

Computing Risk-Based Inspection Levels for Processing Establishments in 30 Prototype Locations

Introduction

FSIS is introducing a more robust Risk-Based Inspection (RBI) system in processing plants to better protect public health. By better utilizing information regularly collected by inspection program personnel at processing establishments, the Agency will focus resources on products that pose the highest inherent risk and processing plants that have demonstrated the least ability to control risk. Daily inspection will continue at processing facilities. Background information on this initiative is available at [http://www.fsis.usda.gov/Regulations & Policies/RBI in Processing/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/RBI_in_Processing/index.asp).

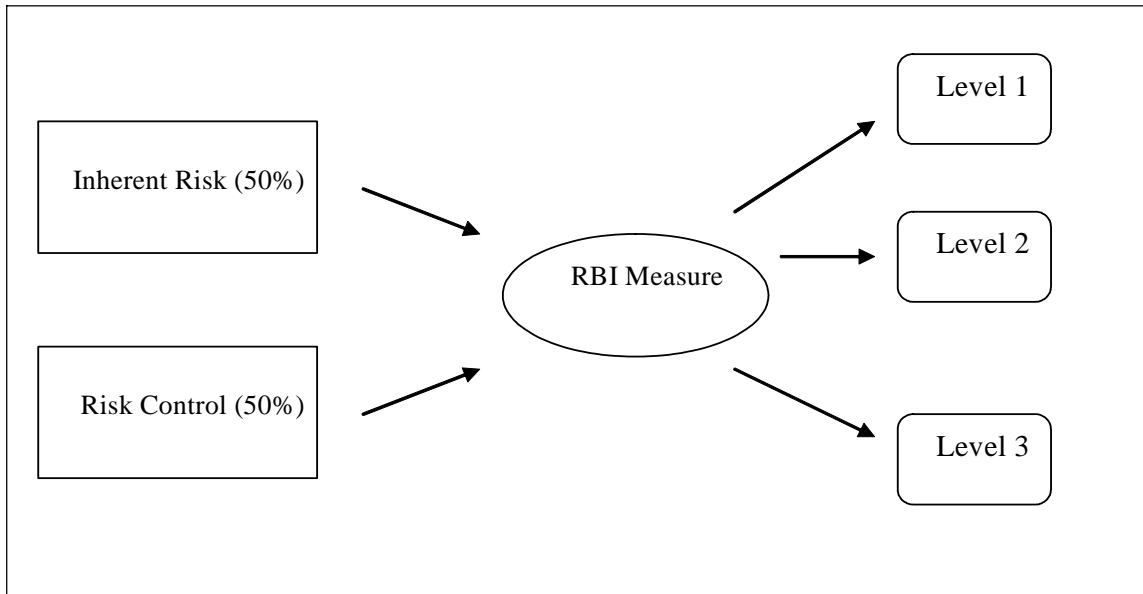
FSIS is using an algorithm, or mathematical formula, to determine the level of inspection that needs to be performed in processing plants. The algorithm combines two measures. The first is the inherent risk measure associated with different types of processed products and the volume of the processed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

FSIS will test the algorithm in 30 prototype locations beginning in spring 2007 and is providing additional information on how the algorithm will be determined in these prototype locations. This paper describes how the Inherent Risk Measure and the Risk Control Measure will be used to determine the level of inspection in processing plants during the initial test at the prototype locations. Two companion papers explain how the Inherent Risk Measure and the Risk Control Measure are determined, and how those measures are translated into one of three Levels of Inspection (LOI). All three papers are available at www.fsis.usda.gov.

RBI Risk Measure

Both the Inherent Risk Measure (IRM) and Risk Control Measure (RCM) are on a 100-point scale. An establishment's RBI Measure is straightforwardly computed as the average of its IRM and RCM. For example, an establishment with an IRM of 60 and a RCM of 20 has an RBI Measure of $(60 + 20)/2 = 40$. At RBI start-up at these 30 prototype locations, the IRM and RCM are thus equally-weighted in the RBI Measure.

