RISK-BASED INSPECTION: IT COULD BE RISKY!

FSIS has ambitiously embarked on an attempt to implement a more robust Risk Based Inspection (RBI) system. This paper identifies numerous legitimate components which dramatically impact risk such as volume of production, product type such as RTE, and microbial test results. This paper also identifies shortcomings which could skew a scientific identification of risk, and potentially increase risk to consumers rather than decrease risks. This paper suggests a dramatic increase in agency microbial testing, and delineates the need for FSIS to perform trace backs to the true origin of contamination if effective corrective action is desired to prevent recurrences.

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After reading the agency's two technical papers on Risk-Based Inspection ("*Measuring Establishment Risk Control for Risk-Based Inspection*", and "*Measuring Product Inherent Risk for Risk-Based Inspection")*, I'd like to pose some suggestions and some cautions to FSIS as it considers this new robust inspection system.

Admittedly, there is general agreement that Ready-To-Eat (RTE) products carry an inherently higher risk than products which must be cooked prior to consumption. Species such as poultry which carry a high load of Salmonella also justify increased regulatory oversight. Other considerations such as volume, history of regulatory compliance, as well as historical incidents of contaminated meat generate highly divergent opinions of how FSIS can develop science-based risk determinations by plant.

FSIS technical papers refer to "*measuring establishment risk control effectiveness*", and discusses "*performing more inspection in establishments with less effective risk controls"*. FSIS determination of an establishment's ability to implement effective risk control merits intensive discussion. How can FSIS independently validate the efficacy of a plant's risk control measures? Should the agency assume that a plant which has implemented a plethora of multiple hurdle intervention steps is more likely to produce wholesome products? Should the agency assume that small volume plants lacking finances to implement numerous intervention steps be assumed to be more likely to produce contaminated meat? Should plants which produce strictly raw products and no RTE products be assigned fewer inspection personnel? Answers to these questions must be provided by scientific validation of a plant's historical records. The agency has and is conducting baseline studies which provide evidence of a plant's compliance with HACCP's Safe Food mandate.

Validation is best provided via substantial microbiological testing, both by FSIS and by industry. When adverse lab test results are determined, neither the industry nor the agency has anywhere to hide: in spite of our much-ballyhooed intervention steps, failures do occur which expose the difference between theory and reality. The industry has made

great strides in lowering the incidence of contaminated meat and food borne outbreaks as elucidated by CDC statistics. HACCP has provided the impetus to the FSIS/Industry partnership to identify hazards and interject control measures to promote the twin goals of food safety and public health. Unfortunately, microbial testing and its lab results have come under intense criticism in recent years, and its pertinence in a HACCP plant with numerous interventions has limited usefulness in the eyes of many.

Validating the effectiveness of a plant's pathogen reduction system is best accomplished via a sizeable microbiological testing scheme, both by the agency as well as the industry. Just like agency-conducted baseline studies, a high degree of testing must be initially conducted. Testing frequency can be reduced as the lab results continue to prove a plant's success in preventing, eliminating and reducing pathogens. Several problems rear their ugly heads as a result of adverse lab results. The first question is how can pathogens occur (sometimes frequently) at plants which boast of having in use all the modern interventions known to mankind? Merely reciting a lengthy litany of the numerous interventions in place at a plant may be relatively meaningless and untested in the absence of a substantial volume of microbial testing lab results (all of which must be shared between FSIS and the plant involved).

A recent example of the potential disconnect between the existence of multiple interventions and lab results was seen during ConAgra's 19 million lb recall in 2002 and the OIG's 2003 report after its investigation of the recall. Prior to the recall, one ConAgra publication stated that a Colorado State University study "*….validated in-plant conditions at all ConAgra Beef Company plants"*. The publication stated "*Most importantly, the study resulted in a 6 log or 99.9999 percent reduction in pathogenic bacteria from the live animal to the chilled carcass, virtually sterilizing the carcass"*. In 2002, ConAgra notified its customers that its new Thermal Organic Rinse (TOR) intervention provided an additional 1 log reduction to its intervention system, which when added to its previous system now provided a 7-log reduction (99.99999%!). Subsequent to post-recall changes at the plant, an article appeared in Meatingplace.com on November 26, 2002 which reported "*The Greeley plant received 19 NRs since August* [2002] *for violations involving fecal matter on carcasses"*. Interestingly, the subsequent 2003 OIG report stated "*Data was available to both ConAgra and USDA in the period prior to the recall that indicated that E.coli contamination was becoming a CONTINUOUS* (emphasis added) *problem at ConAgra"*.

