model is significant. The four input risk factors contribute significantly in explaining the total variability; therefore the component uncertainty is not important. Table 49 shows the total variance partition that is primarily influenced by the Risk2 ranks. With this model, only 95.5% of the total variability in the establishment *L.monocytogenes* risk ranks is accounted for and 0.5% of the variability is not accounted for by the model. The variability not explained by the model is partitioned into 0.03% risk rank parameter variability and 0.37% parameter uncertainty.

Establishment Alternative and RTE Product Production Volume Bootstrap Uncertainty Estimates, 2005 Dataset

Bootstrap estimates for U-estimators were done in parallel with rank regression coefficient estimates, as well as establishment alternative and RTE product production volumes. These estimates provide uncertainty estimates for the variables that show the range of values for each particular distribution that cannot be observed for the static dataset. Table 50 shows the variability in alternatives for the establishment population. Similarly, Table 51 shows the bootstrapped uncertainty for the percent of establishments producing each of the three RTE product categories. Notice that the total percentage is greater than 100% because establishments can produce more than one category of RTE product. Table 51 also shows the percentage uncertainty in the annual volume of production. In this year, there was substantial variability in the 'other' RTE products category. Each of the factors listed in these two tables impact the *Lm* risk ranking algorithm output rank variable according to their range of variability. The percent standard errors correspond to uncertainty estimates for these variables.

Table 50. Bootstrap Estimates for Percent of 1,981 Establishments in *Lm* Risk Alternatives, 2005 Dataset

	2005			
Alternative	Average%	Stderr%	Min%	Max%
1	5.93	0.52	4.09	7.98
2a	2.88	0.37	1.41	4.34
2b	20.06	0.91	16.56	23.67
3	71.13	1.02	67.14	74.91

Table 51. Bootstrap Estimates for Percent of 1,981 Alternatives from 1,820 Establishments Producing Three Categories of RTE products and Percent of the Total Annual Volume Production, 2005 Dataset

	2005			
%Establishments	Deli Meat	Hot Dog	Other	Total
Average	38.73	20.61	83.5	142.84
Stderr	1.1	0.91	0.84	
%Volume	Deli Meat	Hot Dog	Other	Total
Average	6.66	3.99	89.35	100
Stderr	0.86	0.71	75.54	

2006 Dataset Algorithm

The 2005 dataset estimates uncertainty by bootstrapping the population at the size of the population. It fixes the uncertainty analysis at 2,493 data points per input variable rank distribution.

Baseline Risk Ranking – Two-Stage Algorithm

The following two-stage *Lm* risk model was used for the final analysis of the 2006 dataset.

rank Risk2 = rank Deli Meat + rank Hot Dogs + rank Other RTE products

Lm Risk Rank = rank Risk1 + rank Risk2 + rank Risk3 + rank Risk4

The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. Table 52 shows the rank variance partitioning in two stages. The first stage bootstrapped rank regression explains 80% of the total variance with 20% unexplained by the model. The variance components are all significant, Therefore, the uncertainty is not significant. The uncertainty is proportional to the component variability.

Because each of these risk components also had significant sensitivity in this model, the associated uncertainty of each risk component can be ignored and improvement in the model is not necessary. The establishment *Listeria monocytogenes* risk ranking is reasonable.

Table 52. Percent Variability and Uncertainty in Baseline Risk Ranking for 2006 Dataset

First-Stage	Bootstrapped		
Variable	Var%	Svar%	Uvar%
Deli Meat	71.03%*	1.33%	8.82%
Hot Dog	3.30%*	0.52%	3.41%
Other	5.81%*	0.76%	5.02%
R-Squared	80.14%*	2.61%	17.25%
Second-Stage	Bootstrapped		
Variable	Var%	SVar%	UVar%
Rank Risk2	98.90%*	0.16%	0.10%
Risk1	0.47%*	0.11%	0.06%
Risk3	0.05%*	0.01%	0.00%
Risk4	0.12%*	0.01%	0.00%
R-Squared	99.55%*	0.28%	0.17%

*Significant percent variability component

Adjusted *Listeria monocytogenes* Establishment Risk Ranking – Two Stage algorithm

The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. Table 52 shows the rank variance partitioning in the second stage analysis. The bootstrapped rank regression explains 99.55% of the total variance with 0.45% unexplained by the model. The variance components are all significant so none of the uncertainty components are significant. The variability in the orthogonal regression coefficient variance component explains 0.28% of the variability unexplained by the model leaving 0.17% to the uncertainty components.

Because each of these risk components also had significant sensitivity in this model, the interpretation is that there is no significant uncertainty associated with the risk rank adjustment components. No model improvement for this part of the establishment *Listeria monocytogenes* risk ranking algorithm is needed.

Establishment Alternative and RTE Product Production Volume Bootstrap Uncertainty Estimates, 2006 Dataset

Bootstrap estimates for U-estimators were done in parallel with rank regression coefficient estimates, as well as establishment alternative and RTE product production volumes. These estimates provide uncertainty estimates for these variables that show the range of values for each particular distribution that cannot be observed for the static dataset. Table 53 shows the uncertainty in alternatives for the establishment population. Similarly, Table 54 shows the bootstrapped uncertainty for the percent of establishments producing each of the three RTE product categories. Notice that the total percentage is greater than 100% because establishments can produce more than one category of RTE product. Table 54 also shows the percentage uncertainty in the annual volume of production.

Table 53 Bootstrap Estimates for Percent of 2.493 Establishments in *Lm* Risk Alternatives - 2006 Dataset

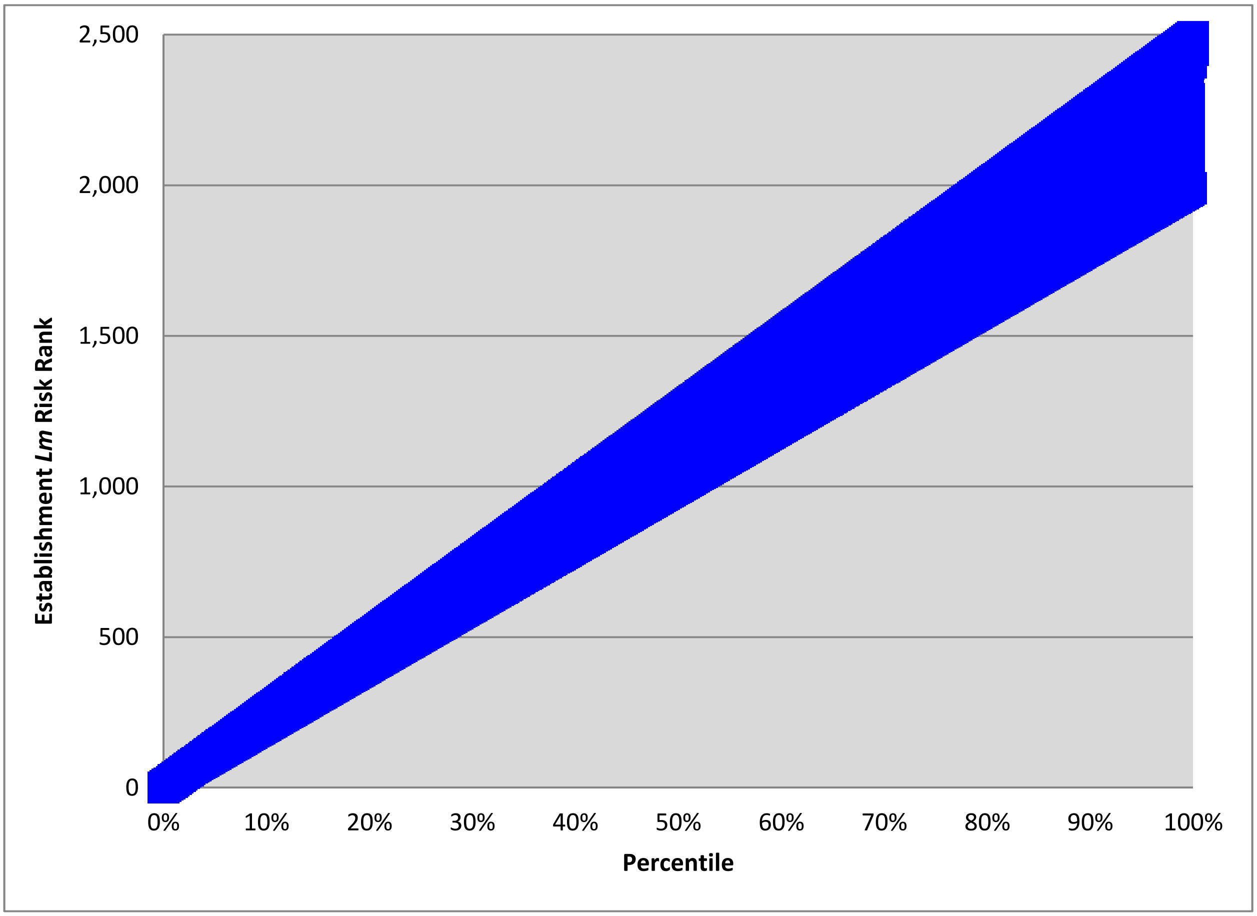
	2006			
Alternative	Average%	Stdev%	Min%	Max%
1	5	0.49	3.38	6.87
2a	12.55	0.74	9.79	15.6
2b	26.25	0.98	22.67	29.88
3	56.2	1.1	52.3	60.22

Table 54 Bootstrap Estimates for Percent of 1,981out of 2,493 Alternatives from 2,067 Establishments Producing Three Categories of RTE products and Percent of the Total Annual Volume Production – 2006 Dataset

	2006			
%Establishments	Deli Meat	Hot Dog	Other	Total
Average	35.97	19.47	84.15	139.59
Stdev	1.08	0.9	0.81	
%Volume	Deli Meat	Hot Dog	Other	Total
Average	9.39	4.12	86.49	100.00
Stdev	1.33	0.04	0.02	

Figure 24 illustrates the scope of bootstrapping . The linear wedge shape is produced as a percentile plot of the cumulative risk rank distributions beginning on the lower edge with 1,981 ranks and proceeding with increasing slope to the top of the wedge with 2,493 ranks. This plot shows the limits of the uncertainty distributions over all of the possible rank regression models bounded by the upper and lower limits of 1,981 and 2,493 ranks respectively. This figure indicates the unique structure of rank regression uncertainty because the rank distributions are bounded by the variability of the ranks themselves and the uncertainty lies in the permutations of the ranks rather than unbounded limits that may be difficult to estimate.

Figure 24. Percentiles of the *Lm* Risk Rank Distributions Possible from 2005 through 2006 Bounding Risk Rank Variability and Uncertainty



2008 Dataset Algorithm

Baseline Risk Ranking

The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. Table 55 shows the rank variance partitioning. The bootstrapped rank regression explains 63% of the total variance with 37% unexplained by the model. Four of the variance components are significant. The associated uncertainty components are not significant. By inference, the uncertainty associated with the frozen and pate RTE products is important but the magnitude is negligible. The uncertainty is proportional to the component variability. The order of uncertainty is: Pate > Frozen RTE products. Figure 25 shows this relationship clearly because the horizontal bar plot shows the exact variance partitions that total 100% of the Risk2 rank variance.

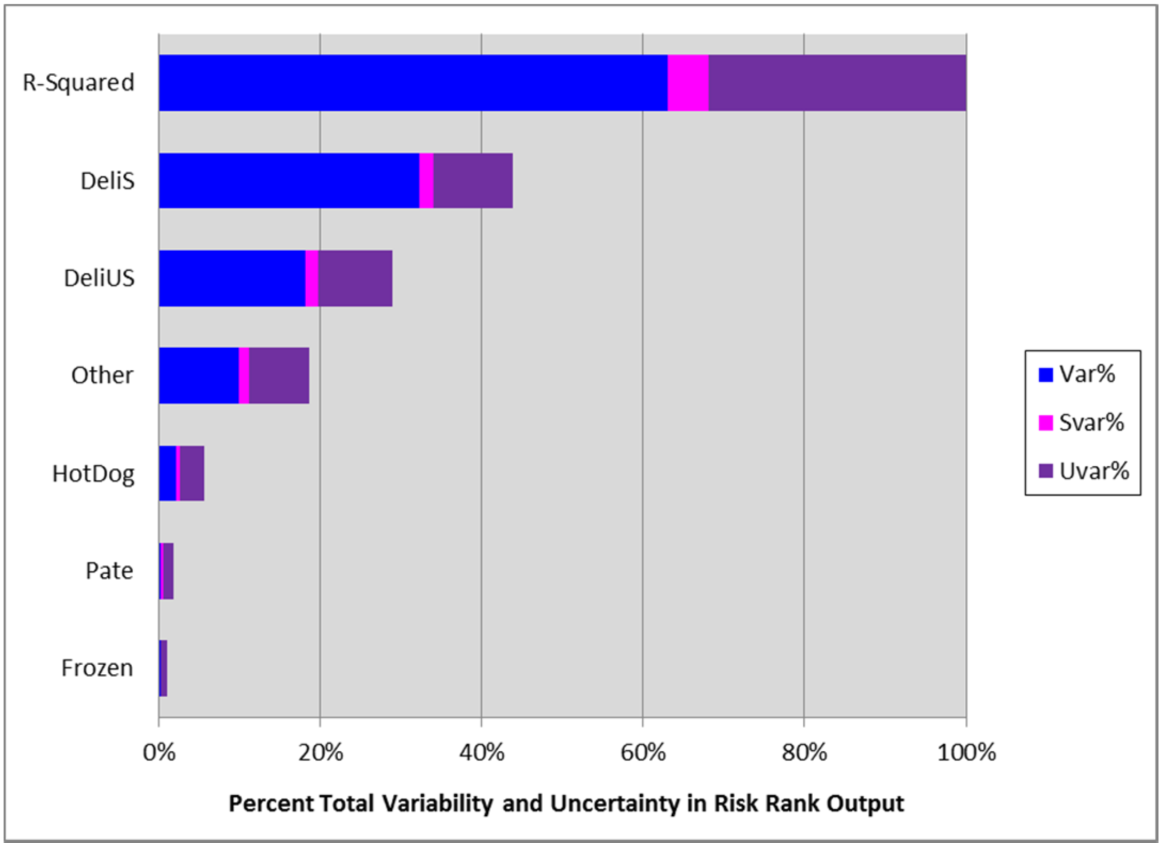
Because each of these risk components also had significant sensitivity in this model, the associated uncertainty of each risk component can be ignored. Model improvement to reduce the component uncertainty is not necessary because it can produce a reasonable establishment *Listeria monocytogenes* risk ranking.

Table 55. Percent Variability and Uncertainty in Baseline Risk Ranking for 2008 Dataset

Variable	Var%	Svar%	Uvar%
DeliS	0.3232*	0.0162	0.0995
DeliUS	0.1817*	0.015	0.092
HotDog	0.0215*	0.005	0.0304
Other	0.0991*	0.0123	0.0754
Frozen	0.0019	0.0012	0.0071
Pate	0.0027	0.0022	0.0136
R-Squared	0.6300*	0.0519	0.318

*Significant percent variability component

Figure 25. Percent Variability and Uncertainty in Baseline Risk Ranking Input Components, 2008 Dataset



Adjusted Listeria monocytogenes Establishment Risk Ranking

The 2008 dataset incorporates new risk variables in the algorithm equations for the Risk2 Rank adjustment. A subcomponent analysis was done to evaluate the effect of incorporating the new risk components for food contact surfaces and environmental area laboratory results. Table 56 shows the uncertainty analysis, where 99.45% of the risk rank variance is accounted for by the rank regression leaving 0.55% for the error variance and uncertainty components. All but two of the variance components are significant. The Risk4 environmental test results are not significant. Only the associated uncertainty may be important. However, the magnitude of these uncertainties appears negligible. Comparison with the aggregated risk factor model showed there was no advantage to having detailed subcomponents because the total variance explained is the same. Table 57 shows the risk component variance contributions for the aggregated model. R-squared is

0.9950 versus 0.9945 for the subcomponent model so there is no advantage with this model especially when all variance components of the aggregated model are significant. The uncertainty in the aggregated model is therefore not significant. Figure 26 corresponds to Table 56 for the subcomponent analysis. Figure 27 corresponds to Table 57 and shows the horizontal bar graphs indicating almost all the variance is partitioned into the rank Risk2 component although the adjusting risk factors are also significant.