Figure 1. Determination of RBI Measure and Three Levels of Inspection



RBI Level of Inspection

There will initially be three levels of inspection in RBI. Level 2 inspection establishes a standard set of food safety inspection activities that is approximately equivalent to the level of inspection that PBIS now schedules in all establishments. It entails a HACCP 01 procedure *once per week per processing category* (see 9 CFR 417.2 for the nine HACCP processing categories), the HACCP 02 procedure *twice weekly per processing category*, pre-op *and* operational sanitation procedures daily, and Sanitation Performance Standards (SPS) procedures weekly. Level 1 inspection is for establishments that have *lower* inherent risk and/or better risk controls, and is like Level 2 inspection except that it *reduces* the performance of the HACCP 01 procedure to once per week in a *single* selected processing category and requires the performance of *either* a pre-operational *or* operational sanitation procedure daily. Level 3 inspection is for establishments that have *higher* inherent risk and/or less consistent risk controls, and is like Level 2 inspection except that it *elevates* inspection by the *weekly addition* of one HACCP 01 procedure in each processing category and the *weekly addition* of one SPS verification procedure. All three levels of inspection maintain daily presence in inspected establishments.

The LOI for each establishment is based on its RBI Measure.¹ By design, approximately 60% of the establishments are assigned LOI 2, and approximately 20% are assigned LOIs 1 and 3, respectively. Establishments with RBI Measures below the 20th percentile are Level 1, those with RBI measures above the 80th percentile are Level 3, and all other establishments (and all canning establishments) are Level 2.

¹ The exceptions are “canning” establishments, which are assigned Level 2 inspection pending the results of a new expert elicitation.

The Agency will conduct an evaluation of RBI as it is implemented in the 30 prototype locations that will assess, among other things, whether the IRM and RCM should remain equally-weighted in the RBI Measure and whether three levels of inspection are appropriate.

Soon after RBI begins at the prototype locations, the numbers of establishments in each of the three LOIs can be expected to change. While an establishment's LOI could certainly rise or fall as a result of changes in the types and volumes of products it produces, LOI changes are *more* likely to result as establishments are found more or less compliant with regulatory requirements, experience more or fewer consumer complaints or recalls, achieve greater or lesser control of *Salmonella* in raw products, or achieve greater or lesser control of pathogens in raw ground beef and/or RTE products (all Risk Control considerations). Establishments' LOIs will be computed monthly and therefore could change if its inherent risk or risk control effectiveness changes sufficiently.

Levels of Inspection Computation Examples²

Figure 2 illustrates how IRMs, RCMs, RBI Measures, and LOIs are computed.

Establishment A produces a medium volume of raw intact beef, which has a medium inherent risk. With an inherent product risk value of 10 (on a 2-20 point scale from the expert elicitation described in the Inherent Risk paper) and a volume multiplier of 3 (on a 1-5 point scale), the establishment's IRM= 30. The establishment's RCM = 25, based on a nearly-average public health NR rate and an otherwise reasonably good performance history. It has had two verified food safety consumer complaints in six months, but has experienced no food safety recalls or enforcement actions. There is no *Salmonella* verification or pathogen testing program because this is the only product this establishment produces, nor is the product ready-to-eat (RTE), so these factors are not included in the RCM. Establishment A's RBI measure is the average of its IRM (30) and RCM (25) -- 27.5. With an RBI measure between 24 and 55,³ the establishment's LOI is 2.

Establishment B instead produces raw *ground* beef, which has a higher inherent hazard than raw intact beef, and produces a somewhat lower volume. Still, its IRM (40) is higher than that of Establishment A's. The establishment's record of non-compliance and consumer complaint history is a little better than establishment A's. In addition, FSIS has *more types of data* on food safety system process control in Establishment B (i.e. *Salmonella* verification results and *E. coli* O157:H7 laboratory results) *and* the evidence is *favorable*. As a result, establishment B's risk control measure is 6.3— which is better than establishment A's. So even though Establishment B has a higher inherent risk than Establishment A, its better risk control performance yields a lower RBI measure (23.1) and it is assigned a diminished LOI (1).

Establishment C produces fully-cooked RTE beef patties in low volume, yielding an Inherent Risk value of 6. Its public health NR rate is fairly low, and it has experienced no enforcement actions, consumer complaints, or recalls. The establishment uses an antimicrobial agent in addition to sanitation operating procedures as its *Lm* control measure and has not had any positive pathogen laboratory findings in the past year. The resulting RCM of 9.4, combined with its IRM of 6, yields a RBI Measure of 7.7. The RBI measure below 24 determines its LOI (1).

