26 Oct 2006

Via E-Mail: riskbasedinspection@fsis.usda.gov

Ms. Ellyn Blumberg,
RBI Public Meeting,
United States Department of Agriculture,
Food Safety and Inspection Service,
14th & Independence Avenue, SW.,
Mail Drop 405 Aerospace,
Washington, DC 20250

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2006-0028
2006-0028-30
Michael L. Rybolt

Re: Docket No. FSIS-2006-0028: Risk-Based Inspection System

Dear Ms. Blumberg:

The National Turkey Federation (NTF) respectfully submits these comments on the Food Safety and Inspection Service's (FSIS) Risk Based Inspection Initiative (RBI).

NTF is the only national trade association representing the turkey industry exclusively. NTF's members include breeders, growers, slaughterers and processors. NTF's members account for virtually all the turkey sold in the United States. Accordingly, we have an interest in improving the effectiveness of the Federal inspection system.

As an initial matter, we appreciate FSIS' openness and transparency in moving forward on RBI and hope the agency finds our comments below useful. These comments are presented in two parts. Part I provides our general comments and suggestion on RBI overall. Part II provides our answers to the specific questions raised by FSIS at the public meeting.

I. Risk-Based Inspection

Background

Since 1906 when the Federal Meat Inspection Act was signed into law, the United States meat and poultry supply has been consistently improving as the U.S. Department of Agriculture (USDA) Food Safety Inspection System has evolved to keep up with technological advances and a growing population. Originally in 1906, the USDA's main goal was to eliminate adulteration and filth as documented in the infamous Upton Sinclair book, *The Jungle*. At the turn of the 20th Century, the most reliable way of determining the quality of meat and poultry was visual observation by USDA inspectors of the animal carcass throughout slaughter and processing.

Over time, however with technological advances, Congress has enacted laws that reflect FSIS' improved inspection procedures and has redirected efforts & goals from adulteration and filth to

concentrate on public health. Additional Acts were signed into law and new regulations were adopted by FSIS including the Poultry Products Inspection Act, 1957; the Wholesome Meat and Wholesome Poultry Products Acts, 1967-1968; the Pathogen Reduction Hazard Analysis and Critical Control Point System, 1996-2000; and the 1999 testing for *Listeria monocytogenes*. Each of these changes has utilized the latest research and technology to more efficiently inspect the U.S. meat and poultry supply. These regulations that FSIS has implemented show the agency's strong commitment to its goal of producing the world's safest meat and poultry products and to continue to protect the public health of the country.

The turkey industry applauds FSIS' dedication to the evolution of inspection over the past century and is eager to work with it on the development and implementation of Risk Based Inspection. The industry also understands the budget constraints the agency is under and how important it is to allocate its resources to those establishments that pose the greatest risk to public health.

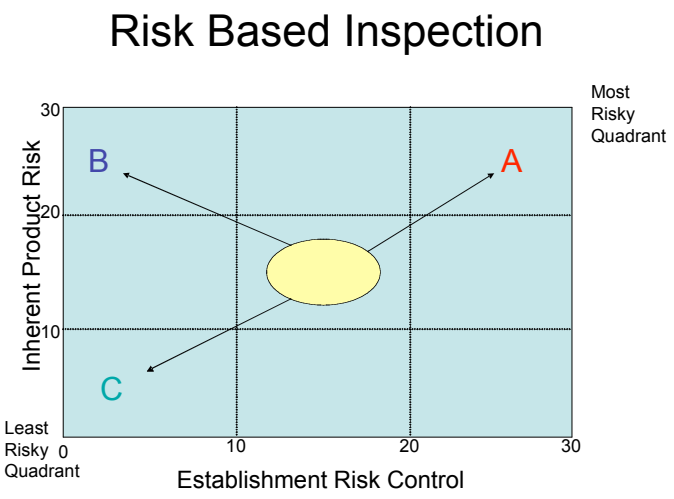
To accomplish this, the agency's next step in the evolution of inspection is a move toward a risk-based allocation system, where many variables should be considered rather than just the incidence of pathogens on raw meat and poultry. For example, the 1999 Testing for *Listeria monocytogenes* is a reflection of a risk-based methodology, which incorporates multiple factors. Likewise, the agency should not focus solely on the specific pathogen incidence when attempting to categorize a meat or poultry establishment. Rather, it should incorporate other factors as discussed herein.