Table 56. Percent Variability and Uncertainty in Risk Subcomponent Adjusted Baseline Risk Ranking for 2008 Dataset

Variable	Var%	Svar%	Uvar%
Rank Risk2	0.9765*	0.0003	0.0023
Risk1	0.0121*	0.0003	0.0021
Risk3-P	0.0004*	0	0.0001
Risk3-FCS	0.0001	0	0.0001
Risk3-ENV	0.0003*	0	0.0001
Risk4-P	0.0034*	0	0.0001
Risk4-FCS	0.0016*	0	0.0001
Risk4-ENV	0	0	0
R-Squared	0.9945	0.0006	0.0049

*Significant percent variability component

Table 57. Percent Variability and Uncertainty in Adjusted Baseline Risk Ranking for 2008 Dataset

Variable	Var%	Svar%	Uvar%
Rank Risk2	0.9812*	0.0014	0.0011
Risk1	0.0112*	0.0013	0.001
Risk3	0.0005*	0.0001	0.0001
Risk4	0.0022*	0	0
R-Squared	0.9950*	0.0028	0.0021

*Significant percent variability component

Figure 26. Percent Variability and Uncertainty in Adjusted Baseline Risk Ranking Input Components, 2008 Dataset

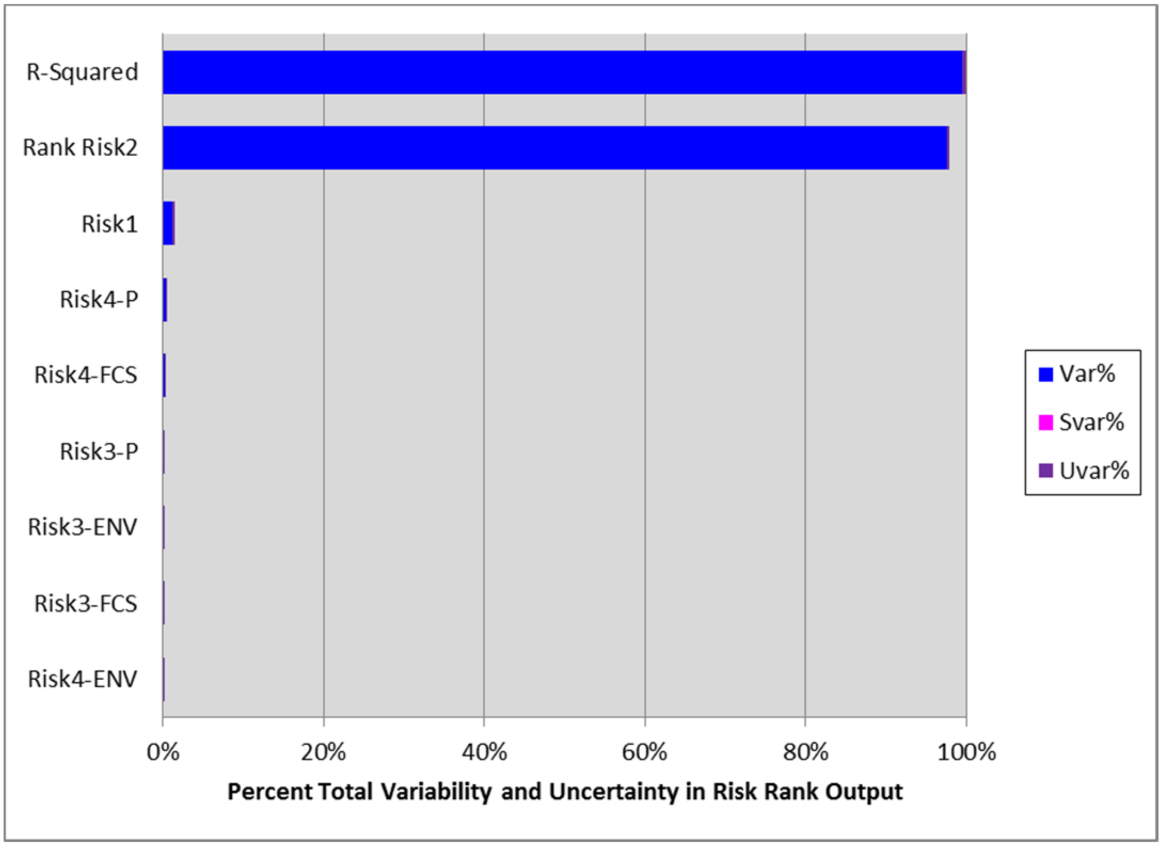
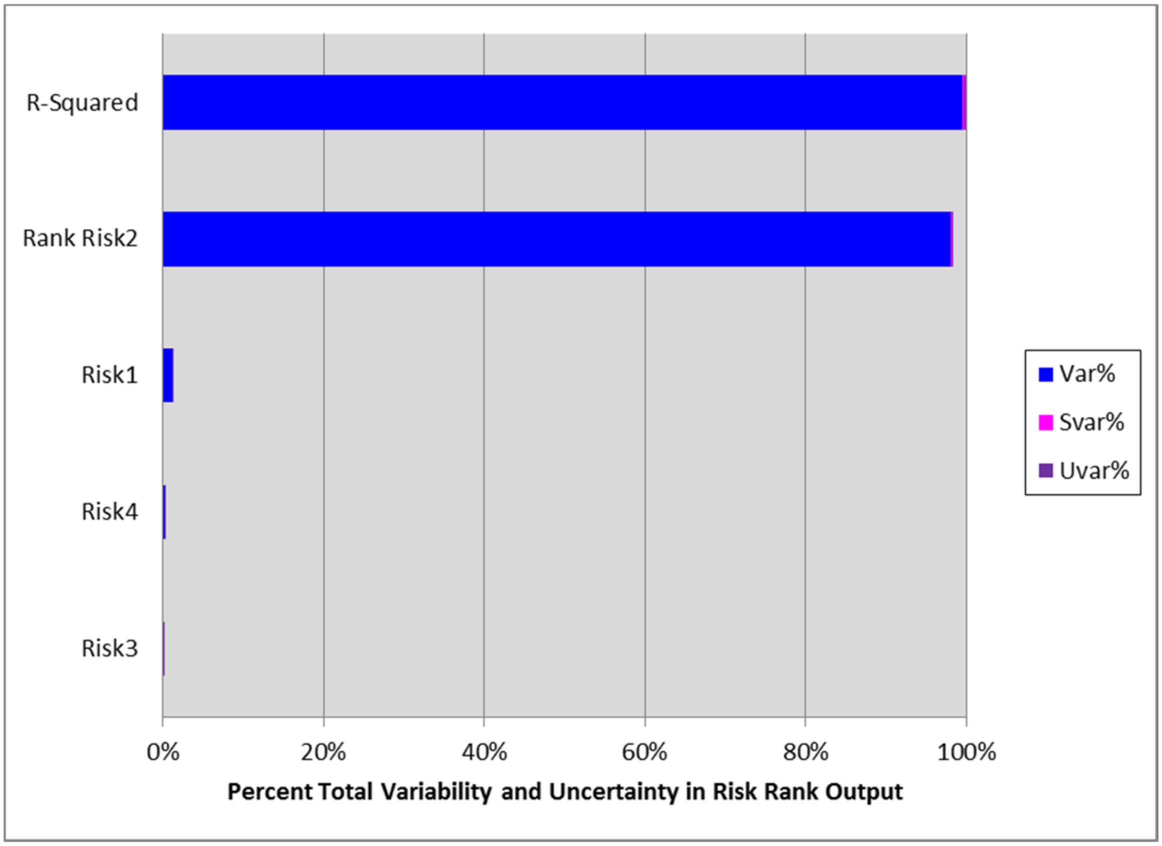


Figure 27. Percent Variability and Uncertainty in Adjusted Baseline Risk Ranking Input Components, 2008 Dataset



Establishment Alternative and RTE Product Production Volume Bootstrap Uncertainty Estimates – 2008/2011 Dataset

Bootstrap estimates for U-estimators were done in parallel with rank regression coefficient estimates, as well as establishment alternative and RTE product production volumes. These estimates provide uncertainty estimates for the variables that show the range of values for each particular distribution that cannot be observed for the static dataset. Table 58 shows the variability in alternatives for the establishment population. Similarly, Table 59 shows the bootstrapped uncertainty for the percent of establishments producing each of the three RTE product categories. Notice that the total percentage is greater than 100% because establishments can produce more than one category of RTE product. Table 59 also shows the percentage uncertainty in the annual volume of production.

Table 58. Bootstrap Estimates of Size 1.981 from 3,002 Alternatives in 2,315 Establishments - 2008/2011 Dataset

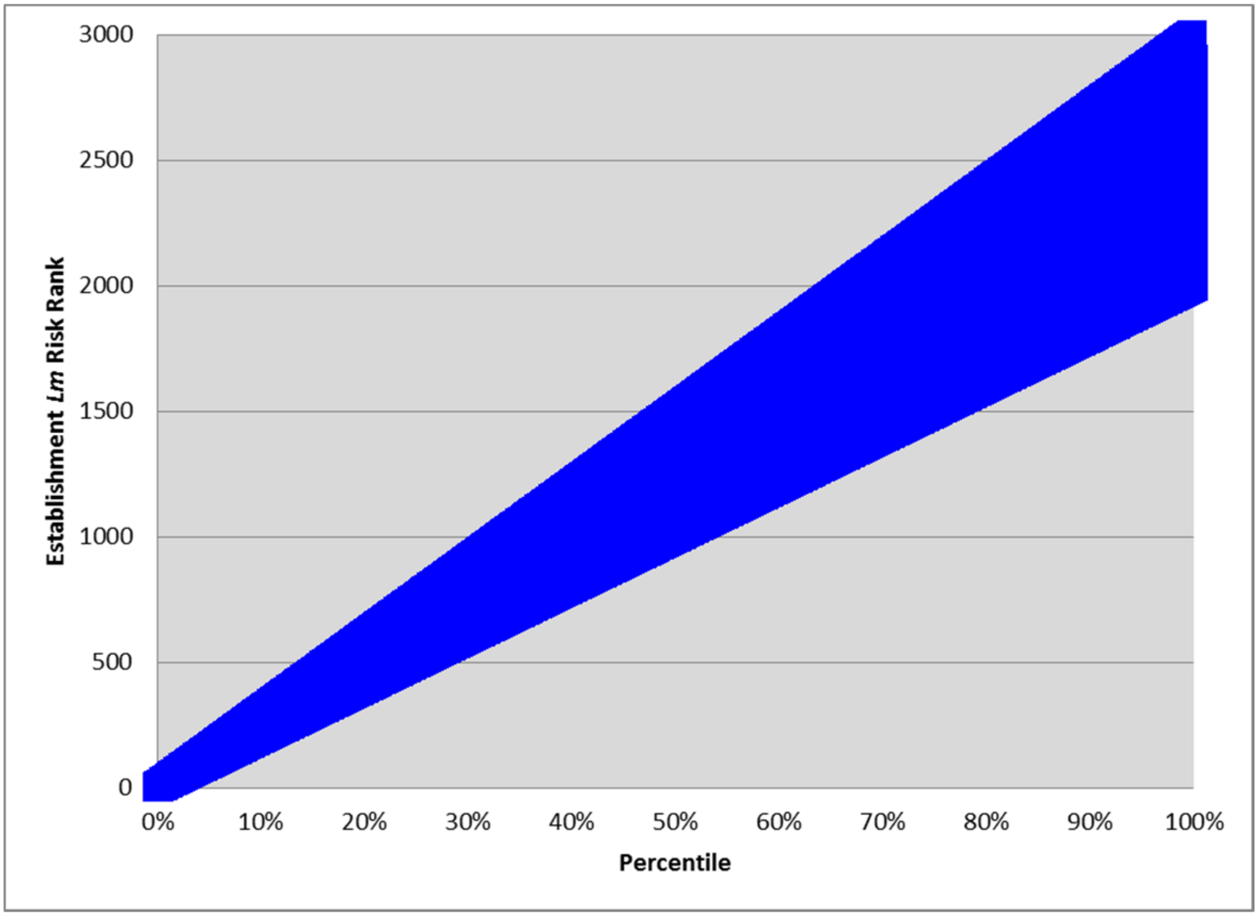
	2008			
Alternative	Average%	Stdev%	Min%	Max%
1	5.67	0.52	3.69	8.13
2a	9.24	0.65	6.87	11.71
2b	30.13	1.04	26.1	34.53
3	54.96	1.14	50.68	59.11

Table 59. Bootstrap Estimates for Percent of 1,981out of 3,002 Alternatives from 2,315 Establishments Producing Nine Categories of RTE products and Percent of the Total Annual Volume Production – 2008/2011 Dataset

	2008				
%Establishments	DeliS	DeliUS	HotDog	Cooked	Ferm
Average	22.78	20.76	16.89	68.2	9.89
Stdev	0.95	0.91	0.84	1.05	0.68
%Volume	DeliS	DeliUS	HotDog	Cooked	Ferm
Average	10.49	8.04	7.9	56.36	3.64
Stdev	1.8	1.13	1.71	28.06	0.77
	2008				
%Establishments	Dried	Cured	Frozen	Pate	Total
Average	14.45	4.6	12.44	1.5	166.92
Stdev	0.79	0.47	0.74	0.27	
%Volume	Dried	Cured	Frozen	Pate	Total
Average	0.89	0.26	12.41	0.02	99.74
Stdev	0.23	0.1	1.96	0.01	

Figure 28 illustrates the scope of bootstrapping. The linear wedge shape is produced as a percentile plot of the cumulative risk rank distributions beginning on the lower edge with 1,981 ranks and proceeding with increasing slope to the top of the wedge with 3,003 ranks. This plot shows the limits of the uncertainty distributions over all the possible rank regression models bounded by the upper and lower limits of 1,981 and 3,003 ranks respectively. This figure indicates the unique structure of rank regression uncertainty because the rank distributions are bounded by the variability of the ranks themselves and the uncertainty lies in the permutations of the ranks rather than unbounded limits that may be difficult to estimate.

Figure 28. Percentiles of the *Listeria monocytogenes* Risk Rank Distributions Possible from 2005 through 2006 Bounding Risk Rank Variability and Uncertainty



2011 Dataset Algorithm

Baseline Risk Ranking

The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. This analysis uses the 2008 dataset. However, the baseline equations for this updated algorithm are different from the previous versions. The probability of illness in the susceptible population at the point of consumption is used rather than the total annual *Lm* cfu/g produced at retail. Table 60 shows the rank variance partitioning. The bootstrapped rank regression explains 61% of the total variance with 39% unexplained by the model. Five of the six variance components are significant. The associated uncertainty components are not significant except for pate. By inference, the uncertainty associated with the pate RTE products is important but the magnitude seems negligible only accounting for less than 2% of the total variance. Figure 29 shows this relationship clearly because the horizontal bar plot shows the exact variance partitions that total 100% of the Risk2 rank variance.

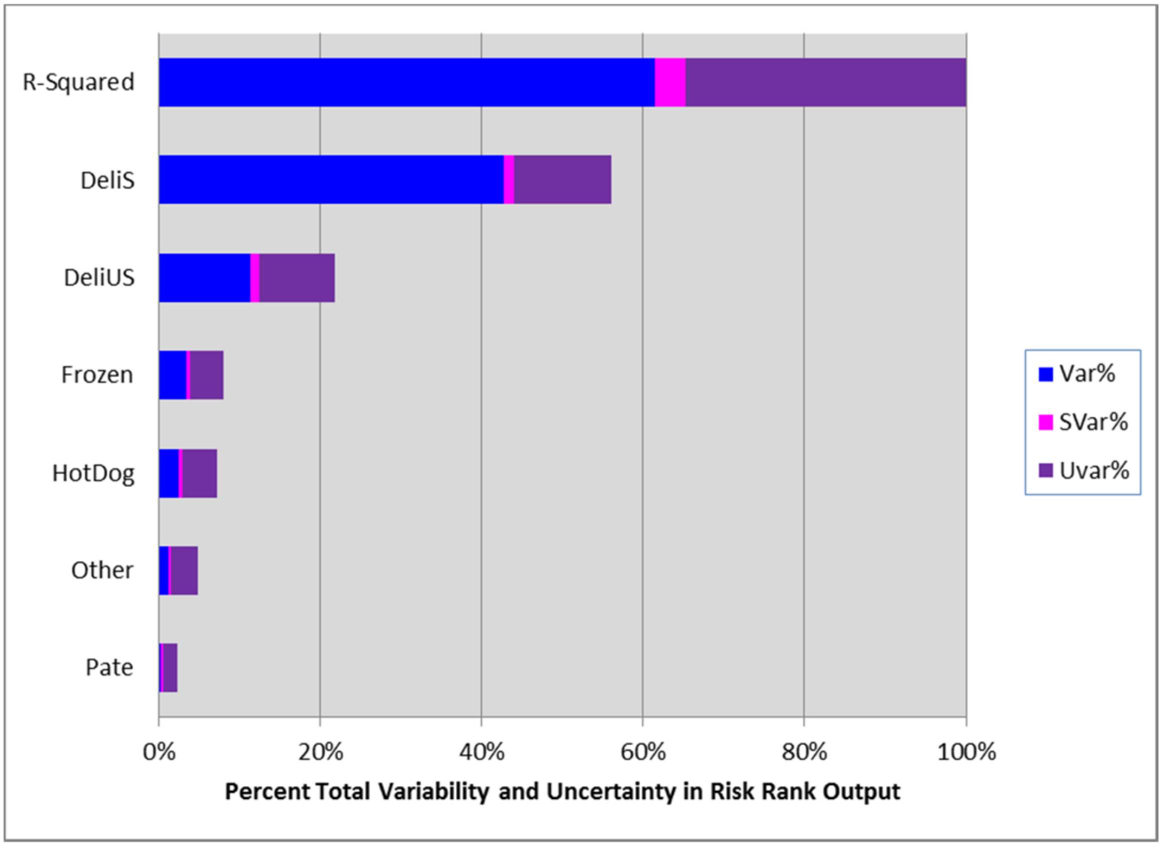
Because each of these risk components also had significant sensitivity in this model, the associated uncertainty of each risk component can be ignored except for pate. Model improvements to reduce uncertainty is not necessary because the model can produce a reasonable establishment *Listeria monocytogenes* risk ranking according to the significant R-squared statistic.