² These numerical examples are not actual establishments.

³ For purposes of this illustration, 24 and 55 are chosen as the 20th and 80th percentile values of the RBI measure to differentiate between inspection levels 1, 2, and 3.

Finally, Establishment D produces large and equal quantities of raw ground and fully-cooked RTE beef patties. Its resulting IRM is 65—higher than any of the other 3 establishments (though still well-below the maximum possible IRM of 100). The establishment's RCM = 51.4. It has experienced a Class II recall, but no enforcement actions. It uses very effective processes to control *Lm* in its RTE operation. It does, however, have an above-average public health NR rate, two verified public health consumer complaints, some *Salmonella* control problems (in its raw ground beef operation), and two positive laboratory findings in the Agency's *E. coli* O157:H7 testing program.⁴ The resulting RBI measure of 58.2 determines the highest LOI (3) being assigned to the establishment.

⁴ No product was recalled as a result of these *E. coli* O157:H7 findings because the sampled lots had been held by the establishment pending the test results. The Class II recall in this illustration is un-related to these pathogen findings.

Figure 2. Illustrations of Inherent Risk, Risk Control, and Level of Inspection in Four Establishments⁵

	Establishment A (Raw Intact Beef)		Establishment B (Raw Ground Beef)		Establishment C (RTE Fully-Cooked Beef Patties)		Establishment D ² (Raw and RTE Ground Beef Patties)	
Inherent Product Hazard	10		20		6		13	
Volume Range ¹	3		2		1		5	
Inherent Risk Measure	30		40		6		65	
	Actual	Possible	Actual	Possible	Actual	Possible	Actual	Possible
NR Data	3	5	1	5	2	5	5	5
Verified Food Safety Consumer Complaint Data	2	3	1	3	0	3	2	3
Food Safety Recall Data	0	6	0	6	0	6	2	6
Enforcement Data	0	6	0	6	0	6	0	6
<i>Salmonella</i> Verification Category	NA	NA	0	3	NA	NA	3	3
<i>E. coli</i> O157:H7 and/or RTE Pathogen Testing	NA	NA	0	9	0	9	6	9
RTE Alternative	NA	NA	NA	NA	1	3	0	3
Total	5	20	2	32	3	32	18	35
Risk Control Measure	25.0		6.3		9.4		51.4	
RBI Risk Measure	27.5		23.1		7.7		58.2	
Level of Inspection	2		1		1		3	

¹ Volume ranges are based on the 20th, 40th, 60th, and 80th percentile values

² 50% Raw Patties and 50% RTE Patties

⁵ The data used in this illustration are not from actual establishments.

While inherent risk and risk control equally influence the Level of Inspection (through the RBI measure) in all establishments, the relative contribution of the various specific risk control factors varies from plant-to-plant depending on the types of data that are available for each.

Consider establishment 1 in Figure 3, which produces a single product like raw intact beef or raw intact pork, and which therefore has no *Salmonella* Verification category, *Lm* Control Alternative, or pathogen testing requirements. This plant’s Risk Control measure, like that in every other plant, comprises 50% of the RBI measure (inherent risk always being the other 50%). Therefore, food safety recalls and Enforcement actions each comprise 15% of its RBI measure, its public health NR rate 13%, and verified food safety consumer complaints 8%.

In establishment 2, however, which produces (for example) raw ground beef patties and fully-cooked beef patties, recalls and enforcement actions each comprise only 9% of its RBI measure, its public health NR rate only 7%, and consumer complaints only 4%. The remainder of its Risk Control measure—which is always 50% of its RBI measure—is determined by its *Salmonella* Verification Category (4%), the Agency’s pathogen test results (13%), and its *Lm* control alternative (4%).

The weights of the specific control factors are different still in establishment 3, which produces (for example) raw intact and raw ground chicken. Such a plant is subject to raw product *Salmonella* testing but does not require an *Lm* control strategy or Agency testing for *E. coli* O157:H7 in products containing raw ground beef or pathogens in RTE products. Additional data configurations of establishments under federal inspection are depicted by establishments 4, 5 and 6 in Figure 3, and the relative contributions of its specific risk control factors vary as well.