Introduction

The ultimate goal of risk-based inspection is to allocate government resources to establishments that pose the greatest risk to public health. Risk-based inspection takes into account multiple factors related to product risk, food safety system design, food safety system implementation and facility history. When combined, these factors will provide a facility profile that can be used to estimate the resources necessary to ensure that the appropriate food safety standards are being met. To do so, an establishment's total process should be considered before establishing its risk control based on the likelihood of a potential risk occurring.

In applying risk-based inspection, some establishments may not pose a significant risk to public health simply because of the products which it produces. On the other hand, depending on the risk/hazard identified, some establishments may, in fact, require greater attention from a food safety perspective, solely based on the products it produces. Nonetheless, an appropriate risk-based inspection paradigm should adequately account for such variations by including all necessary risk factors, which can be grouped into two categories: the type of products produced (inherent risk), and the establishment's risk control.

We agree with FSIS that a chart is a very effective tool to assess risk. The variables we believe should be used are Inherent Product Risk (located on the Y axis) and Establishment Risk Control (located on the X axis). Using the expert inherent product risk ranking that FSIS has recently conducted, the risk ranking (between 1-23) of products has already been assigned. Although the reliability of the risk ranking has been called into question, in the interest of moving forward now, we will accept its use until FSIS reassesses the inherent product risk with quantitative data and expert opinion from all stakeholders. The Establishment Risk Control will be the more variable factor in the risk-based inspection program.



We propose the Establishment Risk Control includes a 6-month to one-year look back window, with a monthly rolling window that can be utilized as a continual assessment of an establishment's: food safety system design; food safety system implementation; pathogen control; other performance indicators; process interventions; and intended use of product. We expect that establishments will vary along this axis continually. In addition, the Establishment Risk Control axis will be separated into categories or groups similar to the Alternative approach with RTE products and *Salmonella* in slaughter facilities. Within each category, volume and frequency of operation should be considered with those establishments that produce similar products using similar processes. Although the X axis is not the only way to measure volume, we strongly oppose volume being used on the Y axis and believe that high volume does not necessarily equate to high risk.

Risk-based Inspection Ranking

The following is an itemization of what exactly should be included in each rank of Inherent Product Risk and Establishment Risk Control.

Inherent Product Risk

Inherent product risk is defined by FSIS as the "relative risk of illness per serving" in a specific product category. For this, FSIS has proposed 24 general product categories and has ranked each based on an expert solicitation. The results of this expert solicitation led to FSIS' current rankings of:

Ranking	Average	**Minimum**	**Median**	Product
1	2.5	1.0	1.0	RTE meat fully-cooked without subsequent exposure to the environment
2	3.7	1.0	1.0	RTE poultry fully-cooked without subsequent exposure to the environment
3	4.0	1.0	2.0	RTE salt-cured meat
4	4.3	1.0	2.0	RTE dried meat
5	5.0	1.0	2.0	RTE Salt-cured poultry
6	5.0	1.0	2.0	RTE dried poultry
7	5.7	1.0	2.0	RTE acidified/fermented meat (without cooking)
8	5.9	1.0	2.0	RTE acidified/fermented poultry(without coking)
9	8.5	1.0	3.0	RTE fully cooked meat
9	8.5	1.0	4.0	Raw intact pork
11	9.4	1.0	5.0	Raw intact beef
12	9.8	1.0	3.0	RTE fully cooked poultry
13	10.9	2.0	5.0	Raw intact meat - no beef or pork
14	13.0	1.0	7.0	Raw otherwise processed meat
15	13.6	1.2	7.0	Raw otherwise processed poultry
16	14.5	1.5	8.0	Raw ground or otherwise non-intact pork
17	15.3	2.0	8.0	Raw intact poultry - no chicken or turkey
18	15.4	2.0	9.7	Raw ground or otherwise non-intact meat - no beef or pork
19	15.6	2.0	8.0	Raw intact chicken
20	16.0	2.2	9.0	Raw intact turkey
21	17.9	3.0	10.0	Raw ground or otherwise non -intact beef
22	18.7	2.5	10.0	Raw ground or otherwise non-intact poultry - no chicken or turkey
23	19.0	2.0	10.0	Raw ground or otherwise non-intact chicken
23	19.0	2.0	10.0	Raw ground or otherwise non-intact turkey