Table 60. Percent Variability and Uncertainty in Baseline Risk Ranking for 2011 Dataset

Variable	Var%	SVar%	Uvar%
DeliS	42.70%*	1.32%	12.10%
DeliUS	11.36%*	1.02%	9.40%
HotDog	2.44%*	0.46%	4.23%
Other	1.18%*	0.35%	3.25%
Frozen	3.44%*	0.44%	4.07%
Pate	0.30%	0.19%	1.74%
R-Squared	61.43%*	3.78%	34.78%

*Significant percent variability component

Figure 29. Percent Variability and Uncertainty in Baseline Risk Ranking Input Components for 2011 Dataset



Adjusted Listeria monocytogenes Establishment Risk Ranking

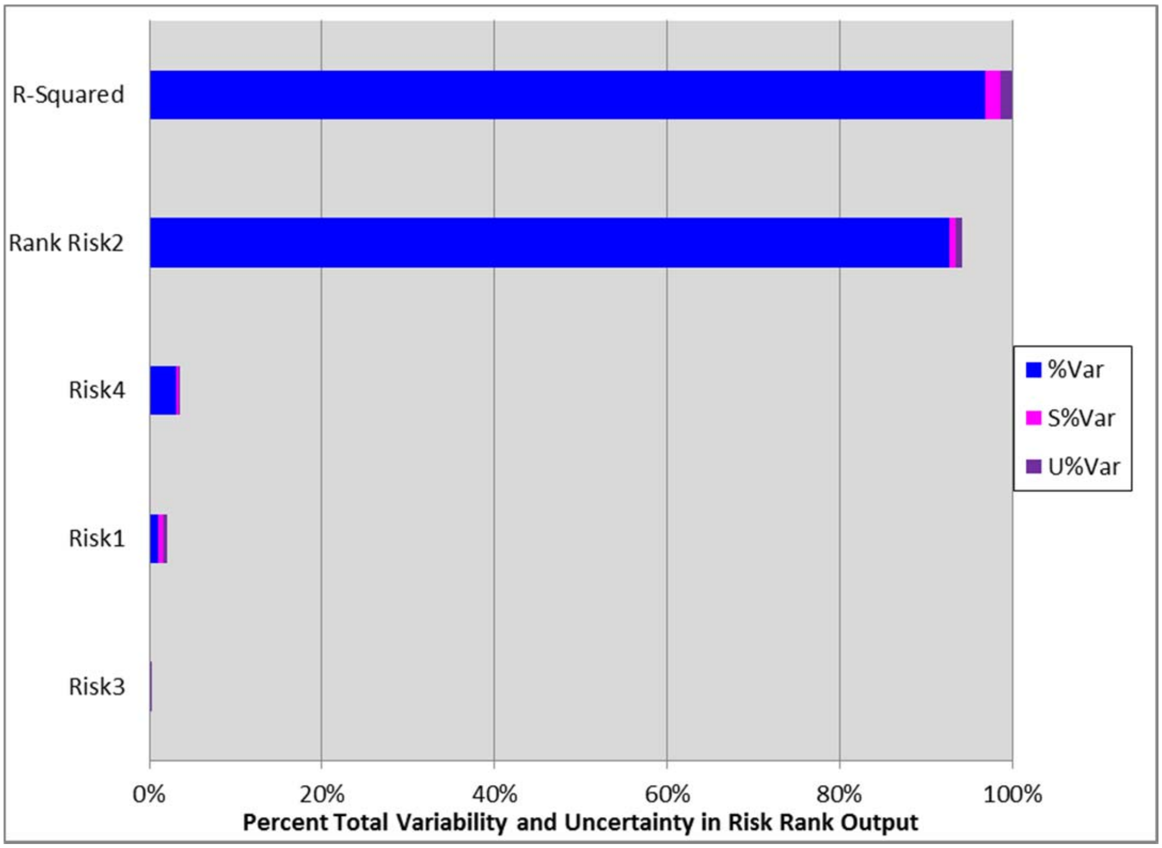
The 2011 dataset uses the same risk variables for the Risk2 rank adjustment. Table 61 shows the uncertainty analysis, where 96.93% of the risk rank variance is accounted for by the rank regression leaving 3.07% for the error variance and uncertainty components. All but one of the variance components is significant. The Risk3 component test results are not significant. Only the Risk3 associated uncertainty may be important. However, the magnitude of these uncertainties appears negligible (less than 0.1% of the total rank variance). Figure 30 shows the horizontal bar graphs indicating almost all the variance is partitioned into the rank Risk2 component; adjusting risk factors Risk1 and Risk4 are also significant indicating that the associated uncertainty is of no concern.

Table 61. Percent Variability and Uncertainty in Adjusted Baseline Risk Ranking for 2011 Dataset

Variable	%Var	S%Var	U%Var
Rank Risk2	92.66%*	0.82%	0.66%
Risk1	1.08%*	0.58%	0.46%
Risk3	0.05%	0.05%	0.04%
Risk4	3.14%*	0.26%	0.21%
R-Squared	96.93%	1.71%	1.36%

*Significant percent variability component

Figure 30. Percent Variability and Uncertainty in Baseline Risk Ranking Input Components, 2011 Dataset



Listeria monocytogenes **Establishment Risk Ranking Algorithm**

Summary of Results

The variability and uncertainty in the establishment *Lm* risk ranking algorithm risk components by dataset used to development versions 2005, 2006, 2008, and 2011 are shown in Tables 62 through 65. The mean and variance U-statistics produced through bootstrapping are denoted as Var% and

SVar% respectively. The bootstrapped and not-bootstrapped estimates are shown for comparison. The not-bootstrapped estimates are found by performing one pass of the algorithm through the entire dataset so there is no resampling. The bootstrapped estimates allow for partitioning of the total risk rank variance into variability and uncertainty components, but the not-bootstrapped estimates do not allow for partitioning of the component uncertainties. The residual variance is partitioned in the bootstrapped estimates between variability in the risk ranks (Var%) explained by the algorithm models and variability that is still unexplained or uncertain (Uvar%). The uncertainty analysis partitions the total rank variance into Var% and the SVar%. Because the total variability is estimable due to the regression on ranks, the remaining unexplained variance UVar% is uncertainty that may be reduced by improving the risk ranking model and thereby increasing the percent of variance explained by the model given by the R-squared statistic. Total uncertainty can therefore be stated as the sum of SVar% and UVar%.

It is apparent that the two-stage model shows some differences in uncertainty estimates among the four algorithm versions. The baseline risk adjustment consistently has the same small amount of uncertainty from 0.5% to 3% of the total rank variance. The baseline algorithm uncertainty estimates have a greater range (19% to 39%) but are still acceptable as stated in the respective uncertainty analyses.

Table 62. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2005 Dataset

2005	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Deli Meat	65.10%	5.90%	Deli Meat	65.02%*	1.51%	5.50%
HotDog	2.40%	5.90%	HotDog	2.39%*	1.81%	6.61%
Other	8.60%	5.90%	Other	8.65%*	1.83%	6.68%
R-squared	76.0%*	24.00%	R-Squared	76.06%*	5.15%	18.79%
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Rank Risk2	97.70%*	0.01%	Rank Risk2	97.69%*	0.01%	0.20%
Risk1	1.55%*	0.01%	Risk1	1.62%*	0.01%	0.17%
Risk3	0.21%*	0.01%	Risk3	0.21%*	0.00%	0.01%
Risk4	0.08%*	0.01%	Risk4	0.08%*	0.00%	0.00%
R-Squared	99.54%*	0.46%	R-Squared	99.60%*	0.03%	0.37%

*Significant percent variability component

Table 63. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2006 Dataset

2006	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Deli Meat	71.07%*	0.05%	Deli Meat	71.03%*	1.33%	8.82%
Hot Dog	3.26%*	0.05%	Hot Dog	3.30%*	0.52%	3.41%
Other	5.79%*	0.05%	Other	5.81%*	0.76%	5.02%
R-Squared	80.11%*	19.89%	R-Squared	80.14%*	2.61%	17.25%
Variable	Var%	SVar%	Variable	Var%	SVar%	Uvar%
Rank Risk2	98.63%*	0.04%	Rank Risk2	98.90%*	0.16%	0.10%
Risk1	0.36%*	0.04%	Risk1	0.47%*	0.11%	0.06%
Risk3	0.06%	0.04%	Risk3	0.05%*	0.01%	0.00%
Risk4	0.06%	0.04%	Risk4	0.12%*	0.01%	0.00%
R-Squared	99.10%*	0.90%	R-Squared	99.55%*	0.28%	0.17%

*Significant percent variability component

Table 64. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2008 Dataset

2008	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
DeliS	32.23%*	0.17%	DeliS	32.32%*	1.62%	9.95%
DeliUS	18.25%*	0.17%	DeliUS	18.17%*	1.50%	9.20%
HotDog	2.11%*	0.17%	HotDog	2.15%*	0.50%	3.04%
Other	9.88%*	0.17%	Other	9.91%*	1.23%	7.54%
Frozen	0.17%	0.17%	Frozen	0.19%*	0.12%	0.71%
Pate	0.22%	0.17%	Pate	0.27%	0.22%	1.36%
R-Squared	62.85%*	37.15%	R-Squared	63.00%*	5.19%	31.80%
Variable	Var%	SVar%	Variable	Var%	Svar%	Uvar%
Rank Risk2	98.10%*	0.05%	Rank Risk2	98.12%*	0.14%	0.11%
Risk1	1.09%*	0.05%	Risk1	1.12%*	0.13%	0.10%
Risk3	0.05%	0.05%	Risk3	0.05%*	0.01%	0.01%
Risk4	0.22%*	0.05%	Risk4	0.22%*	0.00%	0.00%
R-Squared	99.45%*	0.55%	R-Squared	99.50%*	0.28%	0.21%

*Significant percent variability component

Table 65. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2011 Dataset

2011	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
DeliS	42.66%*	0.63%	DeliS	42.70%*	1.32%	12.10%
DeliUS	11.33%*	0.63%	DeliUS	11.36%*	1.02%	9.40%
HotDog	2.42%*	0.63%	HotDog	2.44%*	0.46%	4.23%
Other	1.16%*	0.63%	Other	1.18%*	0.35%	3.25%
Frozen	3.42%*	0.63%	Frozen	3.44%*	0.44%	4.07%
Pate	0.28%	0.63%	Pate	0.30%	0.19%	1.74%
R-Squared	61.39%*	38.61%	R-Squared	61.43%*	3.78%	34.78%
Variable	Var%	SVar%	Variable	%Var	S%Var	U%Var
Rank Risk2	92.61%*	0.53%	Rank Risk2	92.66%*	0.82%	0.66%
Risk1	1.06%	0.53%	Risk1	1.08%*	0.58%	0.46%
Risk3	0.03%	0.53%	Risk3	0.05%	0.05%	0.04%
Risk4	3.12%*	0.53%	Risk4	3.14%*	0.26%	0.21%
R-Squared	96.87%*	3.13%	R-Squared	96.93%*	1.71%	1.36%

*Significant percent variability component

Figure 31 lists the percent of establishments producing post-lethality exposed RTE products falling into the *Listeria monocytogenes* risk alternatives for each of the datasets. The uncertainty in the estimates shown by Stdev% is the N-weighted U-estimator. The uncertainties are relatively small within each dataset but will be larger if the increase and decrease of each alternative with time is taken into account. Similarly, Figure 32 shows the percent of establishments producing RTE products in the three major categories of deli meats, hot dogs, and other RTE products. There is less of a difference between the averages than with the percent in alternatives but trends are still obvious. Additionally, Figure 33 shows the percent of total annual post-lethality exposed RTE production in the same three RTE product categories where trends in the averages are also obvious. The percent variability for 'other' RTE products is substantially larger than for the other RTE products.

The total variability in each of the datasets used for algorithm development is bracketed by the risk ranks used in modeling the data. The extent of this total variability is shown in Figure 34. The 2005 dataset represents the lower edge of the wedge shaped cumulative rank distribution while the 2008–2011 dataset is represented by the upper edge of the distribution. Therefore, the risk rank regression model permits reasonable estimates of variability and uncertainty that are fitted to conform to the known limits of the possible rank distributions.

The total variability in each of the datasets used for algorithm development is bracketed by the risk ranks used in modeling the data. The extent of this total variability is shown in Figure 35. The 2005 dataset represents the lower edge of the curved wedge shaped cumulative rank distribution while the 2008/2011 dataset is represented by the upper edge of the distribution (the variances in this figure correspond to the ranks shown before in Figure 34). Therefore, the risk rank regression model permits reasonable estimates of variability and uncertainty that are fitted to conform to the known limits of the possible rank distributions. The standardized risk component uncertainties are shown in Figure 36. The first stage deli meat, hot dog, and other RTE product uncertainties are greater than the second stage uncertainties for historical adjustment of the risk ranks. More data will have to be gathered to discern actual trends in the component uncertainty distributions with increasing numbers of ranks because of the observed inconsistent component trends. Figure 37 shows the standardized overall uncertainty trend over the four algorithm versions seems to be increasing with increasing numbers of risk ranks but further analysis is required to establish this with certainty.