The combinations of inherent risk and risk control factors in Figure 3 are not exhaustive. The contributions of the factors can even vary across establishments of the same “type” depending on the *number* of “zero tolerance” (raw ground beef *E. coli* O157:H7 and pathogens in RTE products) laboratory samples the Agency has in the prior twelve months. In effect, an establishment with no positive zero-tolerance samples based on only one or two samples will not have a Risk Control measure as low as an otherwise identical establishment from which the Agency has three or more samples.

Figure 3. Contribution of Inherent Risk and Risk Control Factors in Different Plant Types

	1	2	3	4	5	6
Inherent Hazard Expert Value(s)	25%	25%	25%	25%	25%	25%
Volume of Product(s)	25%	25%	25%	25%	25%	25%
Inherent Risk Measure	50%	50%	50%	50%	50%	50%
Public Health NRs	13%	7%	11%	8%	9%	8%
Verified Food Safety Consumer Complaints	8%	4%	7%	5%	5%	5%
Food Safety Recalls	15%	9%	13%	9%	10%	9%
Enforcement Actions	15%	9%	13%	9%	10%	9%
<i>Salmonella</i> Verification Category	NA	4%	7%	NA	NA	5%
Pathogen Testing In Raw Ground Beef and RTE Products	NA	13%	NA	14%	16%	14%
<i>Lm</i> Control Alternative	NA	4%	NA	5%	NA	NA
Risk Control Measure	50%	50%	50%	50%	50%	50%
RBI Measure	100%	100%	100%	100%	100%	100%

Figure 4 illustrates relationships between the RBI measure, the inherent risk measure, and the risk control measure using 500 hypothetical establishments with randomly-chosen IRMs between 1 and 100⁶ and randomly-chosen RCMs between 0 and 50.⁷ Because the RBI measure (the up-ward sloping green line in Figure 2) is the average of the IRM (the up-ward sloping blue line) and the RCM (the up-ward sloping red line), it is always mid-way between the two values. As establishment inherent risk rises, it takes increasingly better (lower) risk control measures to maintain any given RBI measure. For example, an establishment with an inherent risk of 20 needs a risk control measure of 40 to have an RBI measure of 30. To maintain the same RBI measure of 30 (and the same LOI), an establishment with an inherent risk of 40 needs to have a risk control measure of 20.

In the illustration—which to reiterate is not based on actual data—the approximately 100 establishments with RBI measures below about 24 would have Level 1 inspection, while the approximately 100 establishments with RBI measures higher than approximately 55 would have Level 3 inspection. The other approximately 300 establishments would have Level 2 inspection. These “threshold” RBI values of 24 and 55 in the illustration are computed so that approximately 60% of all establishments are in Level 2, and 20% each are in levels 1 and 3.