Knowing the U.S. meat and poultry supply is one of the best and safest available in the world, any consumer of U.S. produced meat or poultry can be assured that all food is safe no matter which 'inherent product category" FSIS has assigned. We do not feel that it is necessary to debate whether any specific product category has more or less "inherent" safety in the initial relative risk chart above. The fact is all U.S. products are safe and all potential hazards in each product category are effectively controlled by industry under our current inspection system.

Under any RBI model, every establishment in industry will still be inspected by FSIS based on the same criteria as all other establishments making similar products and every establishment in industry can control their own processes with FSIS oversight levels on the "establishment risk control" variable of RBI. However, we encourage FSIS to look at attribution data related to what

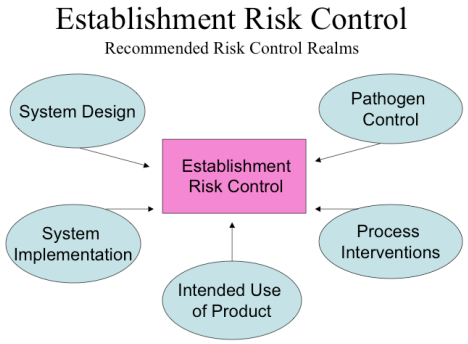
products actually impact public health and what quantitative information is available to be used in determining "inherent product risk". Using attribution data, more quantitative in nature, would make RBI more effective, more accurate and more efficient.

We do not believe the following factors should be included in the Product Inherent Risk side of the RBI model: production volume or establishment interventions. While it is critical establishment interventions be included in RBI and it is also true potential public exposure (*i.e.*, volume) can effect public health outcomes, we believe these variables along with all plant controlled variables (potential exposure/volume, interventions, NRs, sampling results etc.) be evaluated in calculating the "Establishment Risk Control". Secondly, we encourage FSIS to consider the product's intended use in any RBI program and like other plant controlled attributes of RBI, this factor should be addressed in the "Establishment Risk Control" side of the model. Product "intended use" is whether or not an item is intended for retail sale, food service or further processing at another establishment.

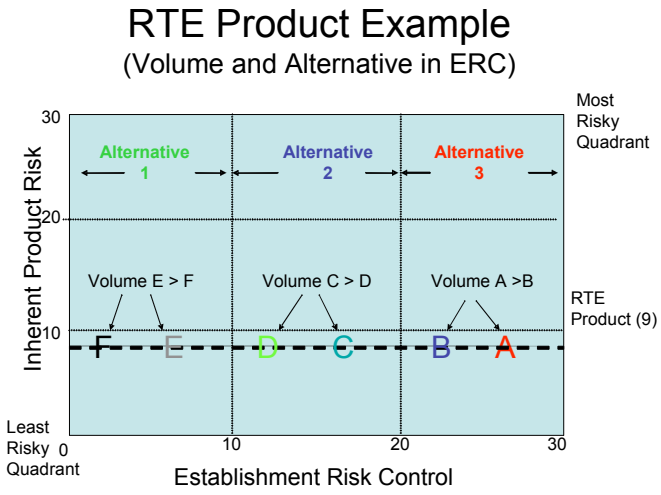
Establishment Risk Control

Industry believes FSIS should use the following five risk-control realms when measuring "Establishment Risk Control":

1. Food safety system design;
2. Food safety system implementation;
3. Pathogen control;
4. Process interventions; and
5. Intended use of product.