Figure 31. Percent of Establishment in *Lm* Risk Alternatives 1, 2a, 2b, and 3 for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005, 2006, and 2008)

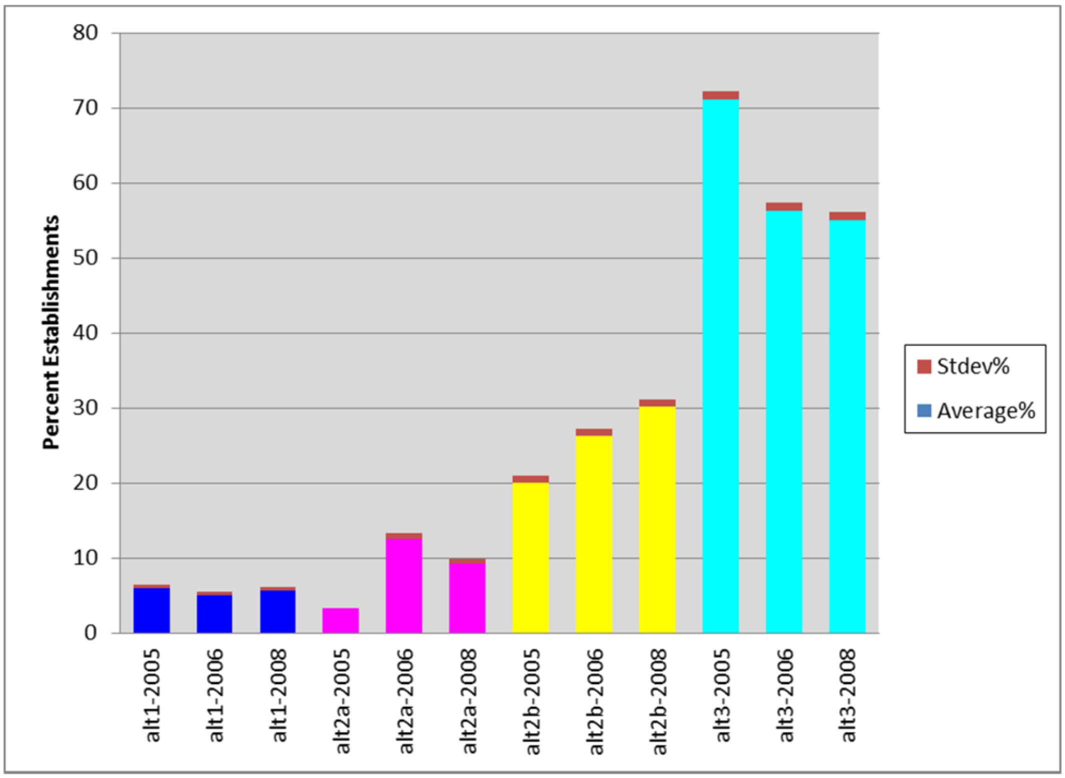


Figure 32. Percent of Establishments Producing Post-Lethality Exposed RTE Products for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005, 2006, and 2008)

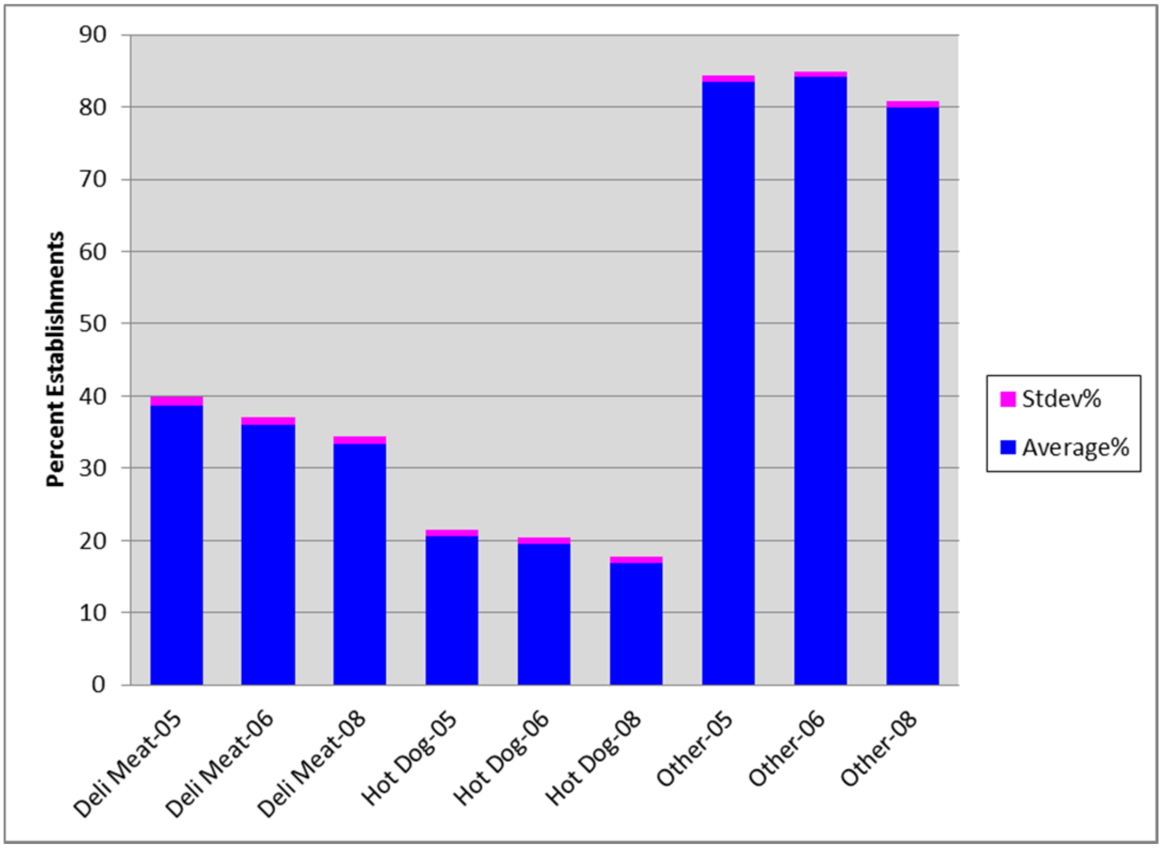


Figure 33. Percent Annual Post-Lethality Exposed RTE Products Produced for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005, 2006, and 2008)

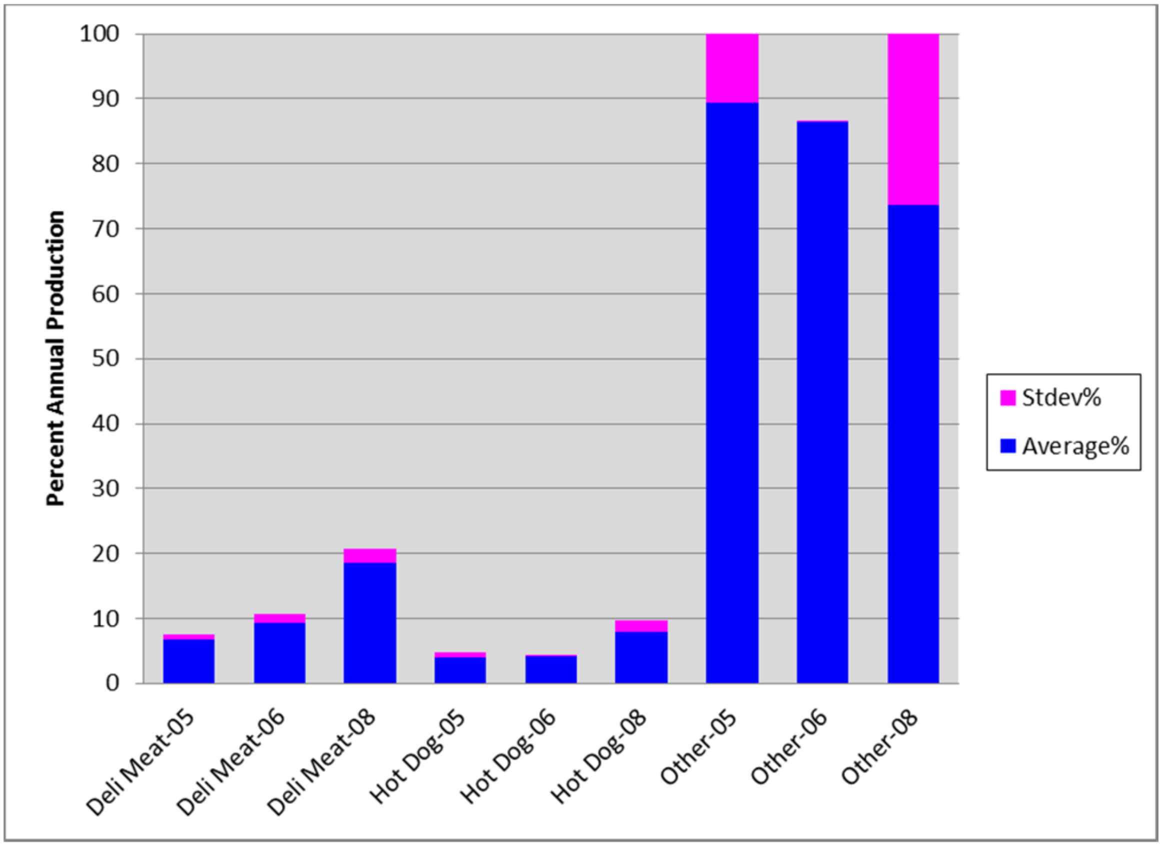


Figure 34. Percentiles of the *Lm* Risk Rank Distributions Possible from 2005 through 2011 Bounding Risk Rank Variability and Uncertainty

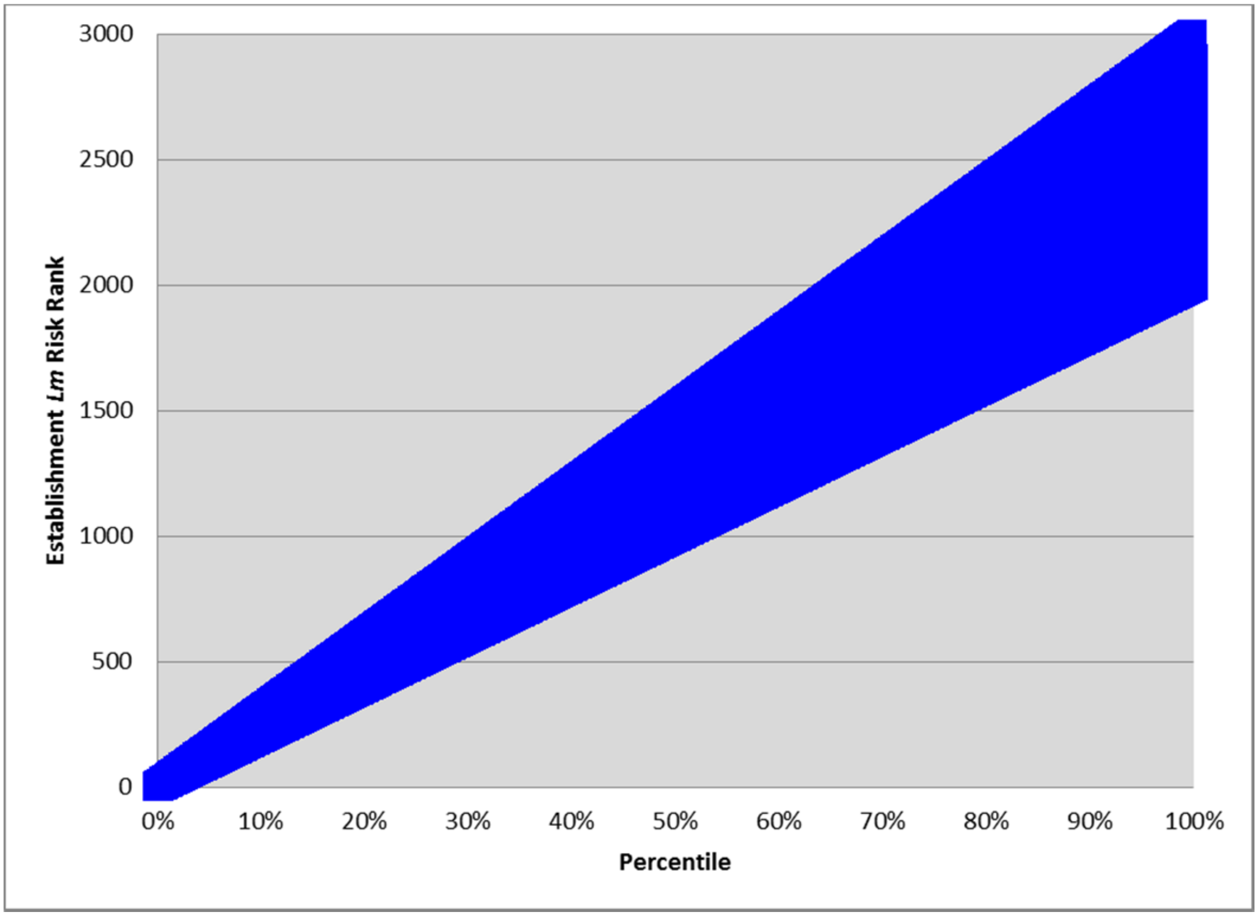


Figure 35. Percentiles of the *Lm* Risk Rank Variance Distributions Possible from 2005 through 2011 Bounding Risk Rank Variance

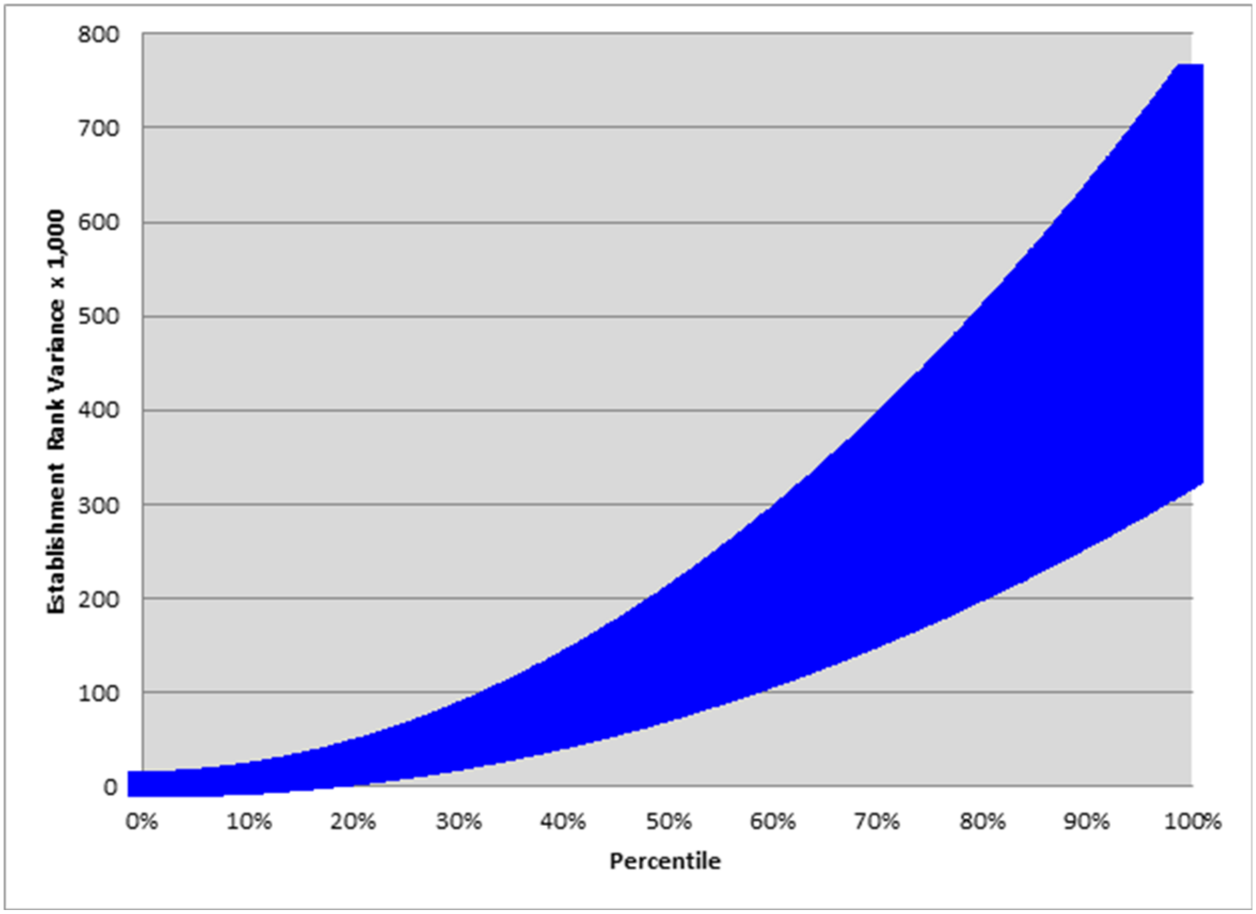


Figure 36. Percentages of Standardized Uncertainty by Risk Variable for 2005, 2006, 2008, and 2011 Algorithm Datasets