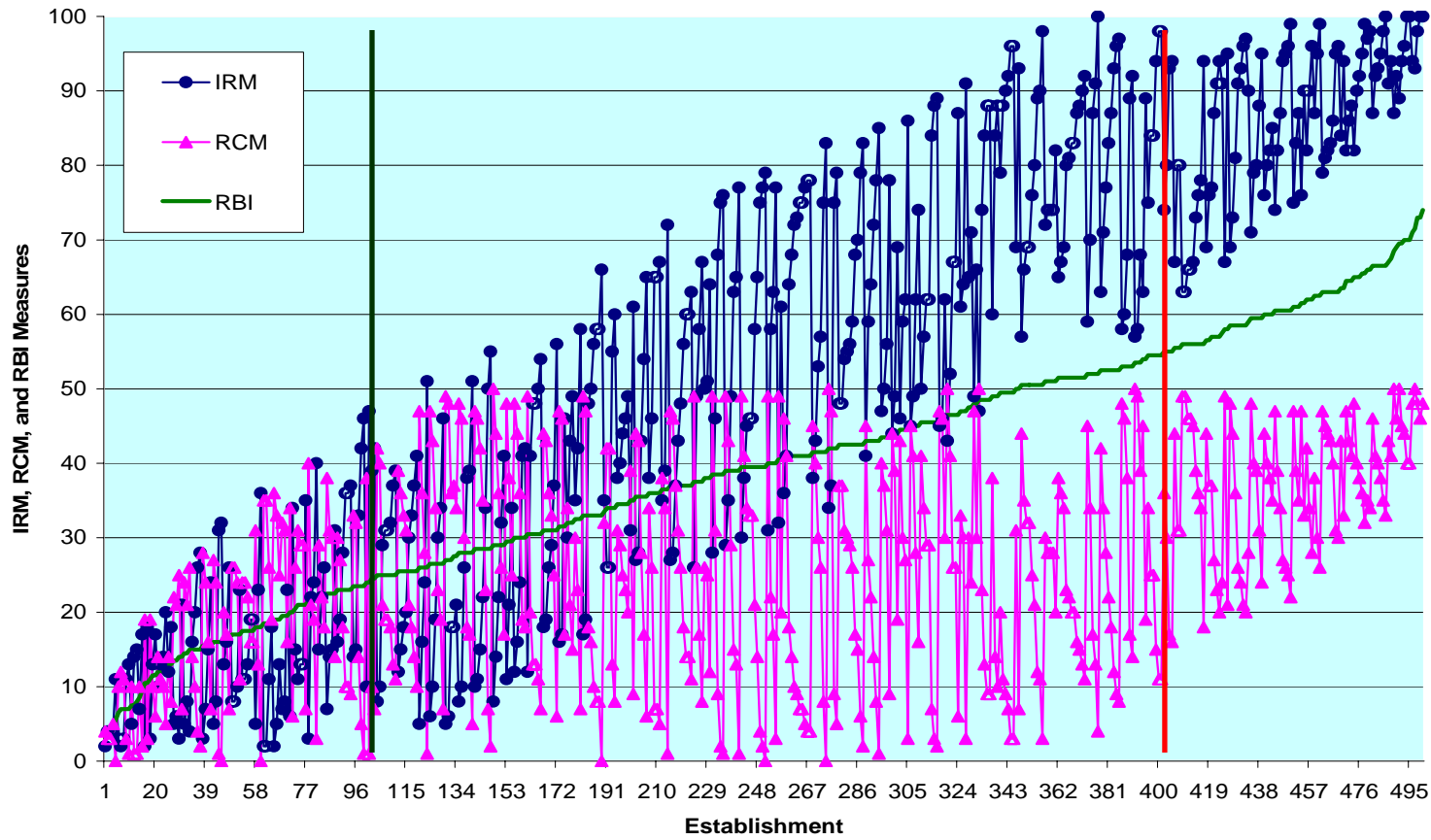
In this illustration, even establishments with the highest possible inherent risk (100) can achieve Level 2 inspection by achieving risk control values of 10 or lower. The establishment would not, however, be able to achieve Level 1 inspection-- even with a risk control score of 0. In fact no establishment with an inherent risk value above 48 can achieve Level 1 inspection if the RBI threshold range for Level 1 inspection is capped at 24. Consider an establishment with an inherent risk of 49. Its minimum attainable RBI measure, which it attains with a RCM = 0, is $(49+0)/2 = 24.5$. Thus, its lowest possible LOI = 2. The establishment will remain a Level 2 plant as long as its RCM remains below or equal to 61. With a RCM = 62, its RBI measure = $(49+62)/2 = 55.5$ and would designate it as an inspection Level 3 establishment.

The information contained in this paper represents an initial step that FSIS is taking to test the system. FSIS will analyze the actual inherent risk and risk control data to determine how many levels of inspection there should be an appropriate number and percentage of establishments to have in each level of inspection, and the threshold RBI values needed to accomplish those objectives. FSIS also expects to further refine and enhance the system in ways that will improve how we measure inherent risk, the effectiveness of the food safety system (e.g., which interventions are used and the degree of control the food safety system demonstrates through more objective FSIS-conducted verification procedures and assessments), and risk control. These enhancements should provide a mechanism for establishments, including large producers with high inherent risk, to move between assigned inspection levels in ways they can't today.

⁶ IRMs for the population of federally-inspected meat and poultry establishments actually do range from 1-100. The mean and median IRM is about 33.5 and 30, respectively.

⁷ Even though the theoretical range of the RCM is between 0 and 100, establishments would rarely have RCM values higher than about 50.

Figure 4. Relationships between Inherent Risk, Risk Control, RBI Measures, and LOI⁸



⁸ These data are not from actual establishments. The inherent risk and risk control values are for illustrative purposes only.