This disconnect has been observed at other plants as well, including the larger September 2002 recall of product from Wampler Foods/Pilgrim Pride, so ConAgra is certainly not unique. How can this dichotomy exist? How can a plant with an independently validated 7 log pathogen reduction system produce, according to the agency, ***"continuous"*** e-coli contaminated product? The mere implementation of interventions is no guarantee that they will successfully produce wholesome products. These situations clearly reveal that microbial testing is a necessary method of validating the efficacy of each plant's intervention system.

Therefore, any thorough FSIS attempt to identify risks associated with individual plants must place a high priority on a sizeable quantity of microbial test results. Furthermore, all test results collected either by FSIS or the industry must be shared on a real time basis with each other. It is also advisable that the industry instantly share all "Presumptive Positive" lab results with the agency, and to carry out further testing to determine either a confirmed negative or confirmed positive determination. Industry unwillingness to disclose presumptive positive results obviates FSIS access to or knowledge of these presumptive positive test results. The absence of finalized test results also circumvents the possibility of exposing pathogen failures in a plant. Plants which sincerely want to produce safe food will aggressively pursue any potential unsanitary practices in their plant, and proactively implement corrective actions to prevent recurrences. Failure to complete lab testing of presumptive positive samples prevents the scientific identification of serious plant deficiencies, virtually guaranteeing recurrences. Prematurely truncating lab testing and failure to notify FSIS of all lab test results prevents the agency from accurately determining the true risk associated with each plant's production system. The agency should implement a policy whereby any plant failing to continue presumptive positive test results to completed and confirmed lab results must be assumed to have greater risk. Likewise, plants which fail to divulge the presence of presumptive positive results to the agency must be assumed to have greater risk which justifies an increased FSIS surveillance. Such plants are afraid of enforcement consequences if the finalized results are confirmed positive. These plants lack a commitment to corrective action and safe food, and are more concerned with their ability to continue operations without implementing changes than they are with consumer health. As such, they must be considered to have more risk, which constitutes FSIS rationale required to implement Risk Based Inspection.

In the agency's technical paper entitled "*Measuring Establishment Risk Control for Risk-Based Inspection"*, the statement was made "*As part of the 1996 PR/HACCP regulation, the Agency embarked on a major initiative to more fully integrate microbiological testing into its food safety inspection program*". FSIS should embark on a sizeable increase of microbial testing at all plants prior to implementing a Risk-Based Inspection System. Microbial testing is at the very heart of any scientific attempt to truly assess risk. FSIS testing in 2005 was woefully inadequate to accurately identify risk at each plant. An independent review of agency-conducted sampling in 2005 provided via a FOIA concluded that the agency conducted approximately 8.8 tests at large plants in 2005, compared to 7.2 tests at very small plants. (These figures represent a 31% increase in agency sampling at very small plants compared to 2004, and a 38% increase at large plants). The plant volume/FSIS testing frequency comparison makes a mockery of any science-based meat inspection system. Plants which kill and/or process thousands of head daily were exposed to only 9 tests during the year, while very small plants with a handful of employees and miniscule production volume were sampled 7 times during the year. This biased sampling scheme assumes that large plants with multiple intervention steps are guaranteed to produce <u>safer</u> food, while very small plants with only one or two intervention steps are assumed to be relatively more likely to produce contaminated product.

Realizing that E.coli and Salmonella originate within animal intestines (and on hides), and realizing that the majority of small plants do not slaughter, the agency's proportionally higher incidence of sampling at very small plants stretches credulity. FSIS insulation of large plants from agency-conducted microbial testing which largely ignores production volume not only imperils public health, but also prevents an impartial and scientific determination of risk by plant. What we don't know won't hurt us……at the big plants.