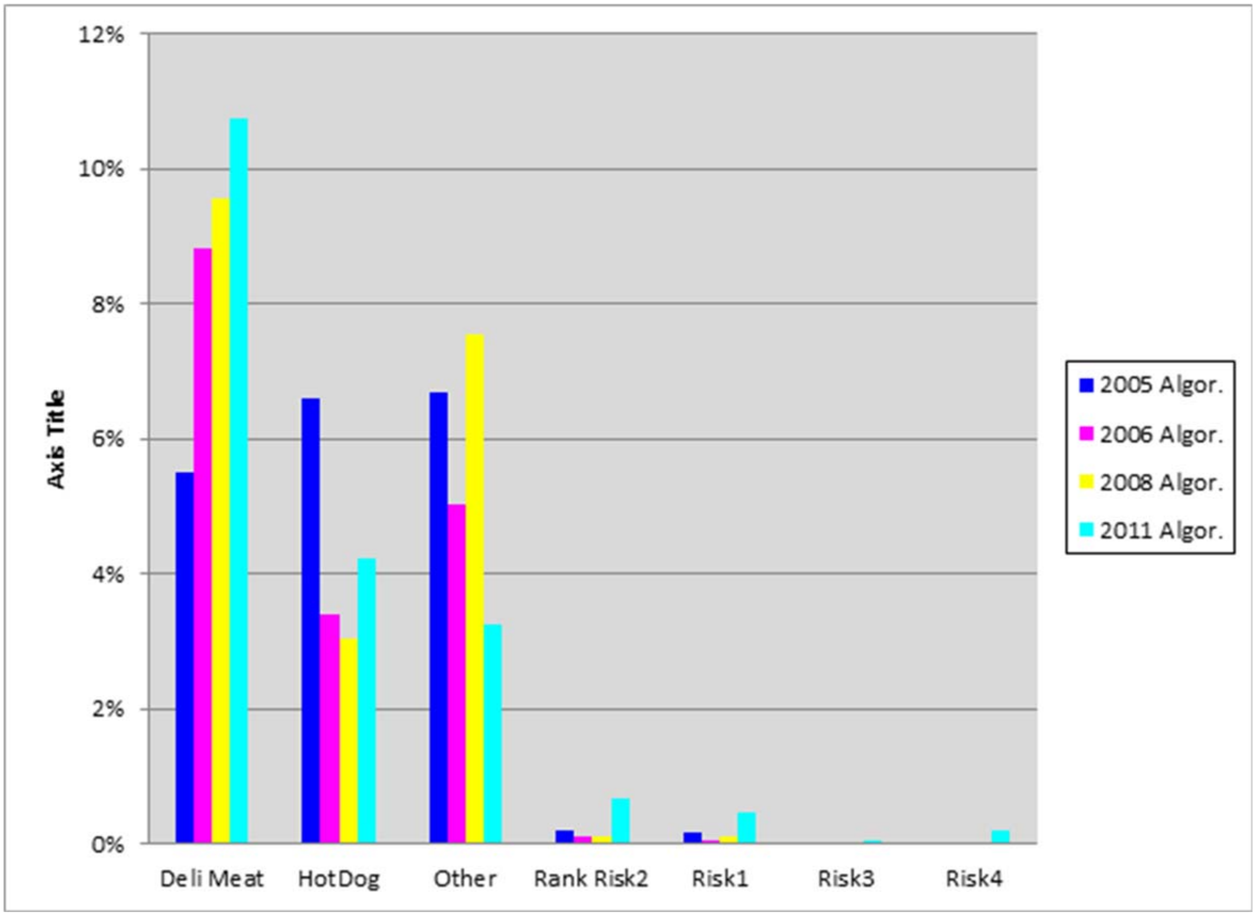
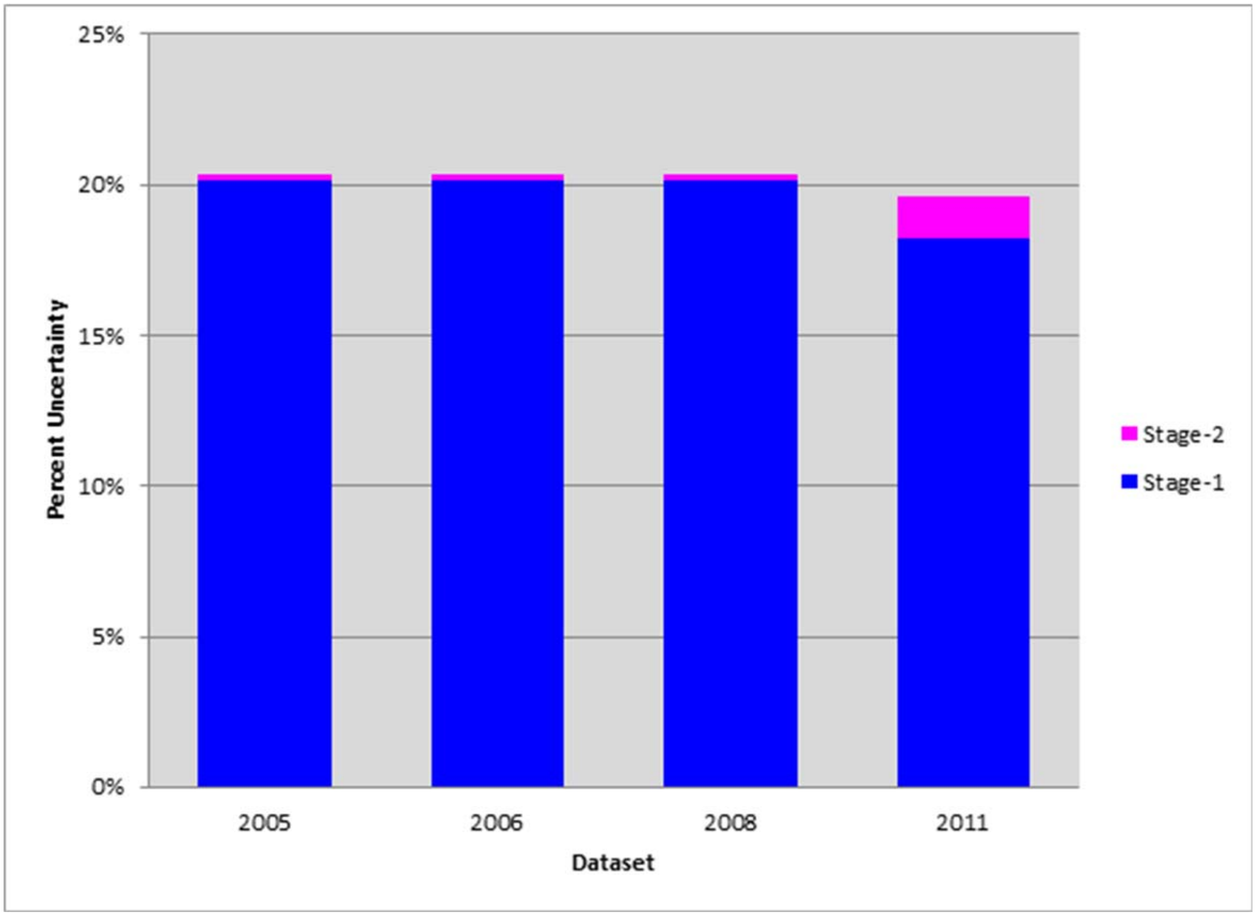


Figure 37. Change in Percentages of Standardized Stage 1 and Stage 2 Uncertainties with Increasing Risk Rank Estimated from 2005 through 2011 Datasets



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The following software packages were used by permission and under license to USDA FSIS: Crystal Ball 2000. Decision Engineering, Inc.; Excel 2007. Microsoft Corporation 2006; NCSS 2000. Statistical System for Windows Number Cruncher Statistical Systems.

Appendix I. FSIS Notices and Directives Related to Listeria monocytogenes Testing- 2007 through 2010

Appendix I. FSIS Notice 64-07 issued 10/12/07

Scheduling Food Safety Assessments and Intensified Verification Testing

PURPOSE

The notice clarified when District Office (DO) personnel are to schedule Enforcement, Investigations, and Analysis Officers (EIAOs) to conduct Food Safety Assessments (FSAs) and Intensified Verification Testing (IVT) in response to a positive pathogen result in FSIS product testing. Also, the instructions in this notice for scheduling FSAs for *Escherichia coli* (*E. coli*) O157:H7 positive results replaced instructions found in FSIS Directive 10,010.1, Microbiological Testing Program for *E. coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components, and Beef Patty Components. Finally, for purposes of this FSIS policy issuance, if another government entity (e.g., a Federal agency, such as the Agricultural Marketing Service, or a State public health laboratory) whose results FSIS will use under FSIS Directive 10,000.1, Policy on Use of Results from Non-FSIS Laboratories) identifies *Listeria monocytogenes* (*Lm*), *E. coli* O157:H7, or *Salmonella* in meat or poultry products, FSIS will conduct follow-up testing on the basis of this finding in the same way that it would if the finding were an FSIS result.

Appendix I. FSIS Notice 78-08 issued 10/30/08

Scheduling Food Safety Assessments and Intensified Verification Testing

This Notice re-issued the content of FSIS Notice 64-07 in its entirety.

PURPOSE

The notice clarified when District Office (DO) personnel are to schedule Enforcement, Investigations, and Analysis Officers (EIAOs) to conduct Food Safety Assessments (FSAs) and Intensified Verification Testing (IVT) in response to a positive pathogen result in FSIS product testing. Also, the instructions in this notice for scheduling FSAs for *E. coli* O157:H7 positive results replaced instructions found in FSIS Directive 10,010.1, Microbiological Testing Program for *E. coli* O157:H7 in Raw Ground Beef Products, and Raw Ground Beef Components, and Beef Patty Components. Finally, for purposes of this FSIS policy issuance, if another government entity (e.g., a Federal agency, such as the Agricultural Marketing Service, or a State public health laboratory whose results FSIS will use under FSIS Directive 10,000.1, Policy on Use of Results from Non-FSIS Laboratories identifies *Listeria monocytogenes* (*Lm*), *E. coli* O157:H7, or *Salmonella* in meat or poultry products, FSIS will conduct follow-up testing on the basis of this finding in the same way that it would if the finding were an FSIS result.

Appendix I. FSIS Directive 10,240.5, Revision 2 issued 2/03/09

Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the *Listeria monocytogenes* Regulation and Routine Risk-Based *Listeria monocytogenes* (RLm) Sampling Program

PURPOSE
This directive was re-issued to provide instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) for collecting samples under the Routine Risk-based *Listeria monocytogenes* (RLm) Sampling Program. In addition, this directive provided instruction to district office personnel on scheduling RLm sampling. The sampling program includes the collection of food contact, environmental (non-food contact), and product samples, as well as completing a Food Safety Assessment (FSA). In addition, brine sampling is now included as part of the RLm Sampling.

Key Points Covered:

1. Changes to the Sampling Policy
2. Sample collection responsibilities of the EIAO under the RLm Sampling Program
3. Enforcement

New Policy

A. EIAOs do not have to wait until the establishment completes pre-shipment review before submitting RTE product samples. Samples should be submitted after the establishment has completed all interventions.
B. FSIS will no longer use the risk-based algorithm but from September 2008 – June 2009, selected establishments for the *Lm* sampling program from a list of those establishments producing 95% of the volume of meat and poultry products. Beginning in July 2009, FSIS increased the number of RLms to meet the agency's goal of at least one FSA in each establishment every four years.
C. EIAOs are to sample brine as part of the RLm sampling program at establishments that use brine to chill product.
D. The number of sampling units collected in an establishment will no longer be based on the number of packaging lines but on the establishment size. EIAOs are to collect three sample units from large establishments, two sample units from small establishments and one sample unit from very small establishments.

Appendix I. FSIS Directive 10,240.4, Revision 2 issued 2/03/09

Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* Regulation and *Listeria monocytogenes* Sampling Programs

PURPOSE

This directive was reissued to provide directions to Consumer Safety Inspectors (CSIs) on submitting ready-to-eat (RTE) product samples under the ALLRTE and RTE001 sampling projects to the laboratory after the establishment has completed all interventions, except for any intervention based on microbiological test results. In addition, this directive changed the products sampled under the ALLRTE project code and instructs CSIs to collect samples under both sampling programs when CSIs receive forms. This directive also provides CSIs with verification instructions for RTE products when establishment product disposition occurs off-site. In addition, this directive provided CSIs with instructions for verifying whether establishments are complying with the regulatory requirements in 9 CFR Part 430, *Requirements for Specific Classes of Product*.

Key Points Covered:

1. CSI Verification of 9 CFR part 430
2. Sample collection responsibilities of the CSI for the ALLRTE and RTE001 sample projects
3. Enforcement
4. Verification of Corrective Actions
5. Disposition of RTE product occurring off-site

Appendix I. FSIS Directive 10,300.1 issued 2/03/09

Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Listeria monocytogenes*

PURPOSE

The directive was issued to provide instructions to Enforcement, Investigation, and Analysis Officers (EIAOs) on collecting product, food contact surface, and environmental (non-food contact surface) samples using the Intensified Verification Testing (IVT) Methodology. The Agency will now include brine sampling as part of the IVT methodology. This document also provided EIAOs with instructions for packing and shipping these samples for testing by Food Safety and Inspection Service (FSIS) laboratories.

Appendix I. FSIS Notice 62-09 issued 9/10/09

Compositing of Environmental Samples Collected During Routine Risk-Based *Listeria monocytogenes* (RLm) Sampling

PURPOSE

The purpose of this notice was to provide instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) for collecting environmental (non-food contact) samples during RLm sampling and completing FSIS Form 10,210-3. This notice also informed EIAOs that the project identification code for environmental samples has been changed from RLMENVR to RLMENVC to denote that the samples will be composited at the laboratory.

This notice was necessitated to clarify that FSIS will perform a Food Safety Assessment (FSA) in all federally inspected establishments at least once in every four year period. For those establishments that produce post-lethality exposed RTE products, FSIS will also conduct routine risk-based RLm sampling at the time of the FSA. Therefore, it is necessary to increase the number of establishments scheduled for sampling each month and modify laboratory procedures.

Appendix I. FSIS Notice 64-09 issued 9/21/09

Intensified Verification Testing and "for cause" Food Safety Assessments in Response to RTE Testing Results

PURPOSE

This notice canceled FSIS Notice 78-08 and provided further information for scheduling a "for cause" Food Safety Assessment (FSA) performed with Intensified Verification Testing (IVT). It also clarified that an IVT FSA will be performed in response to positive food contact surface and product tests from routine RLm testing. In addition, it provided instructions for performing an IVT and "for cause" FSA in response to a RTE product positive for *Salmonella.* Further information about the incidence of *Salmonella* was provided.

Appendix I. FSIS Notice 70-09 issued 10/05/09

Intensified Verification Testing and “For cause” Food Safety Assessments in Response to Ready-To-Eat Testing Results

PURPOSE

The notice provided information for scheduling a “for cause” FSA that is to be performed with Intensified Verification Testing (IVT). It also clarified that an IVT FSA will be performed in response to positive food contact surface and product tests from routine Risk Based *Listeria monocytogenes* (RLm) testing. In addition, it provided instructions for performing an IVT and “for cause” FSA in response to a ready-to-eat (RTE) product positive for *Salmonella*, FSIS will also conduct routine risk-based RLm sampling at the time of the FSA. Therefore, it is necessary to increase the number of establishments scheduled for sampling each month and modify laboratory procedures. Information on the incidence of *Salmonella* was also provided.

Appendix I. FSIS Notice 10-10 issued 2/18/10

Exception for Certain Products from the FSIS RTE Sampling Programs

PURPOSE

The notice instructed inspection program personnel (IPP) not to collect samples of oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats that are RTE until further notice.

Appendix I. FSIS Notice 21-10 issued 4/13/10

Submission of FSIS Form 10,240-1, Production Information on Post-Lethality Exposed RTE Products

PURPOSE

The notice instructed inspection program personnel (IPP) to verify that RTE establishments producing post-lethality exposed products have submitted Food Safety and Inspection Service (FSIS) Form 10,240-1, "Production Information on Post-Lethality Exposed Ready-to Eat Products," within the past year, as required in 9 CFR 430.4(d). In addition, this notice directed IPP to discuss the information on the form with the establishment during a weekly meeting. Finally, it specified the enforcement action that IPP are to take if an establishment has not submitted the form according to the requirements of 9 CFR 430.4(d), or if the form does not accurately reflect product or control measures at the establishment. The notice provided a list of common errors establishments make in completing the form. IPP are to discuss the list with establishments to help ensure proper data entry.

Appendix I. FSIS Notice 59-10 issued 10/08/10

Compositing of Environmental Samples Collected During Routine RLm Sampling

PURPOSE

The notice reissued the content of FSIS Notice 62-09 that provided collection instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) for environmental (non-food contact) samples during an RLm. Instructions for the completion of FSIS Form 10,210-3 were also provided. The notice also informed EIAOs that the project identification code for environmental samples has been changed from RLMENVR to RLMENVC to denote that the samples will be composited at the laboratory

Appendix I. FSIS Notice 60-10 issued 10/08/10

Intensified Verification Testing and "For cause" Food Safety Assessments in Response to RTE Testing Results

PURPOSE

The notice reissued the content of FSIS Notice 70-09 and provided information for scheduling a "for cause" Food Safety Assessment (FSA) performed with Intensified Verification Testing (IVT). It also clarified the conditions that trigger scheduling a "for cause" IVT FSA. Further information about the incidence of *Salmonella* was also provided.

Appendix I. FSIS Notice 41-11 issued 08/10/11

Discontinuation of FSIS FORM 10, 240-1, Production Information on Post-Lethality Exposed RTE Products

PURPOSE

The notice informed inspection program personnel (IPP) that FSIS will be phasing out the use of FSIS Form 10,240-1, Production Information on Post-Lethality Exposed Ready-to-Eat (RTE) Products, and the form will be discontinued as of September 30, 2011. Although FSIS Form 10,240-1 will be discontinued, FSIS will continue to use the information from the form to determine FSIS sampling frequencies until the Agency's Public Health Information System (PHIS) is operational in all establishments. Therefore, this notice also instructed IPP to review the production information for RTE products and advised the establishments to submit an updated FSIS Form 10,240-1 by September 30, 2011, if the information is not accurate or current. Establishments having a change of process or new establishments may still submit production information by phone or e-mail until PHIS is fully implemented at which time form information is replaced by inspector generated data as stated in the notice.