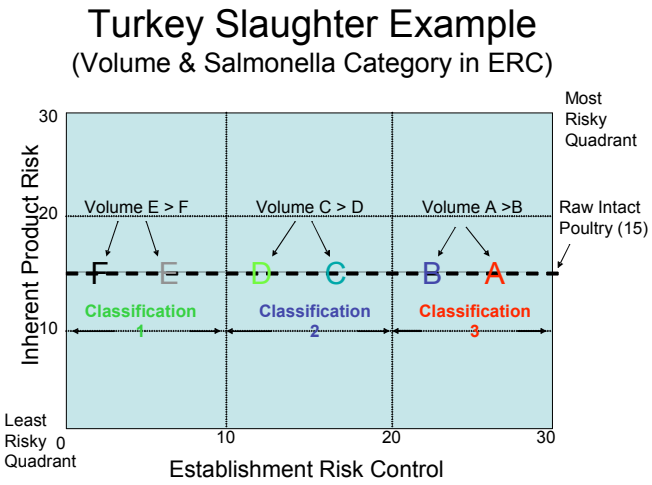


In order to assess these risk-control realms, an establishment may conclude that FSIS data alone is not sufficient to differentiate establishments and develop a true "Establishment Risk Control". Therefore, we recommend FSIS permit, on a voluntary basis, an "Establishment Risk Control" that uses industry generated quantitative results in each of the risk-control realms with appropriate agency verification of data quality.



We encourage FSIS to develop a questionnaire addressing the five risk realms used to determine the establishment risk control; the questionnaire would then be completed by each establishment to determine its own "Establishment Risk Control." This questionnaire would be similar to the method used by establishments to determine its Alternative Classification for RTE products in 9 CFR §

430. After an "Establishments Risk Control" is submitted to FSIS, the Agency would then appropriately verify what the establishment determined through normal verification activities.



In addition to these five risk-control realms, volume and frequency of operation cannot be used alone as a single variable in the "Establishment Risk Control" classification. We believe FSIS should use volume and frequency in conjunction with "control interventions" allowing FSIS to expand off those policies already implemented like RTE "alternative classification" and raw slaughter establishment *Salmonella* "category" determinations. These controls should be used so large volume establishments with validated interventions that reduce risk are not considered a "higher risk" in an RBI program than a smaller volume establishment with no interventions.

The agency is proposing the use of "in-commerce findings" as one of those inputs used in the "Establishment Risk Control" part of an RBI model with the method for generating an "in-commerce finding" being FSIS data. It is our belief that FSIS should not use this risk-control realm at all; it should be removed. The reliability of FSIS data used in "in-commerce findings" and the variability of consumer complaints are the reasons we believe this realm should be removed. We do not believe an adequate system is in place at this time for the use of consumer complaints.

Likewise, we believe FSIS should not use "enforcement actions" as one of the realms of "Establishment Risk Control." This component would not provide a meaningful criteria for classification: (1) it is not applicable to the vast majority of establishments and (2) it is already incorporated into other components, such as system design, system implementation, and pathogen control (since enforcement action results from a deficiency in one or more of these).

Below is a brief discussion on each of the risk-control realms we are proposing.

<u>Specifics on Establishment Risk Control Inputs</u>

1. Risk Control Realm: Food Safety System Design

When evaluating "Food Safety Design" it is critical that FSIS considers all variables that affect/ influence the "Establishments Risk Control." This includes live animal and raw material receiving; microbial control programs; process control documents; GMPs; and lot control along with SSOP and HACCP design. We agree that FSIS can use Food Safety System Assessments (FSSA) as part of the equation for evaluating an establishment by system design, but a better indicator would be to also include an establishment questionnaire. The questionnaire would be designed such that each establishment would determine its appropriate "Food Safety System

Design" control then demonstrate support through control programs, validation, and verification activities. FSIS can then verify the establishment's "determination" and program design through a Food Safety System Assessment (FSSA) to assure accuracy for the "Establishment Risk Control."