FSIS has stated that it desires to conduct microbial testing "*as close to the consumer as possible*". At first blush, this appears to be a laudable pro-public health gesture. The agency has not admitted that this policy simultaneously justifies sampling as far away from the initial slaughter plant as possible.

FSIS has properly claimed from day one of HACCP that one size does not fit all, and that each plant is unique. Likewise, not all interventions are economically viable at all plants, nor are all interventions efficacious at all plants. Some in fact are counter productive at plants of various sizes. Large slaughter plants utilize fast chain speeds, so these plants have implemented numerous costly interventions such as hide-on washes, steam vacuuming, and lactic acid rinses (both pre and post-evisceration). These have proven to be extremely effective. These large plants subsequently break down the carcasses into vacuum packaged boxed beef within two days. In stark contrast, small slaughter plants oftentimes dry age their beef carcasses for 10-20 days before processing into retail cuts, eliminating the need to vacuum pack primals before processing into finished cuts. Numerous small plants which dry age carcasses have complained of the appearance of an unsightly mold-like growth on aging carcasses which had previously been sprayed with lactic acid on their kill floors. This growth had never been observed prior to the implementation of the lactic acid carcass spray. FSIS' historical suggestion (in many cases insistence) that lactic acid rinses be implemented at small plants has unwittingly spawned an unanticipated food quality issue. Since HACCP is a living, ever-changing entity, a mid-stream change in FSIS attitude toward the supposedly universal efficacy of lactic acid rinses in all sizes of plants must be revisited.

Peer-reviewed scientific articles have been written which have validated the efficacy of other intervention steps available to small slaughter plants. Effective and validated interventions include hot water washes (which was ConAgra's previously-mentioned Thermal Organic Rinse), intensive hand trimming (not possible at high speed chain plants), and dry aging of carcasses for extended periods.

Should the agency downgrade small slaughter plants which don't utilize lactic acid sprays on their kill floors, assuming that they therefore have a higher degree of risk, thus justify increased surveillance under RBI? Should FSIS determine that large plants have a higher degree of risk because they don't hand trim carcasses extensively on kill floors or dry age carcasses for prolonged periods? The obvious answer is NO. Generally speaking, the higher production volume plants must utilize a higher number of automated intervention systems to produce consistently clean products. Conversely, lower volume plants

generally experience more labor intensive interventions in their comparatively snails-pace production lines.

Therefore, the large or small number of interventions utilized at individual plants cannot be assumed to be directly proportional to the plant's success or failure to produce safe meat. Again, the plant's success or failure can be scientifically validated via microbial test results which provide indisputable evidence, not subject to individual interpretation of theoretical assumptions made in individual HACCP plan designs.

Do all interventions consistently work, and are all interventions implemented as claimed in all HACCP plans? Dr. Daniel Engeljohn recently told columnist Bernie Shire that some plants are not doing what their HACCP plans claim, a likely cause for ongoing Salmonella failures in finished products. Likewise, if a plant's implementation of interventions is faulty, or the plant fails to utilize the claimed intervention(s), the continued production of unsafe meat should be anticipated.

FSIS should not assign a higher compliance rating to plants which utilize numerous interventions and downgrade plants with fewer interventions. One size does not fit all. Regularly scheduled FSIS verification microbial test results, coupled with plants' validation test results prove if a plant consistently produces wholesome meat, regardless of the number of interventions implemented by the plant.

HACCP design can portray an apparent fail-safe system, but the success or failure of HACCP implementation can be easily proven via verification/validation microbial test results. One or more adverse lab reports might suggest a failure in HACCP design and/or implementation. This is the point where additional or refined intervention steps are necessary to bring a plant's HACCP system into compliance with PR/HACCP imperatives. It is scientifically untenable for FSIS to mandate or suggest that plants incorporate a minimum number of interventions or be charged with HACCP plan design inadequacies, and/or be assigned additional FSIS personnel to monitor this allegedly deficient plant because of artificially determined higher "risk".

A conclusion of the intervention discussion is that a plant which utilizes six interventions may experience recurring production of pathogen-laced meat (history has proven this), while another plant which uses only one intervention may consistently produce safe meat (history has likewise proven this). Ultimate compliance is NOT proven by incorporating numerous interventions into a HACCP plan (they may certainly help), but by verification/validation microbial testing of products subsequent to the interventions.