Appendix I. Example FSIS FORM 10, 240-1

To date, FSIS has issued three versions of the form with the latest dated 08/19/2009. Each iteration improved ease of use, electronic availability, and address the need for additional information. Although the data on the form are self-reported by the industry, it does serve as a very important tool to determine the relative risk of products processed/manufactured in an establishment, to obtain information on the volume of products produced on an annual basis, and to determine under which of the three alternatives RTE product is produced.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS

(See Instructions on Page 4)

1a. ESTABLISHMENT NAME		1b. EST. # *(e.g., 00023 P)*
1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
1d. CITY	1e. STATE	1f. ZIP CODE
1g. PLANT SIZE CATEGORY *(specify very small, small, or large)*:		

ALTERNATIVE 1: Both a post-lethality treatment and an antimicrobial agent or process are used.

2. Annual Production Volume: (enter actual lbs.)

DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS [2]						
SLICED & PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIB. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (with or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS

3. (Select applicable letter below):		DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS [2]						
		SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (With or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS
A. Validated log reduction of *Listeria monocytogenes* by your post-lethality treatment:	a. more than 2 logs b. 2 logs c. 1 log d. less than 1 log									
B. Validated or highest increase in *Listeria monocytogenes* allowed by your antimicrobial agent or process:	a. less than 1 log b. 1 log c. 2 logs d. more than 2 logs									
. How often do you test food contact surfaces per line each year?	a. more than 4 times b. 3 or 4 times c. 2 times d. less than 2 times									

See Footnotes on Page 4

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL	5. SIGNATURE OF AUTHORIZED EST. OFFICIAL	6. DATE

FSIS FORM 10,240-1 (08/19/2009) PREVIOUS EDITIONS ARE OBSOLETE PAGE 1 of 4

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0132. The time required to complete this information collection is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS** *(See Instructions on Page 4)* **ALTERNATIVE 2:** Only a post-lethality treatment OR only an antimicrobial agent or process is used.	1a. ESTABLISHMENT NAME		1b. EST. # *(e.g., 00023 P)*
	1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
	1d. CITY	1e. STATE	1f. ZIP CODE
	1g. PLANT SIZE CATEGORY *(specify very small, small, or large)*:		

2. Annual Production Volume (enter actual lbs.)

DELI PRODUCTS[1]		OTHER THAN DELI PRODUCTS [2]						
SLICED & PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIB. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (with or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS

3. (Select applicable **letter below.** Answer *either* A & B or C & D):	DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS[2]						
	SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (With or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS
A. Validated or **highest** a. less than 1 log									
B. If using **antimicrobial** agent or **process,** how often do you test a. more than **8** times b. 5,6,7or **8 times**									
OR C. Validated log reduction of ***Listeria monocytogenes* by** your post-lethality a. more than 2 logs b. 2 logs c. 1 log									
D. If using post-lethality agent, how often **do** you test food contact surfaces per line a. **more than** 8 times b. 5,6,7 or 8 times c. 4 times									

e Footnotes on Page 4

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL

5. SIGNATURE OF AUTHORIZED EST. OFFICIAL 6. DATE

FSIS FORM 10,240-1 (08/19/2009) PREVIOUS EDITIONS ARE OBSOLETE PAGE 2 of 4

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS

(See Instructions on Page 4)

1a. ESTABLISHMENT NAME		1b. EST. # *(e.g., 00023 P*
1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
1d. CITY	1e. STATE	1f. ZIP CODE
1g. PLANT SIZE CATEGORY *(specify very small, small, or large)*:		

ALTERNATIVE 3: Only a sanitation program with testing is used.

2. Annual Production Volume (enter actual lbs.)

DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS [2]						
SLICED & PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIB. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (with or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS

3. (Select applicable letter below):		DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS [2]						
		SLICED & PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS	FULLY COOKED PRODUCTS	FERMENTED PRODUCTS (With or without cooking)	DRIED PRODUCTS	SALT-CURED PRODUCTS	FROZEN PRODUCTS	PATÉ PRODUCTS
A. How often do you test food contact surfaces per line each month?	a. more than 4 times b. 4 times c. 3 times d. 2 times e. 1 time f. less than 1 time									

See Footnotes on Page 4

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL	5. SIGNATURE OF AUTHORIZED EST. OFFICIAL	6. DATE

FSIS FORM 10,240-1 (08/19/2009) PREVIOUS EDITIONS ARE OBSOLETE PAGE 3 of 4

INSTRUCTIONS FOR COMPLETING THE FORM

As stated in 9 CFR 430, FSIS collects annual production volume and information on post-lethality exposed ready-to-eat (RTE) meat and poultry products. FSIS uses the information as a basis for directing its verification activities, including microbiological sampling, at affected establishments. Establishments must complete this form and submit it to FSIS at least annually and whenever there is a significant change in the alternative category or volume of production.

The regulations classify the products by the *L. monocytogenes* control alternative used:

ALTERNATIVE 1:	Establishment uses a post-lethality treatment and an antimicrobial agent/process
ALTERNATIVE 2:	Establishment uses either a post-lethality treatment or an antimicrobial agent/process
ALTERNATIVE 3:	Establishment uses sanitation and a testing program and uses neither a post-lethality treatment nor an antimicrobial agent or process

Footnotes for Products:

1 Deli Products: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official est., & typically is assembled in a sandwich for consumption (9 CFR 430.1). Examples include ham, bologna, chicken roll, turkey breast, olive loaf.

2 Other than Deli Products:
Hot dog products include a ready-to-eat meat or poultry frank, frankfurter, or weiner such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1). Examples include hot dogs, wieners, frankfurters.

Fully cooked products include chicken nuggets, chili, fully cooked bacon.

Fermented products include dry salami, Lebanon bologna, cervelat, thuringer, summer sausage, pepperoni.

Dried products include include jerky, dried beef, dried duck breast, basturma, carne seca.

Salt-cured products include country cured ham, prosciutto, dry cured duck, coppa, cappicola.

Frozen products include frozen chicken breasts, fully cooked and breaded. Paté products include Paté.

ITEMS 1a - 1g

- Enter establishment's name, number *(See instructions below)*, address and size category.

ITEMS 1a - 1g (Continued)

When entering the Establishment Number (Est. No.), follow these guidelines:

> When entering the Est. No., if it is less than 5 digits, for example 123, complete the Est. No. field by filling in the first two digits with zeroes, or 00123. The same applies for any number with less than 5 digits.

ITEM 1g PLANT SIZE CATEGORY

- A very small plant has fewer than 10 employees or annual sales of less than $2.5 million.

  A small plant has 10 to 500 employees.
- A large plant has more than 500 employees.

ITEM 2 ANNUAL PRODUCTION VOLUME

- Enter your establishment's annual production volume in hundreds, thousands, or millions of pounds, as applicable, of post-lethality exposed RTE meat and poultry products for each Alternative in each product category column.

ITEM 3 ALTERNATIVE 1 - ALTERNATIVE 3

- For Alternative 1 and Alternative 2, in each product category column, as applicable, select the applicable letter that most nearly corresponds to your establishment's control of *L. monocytogenes (Lm)*, the log reduction or growth limitation achieved, and the frequency of food-contact surface verification testing. Please make sure that you select the minimum log reduction achieved by the post-lethality treatment or the highest growth limitation allowed by the antimicrobial agent or process for each product category.
- For products in Alternative 3, select the applicable letter that corresponds to the establishment's frequency of food contact surface testing.

ITEMS 4-6

- Print Name and Title of Authorized Official
- Signature and Date of Authorized Official and Date Signed
  (Note: If you re completing and submitting the form electronically, enter the name of the Authorized Official and the Date completed.)

When entering the Establishment Number (Est. No.), follow these guidelines:

- Enter only one Est. No. on the form. If more than one number applies, for example if you have a number for both meat (M) and poultry (P), use the number for the species which is the most predominantly produced.
- Enter the Est. No. using five numeric and up to three alpha characters for example 00123 M. Enter two blank spaces between the Est. No and the species indicator (M in this example). If there is an additional identifier, place it in the space just preceding the species indicator.

SUBMIT THE COMPLETED FORM ELECTRONICALLY ONLINE, BY MAIL OR FAX:

Policy Operations Division (POD), OPPD, FSIS, USDA
6501 Sunnyside Ave.
GWCC Second Wing Second Floor, Mail Stop 5272
Beltsville, MD 20705
Telephone no.: 1-800-233-3935 or 402-344-5000
Fax no.: 301-504-0886

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APPENDIX II. *Listeria monocytogenes* Sampling Programs for RTE products, Food Contact Surfaces, and the Environment

FSIS began conducting regulatory microbiological testing program on Ready-To-Eat (RTE) meat and poultry products in 1983 (USDA-FSIS, 2010a). Throughout the history of the FSIS microbiological RTE regulatory sampling program, the individual projects have continuously evolved in response to public health concerns (USDA-FSIS, 2010a). Annual data from the results obtained in individual microbiological sampling projects are reported online at www.fsis.usda.gov to provide an overall indication of trends.

The sampling data from the *Listeria monocytogenes* (*Lm*) sampling verification programs for establishments producing post-lethality exposed RTE products is used to calculate their *Listeria monocytogenes* risk ranking with the *Listeria monocytogenes* risk ranking algorithm. All current and 6 months of historical *Listeria monocytogenes* sampling data for interim final *Listeria* rule establishments is used in the monthly establishment risk ranking.

Results of regulatory testing projects are conducted to verify the effectiveness of food safety systems in federally inspected establishments, and are not designed to provide statistically valid baseline estimates of national product prevalence; therefore, results are now reported as the percent of analyzed samples that tested positive. FSIS does not view the results of regulatory testing as estimates of national product prevalence. The Agency does, however, consider the RTE regulatory results to be an excellent indicator of the trends in pathogen presence in RTE products over several years (USDA-FSIS, 2010a). FSIS has zero tolerance policy for *Listeria monocytogenes* in a 25g RTE product sample.

FSIS currently conducts RTE product sampling under four projects, each of which is described as follows plus one additional project that has been discontinued:

ALLRTE- *Listeria monocytogenes* Random Sampling Program

The ALLRTE sampling project was initiated in January 2004 and was designed to obtain random samples across the full range of RTE products and across all establishments producing a RTE product regardless of risk (USDA-FSIS, 2010b). Prior to 2004, establishments were randomly selected for regulatory samples from different sub-populations or from the total population of establishments producing RTE products (http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp). Under the ALLRTE sampling program, establishments are randomly selected for regulatory samples from the total population of establishments producing RTE products. This sampling is conducted by FSIS on all RTE regardless of whether they are post-lethality or non-post-lethality exposed products. The Agency implemented the ALLRTE project in order to have *Listeria monocytogenes* results that could be better compared with earlier years (before CY 2004) as the Agency moved to make its RTE projects less random and more risk-based (USDA-FSIS, 2010a).

RTERISK1- Precursor *Listeria monocytogenes* Risk-Based Sampling Program

This sampling project was initiated alongside the ALLRTE project in January 2004. A priority list in Chapter 3 of FSIS Directive 10,240.4 issued on October 2, 2003 (See Appendix VI) was to be followed by inspection personnel to collect samples of RTE products. This was to continue pending the time that FSIS would have been able to gather alternative and production volume information to develop a new risk-based RTE sampling program. This sampling project was discontinued in 2006 (USDA-FSIS, 2010a).

RTE001- *Listeria monocytogenes* Risk-Based Sampling Program

In January 2005, FSIS implemented a project where establishments are selected for sampling based on different risk factors for *Listeria monocytogenes* (USDA-FSIS, 2010b, USDA-FSIS, 2009). The new project, designated RTE001, was the first phase of the FSIS risk-based verification testing program for testing of post-lethality exposed RTE finished meat and poultry product samples. The project is meant to sample RTE products that are subject to the requirements of the interim final rule, 9 CFR 430. RTE001 became the primary sampling project in 2006, representing almost 70 percent of regulatory product sampling. This is because many establishments are scheduled almost every month under RTE001 and therefore they are not routinely sampled under the ALLRTE (USDA-FSIS, 2010a).

The establishment *L.monocytogenes* risk ranking algorithm has undergone several iterations of improvement due to the incorporation of new data as it became available and improvements on the original model. Risk factors for contamination on food contact surfaces and environmental areas were added in 2008. New RTE post-lethality exposure categories were also added due collection of new information on RTE frozen and pate/meat spreads/deli salads on FSIS Form 10,240-1 (See Appendix VI). During 2007-2008 the algorithm was modified due to the finding that an unusual proportion of a product containing growth inhibitors was *Listeria monocytogenes* positive in 2007 (USDA-FSIS, 2010a). The algorithm was adjusted to ensure that more products using antimicrobials or growth inhibitors were sampled. The algorithm was modified to ensure that 50 percent of the samples each month were scheduled in establishments reporting production of Alternative 2b products, i.e., products with an antimicrobial or growth inhibitor but without any post lethality exposure or post-process pasteurization (USDA-FSIS, 2010a). The algorithm reverted back to its original design after no remarkable findings appeared. In 2011 the algorithm was updated to risk rank establishments according to their expected contribution to the total listeriosis illness reported by CDC rather than their expected contamination of product at retail.

RLm- Routine *Listeria monocytogenes* Sampling Program

In 2006, FSIS introduced the second phase project based on risk factors referred to as phase 2 of *Listeria monocytogenes* risk-based sampling and designated as RLm. RLm includes sampling of products, product contact surfaces and environmental surfaces in conjunction with a comprehensive Food Safety Assessment (FSA). The RLm program is a proactive sampling project conducted routinely every four years and capable of identifying establishments with a higher risk of *Listeria monocytogenes* contamination in the food processing environment so it can take corrective actions accordingly before product contamination actually occur (USDA-FSIS, 2009, USDA-FSIS, 2010c).
Samples collected under this program are limited to establishments subject to the requirements of 9 CFR Part 430 i.e. only establishments where RTE products are exposed to the post-lethality environment (USDA-FSIS, 2010a). The selection of establishments for the RLm program follows another FSIS risk-based algorithm and not the establishment *Listeria monocytogenes* risk ranking algorithm due to the requirement to conduct a parallel FSA with the RLm sampling. This alternate algorithm ensures that the top 95% volume establishments are sampled. Establishment

selection is updated monthly. Accordingly, each month, a scheduling memo is sent to districts to inform them of the establishments selected for RLm sample collection activity (USDA-FSIS, 2009, USDA-FSIS, 2010c).
In conducting the RLm program, FSIS anticipated it would be able to assess the compliance of establishments with regulation 9 CFR 430 regarding the control of *Listeria monocytogenes* in post-lethality exposed RTE production areas and help ensure that RTE products are safe for consumption at the end of the production process. With the RLm program in place, FSIS has the ability to verify and evaluate *Listeria monocytogenes* control alternatives and sanitation practices at individual establishments. The RLm program was also designed in part to increase confidence in the effectiveness of a given establishment's control measures and interventions or alternatives (USDA-FSIS, 2009).

RLm testing involves collecting multiple samples as a unit—3 product samples, 10 product contact samples, and 5 environmental (nonproduct contact) samples—during a production shift[1]. This contrasts markedly with RTE001 and ALLRTE, in which a single RTE product sample is collected at a given point in time. Moreover, because RLm sampling at each establishment is done in conjunction with an FSA, an in-depth evaluation of food safety practices is possible. The product, contact surface, and environmental sample data collected from the establishments can help identify possible risk factors that could be associated with positive results. For example, testing of food contact and environmental samples may permit the identification of establishments where there is evidence of control issues such as harborage (sites of *Listeria monocytogenes* survival or persistence) or poor sanitation practices (USDA-FSIS, 2009).

Because the RLm program was intended to be a routine sampling program to complement the FSA process, FSIS has the expectation that establishments selected for sampling should be in compliance with all regulatory standards. This is because the establishments are selected for sampling on the basis of risk rather than for any particular cause. Accordingly, FSIS evaluates establishments producing RTE products first and foremost to ensure the safety of these products and thus to protect the public from foodborne *Listeria monocytogenes* infections. If a given establishment has positive results from the RLm sampling, FSIS takes enforcement actions as necessary to address product contamination and adulteration. Furthermore, the positive results serve as the impetus for focusing inspection efforts and intensifying inspection resources in that establishment. Such results may indicate poor HACCP design, execution, or both. In addition to determining the vulnerabilities and the adequacy of the establishment's food safety practices with respect to *Listeria monocytogenes*, FSIS develops and implements policies to improve the effectiveness of the establishment's *Listeria* contamination control practices (USDA-FSIS, 2010c).