2. Risk Control Realm: Food Safety System Implementation

Industry understands why FSIS should use appropriate and weighted Non-compliance Reports (NR) as a part of the equation for evaluating/ranking an establishment's "Food Safety System Implementation." However, this weighting needs to be reviewed. Secondly, along with a weighting system, we believe only NRs that have a regulatory cite of 9 CFR § 416.11 through 416.15 and 9 CFR § 417 be included in this risk control realm.

Industry also believe FSIS needs to use the establishment's information related to on-going implementation of pre-requisite programs, its SSOP, and its HACCP system in this risk control realm. Using this information will lead to a better indicator of actual "Food Safety System Implementation." Industry requests again that FSIS develop and include a voluntary establishment questionnaire for determining Establishment Risk Control in which each establishment determines its appropriate "Food Safety System Implementation" control and demonstrates support with on-going records of its pre-requisite control programs, SSOP implementation and HACCP implementation/verification. Again, under this voluntary option, FSIS could verify the establishment's determination and program implementation through in-plant inspection and/or an FSSA to assure accuracy for the "Establishment Risk Control."

3. Risk Control Realm: Pathogen Control

From the information FSIS has provided ("Measuring Establishment Risk Ranking for Risk-Based Inspection"; dated July 19, 2006) FSIS stated it will use "Pathogen Control" as one of the risk control realms for the "Establishment Risk Control." For "Pathogen Control," we assume that pathogen data generated under different FSIS Office of Public Health Science (OPHS) sampling projects will be used for this determination.

One of those projects is "RTE001". Under this project, RTE product samples are sent to one of three FSIS OPHS laboratories for analysis for *Listeria monocytogenes* and *Salmonella.* The following is an example of the limited number of samples at FSIS' disposal.

FY2005 RTE Product Samples (*Listeria monocytogenes* and *Salmonella*)

Pathogen	Total Establishments	Total Samples	Total Positives
Listeria monocytogenes	2806	15,967	108 (0.68%)
Salmonella	2806	15,969	8 (0.05%)
			Total = 116

Using FY2005 data, (even assuming each positive is one plant – which we know is not true – some plants had multiple positives) 116 establishments should be rated such that their "Establishment Risk Control" indicates less control and the remaining 2,690 establishments should be rated equally under "Pathogen Control" (but better than the 116 with positives). This data is an example of the lack of differentiation between establishments if the agency only considers its own data in this risk realm. We encourage FSIS to develop a questionnaire also in this risk realm in which each establishment determine its own "Pathogen Control," similar to the method used by establishments to choose its own Alternative Classification for RTE products in 9 CFR 430. Just like the other realms, FSIS can then verify the establishment's "determination" and program implementation through in-plant inspections or an FSSA to assure accuracy for the "Establishment Risk Control."

4. Risk Control Realm: Process Interventions

Industry believes it is critical that FSIS consider process control interventions as a risk control realm in "Establishment Risk Control." We believe incorporating "Process Interventions" into the "Establishment Risk Control" algorithm is critical because it is the choice of interventions that differentiate between the risky and non-risky establishments. For example, products from an establishment producing under Alternative 1 RTE with a validated process and antimicrobial would generally pose less risk than products from an establishment using Alternative 3 RTE product with sanitation as its sole control mechanism. Likewise, products from a slaughter establishment with interventions demonstrated to reduce *Salmonella* would generally pose less risk than products from a slaughter establishment with no interventions to reduce incidence. FSIS is already evaluating slaughter locations based on the *Salmonella* performance standard data (Category 1, 2, and 3). This data should be used in any algorithm.

Secondly, we believe that "Process Interventions" is the risk-control realm where FSIS should consider the establishment's volume and frequency of operation (or exposure potential). We agree volume should be considered as it relates to exposure, but the best way to consider it is in conjunction with "Process Interventions" within the establishments. Our proposal is that FSIS use volume as a determining factor, only after separating plants based on "Process Intervention." By designing a model, in a way, FSIS would assure the true "risk control" at each establishment is evaluated and volume and frequency of operation (or exposure potential) is only used in differentiating those that achieve the same control level. An RBI model will fail to achieve its objective and will not be science-based if a large volume producer is considered "more risky" that small volume producer only based on pounds produced.