This thinking was superbly addressed by Dr. Dell Allen who at the time was with Cargill-Excel. In May of 2004 Dr. Allen said the following about testing: *"What I can tell you now is that the intensity of effort in our plants has really increased in the last 18 months, and that's due to finished-product testing. There's no where to hide when you do it. Finished product testing is the surest method to know whether you've got H7 in your products or not. When we first started doing it we thought our systems were pretty good. Finished-product testing showed us we were not as good as we thought we were"*. Every

plant is understandably proud of their HACCP plan and interventions, concluding that their systems are pretty good. Testing validates or disproves their conclusions and should not be avoided.

Theoretical design of HACCP plans must grant supercedence to microbial testing. If FSIS emphasizes HACCP design (via suggesting an artificial minimum number of interventions) rather than placing more emphasis on test results, HACCP discussion will bog down in theory……..and pathogens. Academic students achieve success only by successfully passing numerous real-life tests; HACCP plans must experience the same testing gauntlet. Numerous microbial test results validate the success of HACCP interventions, but numerous interventions will not guarantee successful test results. Some shiny and expensive dish washers are lemons, as are some flashy and professionally designed HACCP plans. When FSIS assigns "Risk Factors" to plants, the agency should ascribe relatively minor significance to the number of interventions at individual plants, since some interventions my be superfluous in nature, some are redundant overkill, and some are inadequately implemented at individual plants. Conversely, the agency should ascribe major significance to test results when determining the "risk" existing at each plant. Real life results should always trump theory.

Besides the interventions previously listed, the number of additional interventions available to small plants is limited. Other interventions include:

1. Irradiation. This option is not viable at small plants, nor at large plants without outsourcing.
2. Fully Cooking. The vast majority of meat shipped into commerce from small plants is raw, not fully cooked. Retail meat markets, HRI, and consumers demand raw meat products in much greater quantity than fully cooked products.
3. Chemical interventions, such as lactic acid sprays, acidified sodium chloride, and acidified calcium sulfite. The substantial financial outlays required to implement such systems are not viable for very small plants, as well as many small plants. This equipment would be utilized with reduced frequency at these smaller plants, in fact would sit idle on many days.
4. Rendering. While this option would indeed remove all risk, it would also empty our meat supply pipeline.
5. Plant closure. While this would enable the agency to reduce its payroll costs, the financial impact on thousands of American cities would be unconscionable and unjustified. Furthermore, the source of the contamination would continue to operate in the lack of any corrective actions, further imperiling consumers.

Even if all small down line, further processing destination plants would incorporate several interventions, effective agency-mandated corrective action at the plants where the pathogens were **introduced** would be adroitly avoided.

Small, down line further processing plants effectively fill the role of "filters" in the meat production/inspection environment. Microbial test results at these small plants filter out,

or expose the presence of pathogens, directly benefiting public health. As such, the agency should consider increasing its microbial testing at small plants, but only when coupled with the requirement that copious source evidence be documented prior to and during sample collection. Unjustified closure of small plants unnecessarily removes this valuable "filtering" mechanism from the food production/inspection environment.

Any discussion regarding microbial sampling always leads to the related issue of tracebacks to the origin of contamination. Numerous agency releases have provided agency endorsement of tracebacks. Agency implementation of policies that successfully protect the public from food borne outbreaks require FSIS ability to scientifically and expeditiously identify the plants which are the true origin of contamination. Simultaneously, this identifies the plants that represent a veritable risk to consumers. FSIS success also requires FSIS to aggressively embrace the need to utilize enforcement actions at these plants where contamination originates. If the agency continues to focus its enforcement actions at hapless destination plants rather than the noncompliant source plants, this bias reveals agency failure in both its design and implementation of HACCP-style agency involvement.