[1] Initially, 18 total samples per unit used at each establishment were based on the number of production lines. Currently, the number of sampling units is based on establishment HACCP (Hazard Analysis and Critical Control Point) size, with three, two, and one sample units used at establishments classified as HACCP sizes large, small, and very small, respectively. This system provides for consistency with respect to the logistics of sample collection and testing. It should also be noted that the ratio of 10:5 for contact and environmental samples is because positive contact samples define regulatory consequences, which is not the case for positive environmental samples

IVT - Intensified Verification Testing Program

IVT is a sampling protocol for RTE meat and poultry products under which FSIS tests product, food contact surfaces and environmental surfaces (non-food contact surfaces) for *Listeria monocytogenes* on a for-cause basis. The Agency will typically schedule an IVT for cause e.g., following an ALLRTE or RTE001 *Listeria monocytogenes* positive sample finding (USDA-FSIS, 2009, USDA-FSIS, 2010c). This project is designed for testing in any operation involving any RTE meat or poultry product, regardless of the establishment's control procedures, the production volume, etc., due to the production of adulterated product, investigative purposes (e.g., as a result of an outbreak of foodborne disease), or concern that the establishment may not be properly controlling for pathogens.

An IVT is conducted alongside with a Food Safety Assessment (FSA) and the number of sample units is dependent on the number of lines in each establishment. The maximum number of lines or unit is 5. A sampling unit consists of 3 product samples, 10 product contact samples, and 5 environmental (nonproduct contact) samples—during a production shift. FSIS began compositing the environmental samples in 2010 (see Appendix I. Notice 59-10).

APPENDIX III. Updating the *Listeria monocytogenes* Risk Ranking Algorithm with the Exponential Growth Rate – An excerpt from the 2010 FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats

Algorithm Updates Post 2008

The FSIS comparative *Listeria monocytogenes* risk assessment served as the source of the exponential growth rate (EGR) function used for products with growth inhibitors (GI) and those without GI. The use of GI by an establishment in its RTE products is an important factor since the use of GI is integral to the *Listeria monocytogenes* risk alternative definitions and is made more important by the increased risk mitigation found in this risk assessment that is more than expected compared with the 2003 FDA-FSIS risk assessment. The use of GI is an important modifier of the EGR, which is the major component impacting the estimation of establishment risk ranking at consumption. The time, temperature, and population density functions from this risk assessment also are used in the updated risk ranking algorithm. The expected case rates for elderly, intermediate, and neonatal subpopulations are used to standardize the risk ranking algorithm *Listeria monocytogenes* case estimates. An estimate of the number of annual cases that may result from the reported annual production volumes of each establishment may be obtained through a summation of the individual post-lethality exposed RTE products associated with one or more risk alternatives implemented in the establishment.

FSIS calculated the EGR in the 2010 risk assessment to reflect the increase in the number of establishments that use (GI) in their products. This change resulted from regulatory changes in the control of *Listeria monocytogenes* in post-lethality exposed RTE products since it is expected that the growth rates of products with GI will be less than those of products that do not incorporate GI in the formulation.

The EGR is an important data set of the risk-based sampling algorithm because the GI component reflects current industry trends used to predict the growth of *Listeria monocytogenes* in deli meat from retail to consumption. The risk ranking algorithm also uses from this risk assessment the World Health Organization's (WHO) dose-response model, which incorporates the three age categories of interest—the elderly, intermediate and neonatal groups.

2010 FSIS Comparative Risk Assessment for *Listeria monocytogenes* in RTE Meat and Poultry Deli Meats Excerpts

This risk assessment used the exposure assessment portion of the 2003 FDA-FSIS risk assessment model and adjusted it to account for possible use of antimicrobial growth inhibitor by adjusting the exponential growth rate (EGR) of *Listeria monocytogenes* among RTE meat and poultry deli meats. The 2003 FDA-FSIS risk assessment model estimated that the mean EGR at 5 °C was 0.282 $\log_{10}$ CFU/gram/day. The model treats this as a stochastic parameter and adjusts for stochastic consumer storage time, temperature, and a correlation between the two. FSIS *Listeria monocytogenes* Compliance Guidelines state that to qualify as utilizing one of two most stringent alternative *Listeria monocytogenes* control options (Alternative 1 or 2) in the Interim Final Rule, no more than 2 $\log_{10}$ growth is allowed over the entire shelf life of the product. No temperature is specified during this shelf life, nor is the shelf life itself specified. If this standard is interpreted to be 2 $\log_{10}$ growth over 14 days at 5°C, the exponential growth rate is 2 $\log_{10}$ CFU/gram/14 days = 0.143 $\log_{10}$ CFU/gram/day. Using this calculation, as the product shelf life is reduced; the calculated EGR would increase because the same 2 $\log_{10}$ growth would occur in a shorter time.

If the EGR for product with antimicrobial growth inhibitor (GI) is based on the regulation, then to calculate the EGR for product without GI:

fGI x EGRwith + (1 - fGI) x EGRwithout = EGRFDA
0.175 x 0.143 $\log_{10}$ CFU/gram/d + 0.825 x EGRwithout = 0.282 $\log_{10}$ CFU/gram/day
EGRwithout =0.311 $\log_{10}$ CFU/gram/day
where fGI = fraction of product with growth inhibitor (prior to Interim Final Rule)
EGRFDA = EGR used in 2003 FDA-FSIS risk ranking
EGRwith = EGR for product with growth inhibitor
EGRwithout = EGR for product without growth inhibitor

To adjust the growth rates in the deli meat exposure pathway of the 2003 FDA-FSIS risk assessment model, an additional multiplier based on adjusting the mean EGR was added. If the product did not have GI, the stochastic EGR for each iteration was multiplied by 0.311/0.282 = 1.104. If the product did have GI, the stochastic EGR for each iteration was multiplied by 0.143/0.282 = 0.507. Note that the EGR for product with GI is calculated based on FSIS regulation, not on actual industry performance, which may be different.

The estimated mean number of deaths per year associated with prepackaged product was 34.1, and the estimated mean number of deaths per year associated with retail-sliced product was 166.9, with an estimated total annual number of deaths equal to 201.0. Seventeen percent of the estimated per annum deaths (34.1/201.0 = 16.96%) are attributable to prepackaged product, while the remaining 83% are attributable to retail-sliced product (166.9/201.0 = 83.03%). The relative risk on a per annum basis for deli meats sliced at retail versus those sliced in plants is thus 166.9/34.1 = 4.89. These results are almost identical to the findings of the preliminary analysis from the 2003 FDA-FSIS *Listeria monocytogenes* risk assessment model, which used National Food Processors Association (NFPA) retail data (Gombas *et al.,* 2003).

A similar analysis was conducted for illnesses. The 2003 FDA-FSIS risk assessment model assumes a constant illness to mortality ratio by age group of 3.7, 11.3, and 12.7 for elderly, intermediate, and neonatal age groups respectively. Corresponding results for estimated illnesses are 188.6 (prepackaged), 919.6 (retail-sliced) and 1,108.2 (total) respectively. Because the illnesses are calculated directly from estimated deaths, the attributions between prepackaged and retail-sliced product did not change appreciably.

Appendix IV. *Listeria monocytogenes* Risk-Ranking Algorithm SAS Code and Excel spreadsheet Examples

This appendix provides information for running the three establishment *Listeria monocytogenes* (*Lm)* risk ranking algorithms for the 2006, 2008, and 2011 datasets. The datasets for the SAS code and example Excel spreadsheets are provided in the companion zip file. The equations used for the three algorithm versions are as follows.

Equations used for 2006 Establishment *Lm* Risk Ranking Algorithm

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 1338 x Risk1 + Rank Risk2 + 334.5 x RR x Risk3 / 7.0116 + 334.5 x Risk4 x (RR- 7.011566 – 1) / 7.011566, conditional on Risk1, Risk3, and Risk4

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/17

Equations Used for 2008 Establishment *Lm* Risk Ranking Algorithm

Risk2 = 1.0000 x Delis x Q80 + 0.408293 x Delius x Q80 + 0.058182 x Hot Dog x Q80 + 0.000217 x Other x Q80 + 0.000000625 x Frozen x Q80 + 0.343293 x Pate x Q80

Adjusted Risk Rank = 3002 x Risk1 + Rank Risk2 + 334.5 x RR x Risk3 / 7.011566 + 334.5 x Risk4 x (RR- 7.011566 – 1) / 7.011566, conditional on Risk1, Risk3, and Risk4

Risk1 = ($\text{month1}_{\text{product}}$ + $\text{month1}_{\text{fcs}}$ + 0.0826 x $\text{month1}_{\text{env}}$)

Risk3 = {$(0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{product}}$ + $(0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{fcs}}$ + 0.08626 x $(0.4614 \text{ x month2} + 0.2446 \text{ x month3} + 0.1252 \text{ x month4} + 0.0861 \text{ x month5} + 0.0826 \text{ x month6})_{\text{env}}$ }

Risk4 = {$((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/17)_{\text{product}}$ + $((\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/99)_{\text{fcs}}$ + $(0.0826 \text{ x } (\text{month1} + \text{month2} + \text{month3} + \text{month4} + \text{month5} + \text{month6})/46)_{\text{env}}$ }

Equations Used for 2011 Establishment *Lm* Risk Ranking Algorithm

Risk2 = 1 – exp (-r x {(1.0000 x Delis x EGR + 0.408293 x Delius x EGR + 0.058182 x Hot Dog x EGR + 0.000217 x Other x EGR + 0.000000625 x Frozen x EGR + 0.343293 x Pate x EGR) / Total_Volume}x 35 })

(note: Risk2 is approximated as: -r x {(1.0000 x Delis x EGR + 0.408293 x Delius x EGR + 0.058182 x Hot Dog x EGR + 0.000217 x Other x EGR + 0.000000625 x Frozen x EGR + 0.343293 x Pate x EGR) / Total_Volume}x 35 } because 1 – exp (-x) is approximately –x when x is very small, which applies in this case)

EGR = 10^ Min (log10 (Q80) + 6.599781 x Time x (AMA x 2.64 / loge (10)) x ((Temp x 2.86 / (25 + 2.86))^2, MPD) x

AMA (antimicrobial agent) = 0.507 for Alternatives 1, 2a, and 2b, AMA = 1.182 for Alternative 3

MPD (Maximum Population Density) for *Lm* = 8

R = 1.06×10^{-12}

Adjusted Risk Rank = 3002 x Risk1 + Rank Risk2 + 334.5 x RR x Risk3 / 7.011566 + 334.5 x Risk4 x (RR- 7.011566 – 1) / 7.011566, conditional on Risk1, Risk3, and Risk4

Risk3 = {(0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{product}$ + (0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{fcs}$ + 0.08626 x (0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6)$_{env}$ }

Risk4 = {((month1 + month2 + month3 + month4 + month5 + month6)/17)$_{product}$ + ((month1 + month2 + month3 + month4 + month5 + month6)/99)$_{fcs}$ + (0.0826 x (month1 + month2 + month3 + month4 + month5 + month6)/46)$_{env}$ }

The instructions for running the 2006, 2008, and 2011 algorithms are in the Excel workbook on individual spreadsheets. The Excel establishment risk ranking (1 for greatest risk and 1000 for least risk) correspond to the SAS algorithm risk rankings.

The following SAS code implements the 2006, 2008, and 2011 algorithms of the establishment *Listeria monocytogenes* risk ranking algorithm incorporating the modifications to the original *Listeria monocytogenes* risk ranking algorithm first developed in Excel spreadsheets in January 2005. These modifications are current as of October 2011. The accompanying example database can be used to study the algorithm input and output. In order to use the code, cut and paste into the SAS editor. Create a SAS library "C:\SAS" for the input and output files. The program will read and write files using the SAS library. The example program was created to obtain the establishment *Listeria monocytogenes* risk ranks for one month only. The program produces a list of establishment numbers and *Listeria monocytogenes* risk rankings over all alternatives.

The input dataset "SAS_Example" contains the annual production volumes of 1,000 hypothetical establishments and their intervention alternatives listed by establishment number. The SAS dataset can be created from the Excel file "Excel_Example". The variable names are in the following table that corresponds to the Excel_Example dataset.

Appendix IV. Table 1. Example Variable Names

Item	Variable	Description
1	Establishment	Establishment ID
2	DeliS	Deli meat-Sliced
3	DeliUS	Deli meat-Unsliced
4	HotDog	Hot Dogs
5	Cooked	Cooked RTE Products
6	Ferm	Fermented RTE Products
7	Dried	Dried RTE Products
8	Cured	Salt-cured RTE Products
9	Frozen	Frozen RTE Products
10	Pate	Pate, Meat Spreads, Deli salads
11	Total_Volume	Total annual RTE Volume in pounds converted to grams
12	EDMV	EDMV-Equivalent Deli Meat Volume in pounds converted to grams
13	Volume	Size Volume - H, M, L
14	Alternative	1=1; 2a=2.1; 2b=2.2; 3=3
15	Q80	80th Quantile of *Lm* Contamination Distribution
16	RR	Prevalence Relative Risk at Retail
17	AMA	Antimicrobial Agent Effect
18	PosP1	*Lm* Positive in Product- Month1
19	PosC1	*Lm* Positive on Food Contact Surface- Month1
20	PosE1	*Lm* Positive with Environmental Swab- Month1
21	PosP2	*Lm* Positive in Product- Month2
22	PosC2	*Lm* Positive on Food Contact Surface- Month2
23	PosE2	*Lm* Positive with Environmental Swab- Month2
24	PosP3	*Lm* Positive in Product- Month3
25	PosC3	*Lm* Positive on Food Contact Surface- Month3
26	PosE3	*Lm* Positive with Environmental Swab- Month3
27	PosP4	*Lm* Positive in Product- Month4
28	PosC4	*Lm* Positive on Food Contact Surface- Month4
29	PosE4	*Lm* Positive with Environmental Swab- Month4
30	PosP5	*Lm* Positive in Product- Month5

Appendix IV. Table 1. Example Variable Names (continued)

Item	Variable	Description
31	PosC5	*Lm* Positive on Food Contact Surface- Month5
32	PosE5	*Lm* Positive with Environmental Swab- Month5
33	PosP6	*Lm* Positive in Product- Month6
34	PosC6	*Lm* Positive on Food Contact Surface- Month6
35	PosE6	*Lm* Positive with Environmental Swab- Month6
36	NegP1	*Lm* Negative in Product- Month1
37	NegC1	*Lm* Negative on Food Contact Surface- Month1
38	NegE1	*Lm* Negative with Environmental Swab- Month1
39	NegP2	*Lm* Negative in Product- Month2
40	NegC2	*Lm* Negative on Food Contact Surface- Month2
41	NegE2	*Lm* Negative with Environmental Swab- Month2
42	NegP3	*Lm* Negative in Product- Month3
43	NegC3	*Lm* Negative on Food Contact Surface- Month3
44	NegE3	*Lm* Negative with Environmental Swab- Month3
45	NegP4	*Lm* Negative in Product- Month4
46	NegC4	*Lm* Negative on Food Contact Surface- Month4
47	NegE4	*Lm* Negative with Environmental Swab- Month4
48	NegP5	*Lm* Negative in Product- Month5
49	NegC5	*Lm* Negative on Food Contact Surface- Month5
50	NegE5	*Lm* Negative with Environmental Swab- Month5
51	NegP6	*Lm* Negative in Product- Month6
52	NegC6	*Lm* Negative on Food Contact Surface- Month6
53	NegE6	*Lm* Negative with Environmental Swab- Month6
54	Risk2	Baseline Risk
55	Risk1	Immediate Regulatory Risk
56	Rank Risk2	Baseline Risk Rank
57	Risk3	Increase in Risk Rank for Past Positives
58	Risk4	Decrease in Risk Rank for Past Negatives
59	Adj. Risk2	Adjusted Baseline Risk2 Rank
60	Risk Rank	*Lm* Establishment Risk Rank

Please note: you will need to create a SAS library on your "C" drive labeled "SAS". Place the input file: **"**sas_example" in the SAS library folder. The output files will be in the SAS library folder labeled "Ranks_2006", "Ranks_2008", and "Ranks_2011".