5. Risk Control Realm: Intended Use of Product

FSIS should include "Intended Use of Product" in the "Establishment Risk Control" part of RBI. Using this risk-control realm would allow for FSIS to consider end use of products being produced such as further processing within other federally inspected facilities, food service distribution, and retail sales.

II. Response to the Specific Questions Raised by FSIS at the Public Meeting

At the public meeting on October 10-11, the FSIS presenters posed a series of question dealing with inherent product risk, establishment risk control, and implementation. The precise questions and our answers are set forth below:

A. Inherent Product Risk

Q. 1. *We have tentatively decided to use the median of the expert scores in the Inherent Risk algorithm. Is there an alternative we should consider?*

As an initial matter, we do not have an issue with the use of "median." However, issues surrounding the expert elicitation, including the inconsistency of the results, the lack of uniform criteria, and the unarticulated rationale of the experts, have resulted in the lack of respect and validity for the elicitation by many stakeholders. The agency should use more than an expert panel to decide how product is ranked – it should use all available data. Risk ranking should be developed and thereafter reviewed on an annual basis by experts that consist of a cross section of all stakeholders, including those in the public health community. This continual review of the product categories should reflect any new and emerging food products.

Q. 2. *Thermally-processed, commercially sterile products (e.g. canned products) were not included in the elicitation for scoring by the experts. How exactly should they be fit into the range of Species/Process values now?*

These products should be included in RBI and should be put into the RBI model based on their safety track record.

Q. 3. *To better ensure comparable expert data, experts were asked not to account for any processing after product leaves the establishment of origin, e.g. no cooking at a second establishment or preparation at retail.*
•If a processed product is to receive further processing at another establishment, how should we account for its inherent risk?
•If a processed product is to be further processed at retail, how should we account for its inherent risk?

As a general matter, the intended use of the product is an essential component in assessing risk.

A product's inherent risk changes if it goes to another FSIS inspected plant where the product will be further processed. (It is incumbent on the establishment to prove that product is going to further establishment through labeling.) We would encourage agency to increase categories or create a factor of products going to further processing to reduce such products on the Y axis. However, once the product leaves the federal inspection system, risk should not change whether it is going to foodservice, retail or consumer.

Q. 4. *How do we translate volume data collected for each type of processed product produced at each establishment into an exposure variable for that establishment?*

We respectfully submit that volume simply does ***not*** equate to risk. If volume is used incorrectly, it will mask true risk. If FSIS concludes that volume nevertheless must be considered, it should not be included on the Y axis.

Q. 5. *Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented?*

There should be no automatic answer to this question; rather there are a variety of factors which should be considered such as the nature of the different products, how often are they produced, and the volume percentage of each product (distribution matrix of different products.) Perhaps taking the median or mean of all product's inherent product risk, weighted by production, could be used to determine the ultimate product risk for the establishment.

Q. 6. *To better ensure comparable expert data, we did not ask experts to consider severity of illness that can result from the consumption of contaminated meat and poultry. How should we account for severity of possible illness when calculating the risk inherent to each type of meat or poultry product?*

Notwithstanding this instruction, we respectfully suggest that at least some of the experts did take severity of illness into consideration. In response to Q. 1. above, we suggested the calculation be based on all available data. That being said, we hope that in the future, attribution data is available and used in assessing risk.

B. Establishment Control

Q. 1. *Are these 6 components appropriate and adequate?*

As discussed in Part I of these comments, we agree that system design, system implementation, and pathogen control are appropriate. We would respectfully request that "food defense," "enforcement actions" and "in commerce" need to be taken out and "process interventions" and "intended use" be inserted in lieu thereof so that there are 5 components.

Q. 2 *Are some components more important than others, and thus should some be weighted more than others?*

Objective components should be weighed more than subjective components. Before incorporating subjective (i.e. NRs, FSSAs) components, the agency needs to be able to quantify them.