If RBI is successful, FSIS will be enabled to identify plants with recurring risks, requiring corrective action which would then benefit public health. FSIS could also reduce its number of employees, since its enforcement actions would be primarily dedicated to the one noncompliant source plant rather than redundant and unnecessary regulatory actions against the dozens of destination further processing plants. The only "guilt" associated with these down line, further processing plants often is their unwitting and legal purchase of previously contaminated meat which arrived at their plants in containers bearing the official USDA Mark of Inspection. If FSIS is unwilling to consistently conduct tracebacks to the true origin of contamination, RBI will fail. Simultaneously, consumers as well as further processing destination plants will experience continued exposure to unnecessary risks, which RBI should theoretically ameliorate.

A successful RBI system must by definition identify the plants which fail to prevent, eliminate or reduce pathogen risks, and would require the true source plants to implement effective corrective action to prevent recurrences. Therefore, a successful RBI system must include a massive agency commitment which enables, in fact demands tracebacks to the true origin of pathogen-laced meat.

Consumers share some responsibility via proper handling and cooking of foods, in part by preventing cross contamination. Further processing destination plants are responsible for not **introducing** pathogens into their products. Unfortunately, under HACCP, these destination plants have been assigned primary responsibility by FSIS to purify previously contaminated meat purchased from USDA inspected supplier plants. The ability of these destination plants to (1) detect all incoming invisible pathogens and (2) totally remove the pathogen load is limited. These facts place more importance on FSIS detection of pathogens at the true origin of contamination, coupled with agency enforcement actions at the true source of product contamination.

Therefore, if FSIS is willing to conduct a meaningful frequency of microbial testing in order to determine true risks at each plant, the potential advantages will be minimized if not coupled with an aggressive commitment to tracebacks to the origin of contamination.

Another component of a plant's risk to consumers may be determined by the plant's history of previous agency enforcement actions assessed against the plant. Perhaps the central component of enforcement actions, certainly the most frequently utilized enforcement action is the agency's issuance of Noncompliance Records (NR's). To its credit, FSIS is considering major changes in its usage of NR's. Dr. Richard Raymond has broken with agency tradition and courageously suggested that NR's somehow be rated for severity of the violation, a long-awaited agency admission. Noncompliances were previously classified as Critical, Major and Minor, which allowed for a quick review to determine if the plant posed a significant risk to public health.

The current NR system, devoid of any meaningful relevant categorization of alleged deficiencies, considers all violations as equal, reducing the pertinence of NR's as an effective FSIS regulatory enforcement tool. This also reduces the agency's ability to scientifically determine the true risk at plants based on the sheer number of historical NR's at each plant. An NR can be issued when a lab sample exposes pathogen-laced meat at a plant, or it can be issued when an employee unwittingly forgets to initial one entry in a daily HACCP record which has zero impact on product wholesomeness. Such lumping together of noncompliances which have widely divergent impacts on public health should be excluded from a truly science-based meat inspection system.

Which of the two following plants should FSIS monitor more closely?
Plant A: Experienced 12 NR's last year, comprised of:

1. Six microbiological lab tests which detected the presence of E.coli 0157:H7.
2. Three instances of clerical errors on daily HACCP/SSOP forms.
3. Three instances of dirty food contact surfaces.

Plant B: Experienced 30 NR's last year, comprised of:

1. 25 instances of clerical errors on daily HACCP/SSOP forms.
2. Five instances of dirty food contact surfaces.

Current FSIS data collection procedures would conclude that Plant B, which experienced 150% more positives than Plant A, clearly justifies closer agency surveillance than plant A. This scenario would likewise conclude that plant A has a HACCP plan which more successfully produces wholesome products than Plant B based on the fact it experienced only 40% as many NR's. This conclusion virtually ignores Plant A's recurring production of contaminated product. Existing NR classifications do not allow the agency to quickly review NR totals and conclude which plants pose more risk to consumer health. While such clerical/administrative errors would constitute a major failure in an English major's PhD doctoral dissertation, they usually have no impact on a plant's ability to produce wholesome products. Since Safe Food was the agency's primary stated goal when introducing HACCP in the 1990's, both the agency's and the industry's central focus must be the production of consistently wholesome food, not the production of

consistently perfect clerical reports. We should be involved in a pathogen chase, not a paper chase.