The SAS code for the 2006 Algorithm is:

```
LIBNAME SAS "C:\SAS";
Data sas.data1_2006;
Set sas.example_2006;
Volume= delis+delius+hotdog+cooked+ferm+dried+cured;
EDMV=delis+0.408293*delius+0.058182*hotdog+0.000217*(cooked+ferm+dried+cured)
;

Vol_Size = "M";
If EDMV <= 8191  Then Vol_Size = "L";
If EDMV > 46739 Then Vol_Size = "H";

If Alt = 1 and Vol_Size = "H" Then Risk2=0.000000014*EDMV;
If Alt = 1 and Vol_Size = "M" Then Risk2= 0.0000000125*EDMV;
If Alt = 1 and Vol_Size = "L" Then Risk2= 0.0000000110*EDMV;
If Alt = 2.1 and Vol_Size = "H" Then Risk2 = 0.0000000820*EDMV;
If Alt = 2.1 and Vol_Size = "M" Then Risk2 = 0.0000000674*EDMV;
If Alt = 2.1 and Vol_Size = "L" Then Risk2 = 0.0000000610*EDMV;
If Alt = 2.2 and Vol_Size = "H" Then Risk2 = 0.00000153*EDMV;
If Alt = 2.2 and Vol_Size = "M" Then Risk2 = 0.00000129*EDMV;
If Alt = 2.2 and Vol_Size = "L" Then Risk2 = 0.00000116*EDMV;
If Alt = 3 and Vol_Size = "H" Then Risk2 = 0.00000724*EDMV;
If Alt = 3 and Vol_Size = "M" Then Risk2 = 0.00000708*EDMV;
If Alt = 3 and Vol_Size = "L" Then Risk2 = 0.00000465*EDMV;

If Alt = 1 and Vol_Size = "H" Then RR = 1.097591;
If Alt = 1 and Vol_Size = "M" Then RR = 1.056208;
If Alt = 1 and Vol_Size = "L" Then RR = 1.000000;
If Alt = 2.1 and Vol_Size = "H" Then RR = 1.902718;
If Alt = 2.1 and Vol_Size = "M" Then RR = 1.881717;
If Alt = 2.1 and Vol_Size = "L" Then RR = 1.808987;
If Alt = 2.2 and Vol_Size = "H" Then RR = 4.794365;
If Alt = 2.2 and Vol_Size = "M" Then RR = 4.590511;
If Alt = 2.2 and Vol_Size = "L" Then RR = 4.361056;
If Alt = 3 and Vol_Size = "H" Then RR = 7.011566;
If Alt = 3 and Vol_Size = "M" Then RR = 6.929975;
If Alt = 3 and Vol_Size = "L" Then RR = 6.795457;
Run;


Proc Rank data=sas.data1_2006 out=sas.ranks_2006;
Var number Risk2;
Ranks Rank_number Rank_Risk2;
Run;

Proc sort data= sas.data1_2006;
By number;


Proc sort data= sas.ranks_2006;
```

```
By number;
Run;

Data sas.data2_2006;
Merge sas.data1_2006 sas.ranks_2006;
By number;

Risk1=1338*PosP1;
Risk3=0.4614*PosP2+0.2446*PosP3+0.1252*PosP4+0.0861*PosP5+0.0826*PosP6;
Risk4=(NegP1+NegP2+NegP3+NegP4+NegP5+NegP6)/17;
Adj_Risk2=Risk1+Rank_Risk2+334.5*RR*Risk3/7.011566+334.5*Risk4*(RR-7.011566-
1)/7.011566;

Run;

Proc Summary data=sas.data2_2006;
By Number;
Var Adj_Risk2;
Output out=sas.data3_2006 mean(Establishment)= Establishment
sum(Adj_Risk2)=Risk_Rank;
Run;

Proc Sort data=sas.data3_2006 (keep= number Establishment risk_rank);
By descending Risk_Rank;
Run;

Proc Rank data=sas.data3_2006 out=sas.data4_2006;
Var number Risk_Rank;
Ranks Rank_number Rank_Risk_Rank;
Run;


Proc Sort data=sas.data4_2006;
By Establishment;
Run;

Proc Summary data= sas.data4_2006 ;
By Establishment;
Var Rank_Risk_Rank ;
Output out=sas.data5_2006 mean(Rank_Risk_Rank)=Risk_Rank;
Run;

Proc Rank data=sas.data5_2006 out=sas._2006_Risk_Ranks;
Var Establishment Risk_Rank;
Ranks Establishment_Rank Rank_Risk_Rank;
Run;

Proc Sort data= sas._2006_Risk_Ranks;
By descending Rank_Risk_Rank ;
```

The SAS code for the 2008 Algorithm is:

```
LIBNAME SAS "C:\SAS";

Data sas.data1_2008;
Set sas.example_2008;
Volume= delis+delius+hotdog+cooked+ferm+dried+cured+pate+frozen;
EDMV=delis+0.408293*delius+0.343293*pate+0.058182*hotdog+0.000217*(cooked+fer
m+dried+cured)+0.000000625*frozen;

Vol_Size = "M";
If EDMV <= 20003 Then Vol_Size = "L";
If EDMV > 50129 Then Vol_Size = "H";

If Alt = 1 and Vol_Size = "H" Then Risk2=0.000000014*EDMV;
If Alt = 1 and Vol_Size = "M" Then Risk2= 0.0000000125*EDMV;
If Alt = 1 and Vol_Size = "L" Then Risk2= 0.0000000110*EDMV;
If Alt = 2.1 and Vol_Size = "H" Then Risk2 = 0.0000000820*EDMV;
If Alt = 2.1 and Vol_Size = "M" Then Risk2 = 0.0000000674*EDMV;
If Alt = 2.1 and Vol_Size = "L" Then Risk2 = 0.0000000610*EDMV;
If Alt = 2.2 and Vol_Size = "H" Then Risk2 = 0.00000153*EDMV;
If Alt = 2.2 and Vol_Size = "M" Then Risk2 = 0.00000129*EDMV;
If Alt = 2.2 and Vol_Size = "L" Then Risk2 = 0.00000116*EDMV;
If Alt = 3 and Vol_Size = "H" Then Risk2 = 0.00000724*EDMV;
If Alt = 3 and Vol_Size = "M" Then Risk2 = 0.00000708*EDMV;
If Alt = 3 and Vol_Size = "L" Then Risk2 = 0.00000465*EDMV;

If Alt = 1 and Vol_Size = "H" Then RR = 1.097591;
If Alt = 1 and Vol_Size = "M" Then RR = 1.056208;
If Alt = 1 and Vol_Size = "L" Then RR = 1.000000;
If Alt = 2.1 and Vol_Size = "H" Then RR = 1.902718;
If Alt = 2.1 and Vol_Size = "M" Then RR = 1.881717;
If Alt = 2.1 and Vol_Size = "L" Then RR = 1.808987;
If Alt = 2.2 and Vol_Size = "H" Then RR = 4.794365;
If Alt = 2.2 and Vol_Size = "M" Then RR = 4.590511;
If Alt = 2.2 and Vol_Size = "L" Then RR = 4.361056;
If Alt = 3 and Vol_Size = "H" Then RR = 7.011566;
If Alt = 3 and Vol_Size = "M" Then RR = 6.929975;
If Alt = 3 and Vol_Size = "L" Then RR = 6.795457;
Run;

Proc Rank data=sas.data1_2008 out=sas.ranks_2008;
Var number Risk2;
Ranks Rank_number Rank_Risk2;
Run;

Proc sort data= sas.data1_2008;
By number;
Run;

Proc sort data= sas.ranks_2008;
By number;


Data sas.data2_2008;
Merge sas.data1 sas.ranks;
```

```
By number;

Risk1=1338*(PosP1+PosC1+0.0826*PosE1);

Risk3=0.4614*(PosP2+PosC2)+0.2446*(PosP3+PosC3)+0.1252*(PosP4+PosC4)+0.0861*(


Risk4=(NegP1+NegP2+NegP3+NegP4+NegP5+NegP6)/17+(NegC1+NegC2+NegC3+NegC4+NegC5
+NegC6)/99+0.0826*( NegE1+NegE2+NegE3+NegE4+NegE5+NegE6)/46;

Adj_Risk2=Risk1+Rank_Risk2+334.5*RR*Risk3/7.011566+334.5*Risk4*(RR-7.011566-
1)/7.011566;
Run;

Proc Summary data=sas.data2_2008;
By Number;
Var Establishment Adj_Risk2;
Output out=sas.data3_2008 mean(Establishment)=establishment
sum(Adj_Risk2)=Risk_Rank;
Run;

Proc Sort data=sas.data3_2008 (keep= number Establishment risk_rank);
By descending Risk_Rank;
Run;

Proc Rank data=sas.data3_2008 out=sas.data4_2008 (keep= number Establishment
risk_rank rank_risk_rank) ;
Var  Risk_Rank;
Ranks Rank_Risk_Rank;
Run;


Proc Sort data=sas.data4_2008;
By Establishment;
Run;

Proc Summary data= sas.data4_2008 ;
By Establishment;
Var Rank_Risk_Rank ;
Output out=sas.data5_2008 mean(Rank_Risk_Rank)=Risk_Rank;
Run;

Proc Rank data=sas.data5_2008 out=sas._2008_Risk_Ranks;
Var Establishment Risk_Rank;
Ranks Establishment_Rank Rank_Risk_Rank;
Run;

Proc Sort data= sas._2008_Risk_Ranks;
By descending Rank_Risk_Rank ;
Run;
```

The SAS code for the 2011 Algorithm is:

```
LIBNAME SAS "C:\SAS";

Data sas.data1_2011;
Set sas.example_2011;

Total_Volume = delis+delius+pate+hotdog+cooked+ferm+dried+cured+frozen;
EDMV=delis+0.408293*delius+0.343293*pate+0.058182*hotdog+0.000217*(cooked+fer
m+dried+cured)+0.000000625*frozen;

Time=7;
Temperature=5;
M2=8;
r=1.06e-12;

Vol_Size = "M";
If EDMV <= 8194 Then Vol_Size = "L";
If EDMV > 49495 Then Vol_Size = "H";
AMA=1.128;
if alt = 1 or alt = 2.1 or alt = 2.2 Then ama = 0.507;

If Alt = 1 and Vol_Size = "H" Then Q80=0.0000000140;
If Alt = 1 and Vol_Size = "M" Then Q80= 0.0000000125;
If Alt = 1 and Vol_Size = "L" Then Q80= 0.0000000110;
If Alt = 2.1 and Vol_Size = "H" Then Q80 = 0.0000000820;
If Alt = 2.1 and Vol_Size = "M" Then Q80 = 0.0000000674;
If Alt = 2.1 and Vol_Size = "L" Then Q80 = 0.0000000610;
If Alt = 2.2 and Vol_Size = "H" Then Q80 = 0.00000153;
If Alt = 2.2 and Vol_Size = "M" Then Q80 = 0.00000129;
If Alt = 2.2 and Vol_Size = "L" Then Q80 = 0.00000116;
If Alt = 3 and Vol_Size = "H" Then Q80 = 0.00000724;
If Alt = 3 and Vol_Size = "M" Then Q80 = 0.00000708;
If Alt = 3 and Vol_Size = "L" Then Q80 = 0.00000465;

If Alt = 1 and Vol_Size = "H" Then RR = 1.097591;
If Alt = 1 and Vol_Size = "M" Then RR = 1.056208;
If Alt = 1 and Vol_Size = "L" Then RR = 1.000000;
If Alt = 2.1 and Vol_Size = "H" Then RR = 1.902718;
If Alt = 2.1 and Vol_Size = "M" Then RR = 1.881717;
If Alt = 2.1 and Vol_Size = "L" Then RR = 1.808987;
If Alt = 2.2 and Vol_Size = "H" Then RR = 4.794365;
If Alt = 2.2 and Vol_Size = "M" Then RR = 4.590511;
If Alt = 2.2 and Vol_Size = "L" Then RR = 4.361056;
If Alt = 3 and Vol_Size = "H" Then RR = 7.011566;
If Alt = 3 and Vol_Size = "M" Then RR = 6.929975;
If Alt = 3 and Vol_Size = "L" Then RR = 6.795457;
Run;


Data sas.data2_2011;
Set sas.data1_2011;

M1=log10(Q80)+6.5997807*Time*(AMA*6.24/log(10))*((Temperature+2.86)/(25+2.86)
```

```
c=min(of M1-M2);

Risk2=6.997807*35*EDMV*(10**c)*r/Total_Volume;
Run;

Proc Rank data=sas.data2_2011 out=sas.ranks_2011;
Var number Risk2;
Ranks Rank_number Rank_Risk2;
Run;

Proc sort data=sas.data2_2011;
By number;
Run;

Proc sort data=sas.ranks_2011;
By number;
Run;

Data sas.data3_2011;
Merge sas.data2_2011 sas.ranks_2011;
By number;

Risk1=1338*(PosP1+PosC1+0.0826*PosE1);

Risk3=(0.4614*(PosP2+PosC2)+0.2446*(PosP3+PosC3)+0.1252*(PosP4+PosC4)+0.0861*

011566;

Risk4=((NegP1+NegP2+NegP3+NegP4+NegP5+NegP6)/17+(NegC1+NegC2+NegC3+NegC4+NegC
5+NegC6)/99+0.0826*( NegE1+NegE2+NegE3+NegE4+NegE5+NegE6)/46)*334.5*(RR-
7.011566-1)/7.011566;

Rank_Risk2= Rank;
If Risk1 gt 0 then Adj_Risk2 = Risk1 + Rank_Risk2 ;
If Risk1 eq 0 and Risk3 gt 0 then Adj_Risk2 = Risk3 + Rank_Risk2 ;
If Risk1 eq 0 and Risk3 eq 0 then Adj_Risk2 = Risk4 + Rank_Risk2 ;

Run;


Proc Sort data=sas.data3_2011 (keep= rank Establishment Adj_Risk2 );
By descending Adj_Risk2 ;
Run;

Proc Sort data=sas.data3_2011;
By Establishment ;
Run;


Proc Summary data=sas.data3_2011 ;
By Establishment;
Var  Adj_Risk2;
Output out=sas.data4_2011  mean(Adj_Risk2)=Ave_Adj_Risk2 ;
Run;

Proc Rank data=sas.data4_2011 out=sas._2011_Risk_Ranks;
```

```
Var  Ave_Adj_Risk2 ;
Ranks  Rank_Risk2;
Run;


Proc Sort data= sas._2011_Risk_Ranks;
By descending Rank_Risk2 ;
```

These examples can be used to illustrate the general sampling plan used for risk-based verification sampling if the number of samples allocated per month is specified and if all establishments are to receive a minimum number of sample requests over a year. Because risk-based sampling requires that the highest risk ranked establishments are sampled each month, lower risk establishments may not be sampled at all. In order to avoid this situation, a random sample of establishments not in the high risk sampled group is taken. This random sample size is based on the number of samples needed to sample every low risk establishment once or twice a year.

Because the number of establishments in the example is 1,000, a monthly allocation of 300 is used for illustration. Of the 300 samples, 250 can be given for high risk establishments and 50 can be given for lower risk establishments. The question then becomes—from which list of establishment risk ranks should the selection of establishments to sample be made?

If there is no concern about sampling from each alternative with regard to establishment SBA size or requirement that lower risk alternatives should be sampled less, then the establishment risk ranks totaling all alternative risks can be used. The first 250 risk ranked establishments are selected from the "SAS.establishmentrank" file. The 50 randomly selected establishments are taken from the remaining establishments on the same list. In the following months, sampling without replacement can be used to avoid randomly oversampling the same establishments on the random list.

However, if the SBA size and the alternative are scheduling criteria to follow the "SAS.estaltrank" file should be used for selecting establishments to sample. This file contains the SBA class and the number of alternatives listed by ESTID. The list is first sorted by *Lm* risk rank to obtain the list of the 250 highest ranked establishments. Only the highest ranked alternative will be used for establishments that are listed multiple times. After completing the list of 250 high risk establishments, the random list of 50 establishments is completed from the remaining establishments.

Appendix IV Table 2 shows the breakdown of high risk establishments by alternative and SBA size. Appendix IV Table 3 shows the breakdown of lower risk establishments by alternative and SBA size. By tracking the number of samples requested and analyzed for each establishment annually, it is possible to use criteria limiting the number of samples taken for establishments in a given alternative and SBA class in order to avoid oversampling. This is especially important if the rules have been designed as industry incentives to adopt the more stringent intervention alternatives. Appendix IV Table 4 shows the current FSIS criteria for avoiding oversampling of establishments by alternative and SBA class. Using the guidelines from Appendix IV Table 4, the large alternative 3 and 2b high risk establishments in Appendix IV Table 2 should be sampled every month while the small alternative 2b establishments should be sampled 8 times a year but the small alternative 3 establishments should be sampled every month. The very small alternative 3 establishments should be sampled every other month. Using the guidelines for randomly sampled establishments shown in Appendix IV Table 3 none of these establishments should be randomly sampled again for at least 6 months.

Appendix IV. Table 2. High Risk Establishments Sampled by Alternative and SBA Size - Example

Alternative	Large	Small	Very Small	Total
3	13	129	84	226
2b	14	10	0	24
Total	27	139	84	250

Appendix IV. Table 3. Lower Risk Establishments Randomly Sampled by Alternative and SBA Size- Example

Alternative	Large	Small	Very Small	Total
3	0	10	10	20
2b	2	12	3	17
2a	1	3	1	5
1	0	5	3	8
Total	3	30	17	50

Appendix IV. Table 4. Target Number of Annual Risk-Based Samples by Alternative and SBA Class

Alternative	Large	Small	Very Small
1	<=4	<=4	<=2
2a	<=6	<=6	<=3
2b	<=8	<=8	<=4
3	<=12	<=12	<=6