Q. 3. *Is there other useful information about establishment risk control that FSIS is not considering?*

As noted above, process interventions and intended use of the product should be included in the five components. In addition, other establishment data and the distribution matrix of different products in one establishment should be considered.

Q. 4 *Are there other ways besides Food Safety System Assessments to evaluate establishment food safety system design?*

As mentioned above, FSIS should consider implementing a questionnaire that an establishment completes which it determines its own risk control, which is then verified and validated by the agency. Obviously, to the extent not already encompassed in one of the components, an establishment's history of making safe product as evidenced by industry data could be used. Industry data should remain strictly voluntary.

Q. 5. *Are the NRs FSIS is considering public health-related inclusive or are there others FSIS should be considering?*

We agree with what the agency has put forth, but request that the agency be cautious in classifying NRs simply by the regulation cited without a review of the entire NR.

Q. 6. *What is an appropriate look-back window?*

We suggest six months; in no event, longer than a year. This should be a moving window with an establishment being able to request that FSIS revisit or reassess the classification for cause.

C. Implementation

Q. 1. *How many levels of inspection are optimal?*

The five levels originally put forth by FSIS seem too narrow to fully differentiate establishments. Instead, we suggest nine levels of inspection as optimal.

Q.2. *How do plants move from one level to another?*

Establishments should move based on data considered by FSIS either during the 6 month/ 1 year reevaluation period or in response to new information proffered by the establishment/generated by FSIS.

Q. 3. *How frequently should FSIS evaluate data to make decisions on the plant moving from one level to another?*

As stated in response to Question B. 6. above, We suggest six months and in no event longer than a year. This should be a moving window with an establishment being able to request that FSIS revisit or reassess the classification for cause.

Q. 4. *Should we use predictive indicators?*

Predictive indicators address foreseeable but not consistent hazards. Such hazards should be considered in the establishment's HACCP plan and would be covered in the system design component.

Q. 5. *What would be the recommended inspection activities for different inspection levels?*

Level 1:
Electronic review of records;
Annual review of establishment self assessment on risk control (if applicable);
Review of establishment testing data in support of Level 1 ranking;
Annual review of HACCP reassessment; and
FSSA conducted every 4 years.

Levels 2-3:
Electronic review of records;
Semi-annual review of establishment self assessment on risk control (if applicable);
Review of establishment testing data in support of respective Level ranking;
Annual review of HACCP reassessment; and
FSSA conducted every 3 years.

Levels 4-6
Electronic review of records;
Quarterly review of establishment self assessment on risk control (if applicable);
Review of establishment testing data in support of respective Level ranking;
Annual review of HACCP reassessment; and
FSSA conducted every 2 years

Levels 7-8
On-site review of records;
Monthly review of establishment self assessment on risk control (if applicable);
Review of establishment environmental and product testing data;
Annual review of HACCP reassessment; and
FSSA conducted every 2 years.

Level 9
On-site review of records;
Weekly review of establishment self assessment on risk control, (if applicable);
Review of establishment environmental and product testing data;
Review of establishment raw material testing data;

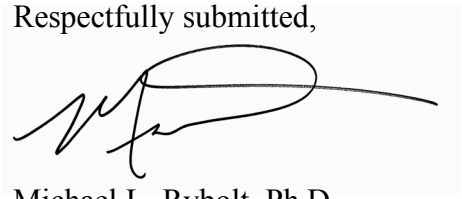
Review of semi-annual sanitation audit by external auditor;
Semi-annual review of HACCP reassessment; and
FSSA conducted annually.

Conclusion

NTF appreciates this opportunity to comment on this important initiative and looks forward to working with FSIS and other stakeholders to improve the effectiveness of inspection and enhancing the public health.

NTF respectfully requests an extension of the RBI comment period until the end of this calendar year to allow for industry response to the Resolve, Inc., report expected to be released in December.

Respectfully submitted,



Michael L. Rybolt, Ph.D.
Director, Scientific and Regulatory Affairs