Recent OPEER investigations of all USDA-inspected plants in Montana, coupled with the investigation's conclusions, publicly reveal the relative impertinence of NR's in the determination of risk at each plant. One focus of the investigation was the increase of NR's following the arrival of a new Front Line Supervisor in June, 2005. Some of OPEER's conclusions included the following statements:

> *"Recorded noncompliance by establishments in Circuit 2015 and in the majority of establishments in Montana* ***increased significantly*** (emphasis added) *after May 2005, when circuit management changed".*
>
> *"…increases in recorded noncompliance reflect improvements in Inspection practices and* ***not increases in actual noncompliance*** (emphasis added) *by establishments in Circuit 2015".*
>
> *"...there is no need for increased or enhanced inspection or enforcement measures in Montana or Circuit 2015 at this time".*

From a Risk-Based Inspection perspective, in spite of a "significant increase" in NR's issued in Montana plants, FSIS has made two startling conclusions:

1. The significant increase in NR's issued was not due to actual noncompliance.
2. The significant increase creates NO need for increased inspection.

How can this be? How can a state experiencing a "significant increase" in NR's not be subjected to increased agency surveillance? Because the agency realizes that many NR's represent absolutely no danger to public health. Also, because the agency realizes that circuit management can arbitrarily decide to mandate an increased issuance of NR's within a circuit and/or within individual plants, even though the plants are not guilty of increases in actual noncompliance. We can conclude that plants, circuits or districts with higher numbers of NR's therefore cannot be judged to be at higher risk than other plants, circuits or districts with a lower incidence of NR's. Therefore, the number of NR's at individual plants is relatively meaningless when determining the true risk emanating from each plant. According to OPEER's findings in Montana, the agency is admitting that the number of NR's is directly proportional to subjective biases residing within individual FSIS supervisory personnel, oftentimes totally unrelated to a plant's ability to produce wholesome product. NR's should be a meaningful management tool for FSIS, but current shortcomings have rendered NR's ineffective to determine a plant's risk to the consuming public. Until scientifically mandated changes are implemented within the entire NR system, the agency should place little emphasis on NR's when establishing risk at each plant.

FSIS should consider the creation of a separate and distinct agency form on which to record noncompliances which fail to rise to the level or severity of an NR, even to the

level of "Minor". Such noncompliances would include innocuous paperwork/clerical errors which have zero impact on public health or the company's ability to consistently produce safe food. This form might be termed an "Administrative Shortcomings Report" (ASR's). However, an appropriate level of accountability must be attached to ASR's to ensure that plants admit to the shortcoming and implement corrective action, often in the form of remedial employee training. Perhaps a second ASR which is linked to a previous ASR should trigger a "Minor" NR.

Another agency Risk Control Realm stated in the FSIS technical paper is "*In Commerce Findings"*. The statement is made "*….certain other findings in commerce evidence process control problems at the establishments that* ***shipped*** (emphasis added) *the implicated products*". As stated earlier, FSIS must place increased emphasis on the need to scientifically identify the source plant which introduced the contaminant, rather than limit and terminate its enforcement actions at down line further processing plants which merely further process previously contaminated meat purchased from supplier plants. Until the agency mandates and implements tracebacks to the true origin of contamination, a listing of plants which shipped contaminated product is grotesquely incomplete and lacking credibility for risk-based inspection determinations.

A contemporary illustration is a study of seven plants which have experienced recalls of E.coli 0157:H7 contaminated meat since May 5 this year. They are USDA recall numbers 15, 21, 24, 25, 26, 27 and 29. Five of these plants do not slaughter, plants whose production is strictly limited to further processing meat purchased from outside suppliers. FSIS should divulge its success in tracing back to the source of contamination at these five non-slaughter plants. In all likelihood, the agency made little or no attempt to trace back to the plants which introduced the pathogen, an intentional oversight which has existed throughout HACCP's history. FSIS circumvention of tracebacks invalidates the agency's attempt to ascribe risk to non-slaughter plants which have unwittingly further processed previously contaminated meat and shipped it into commerce in good faith. This intentional obfuscation of source evidence runs contrary to a truly science-based meat inspection system. The public is best served when the plant which introduced contamination into the meat chain is identified and required to implement corrective action to prevent recurrences. FSIS insistence to place all liability on the destination plant where contaminated meat is shipped and discovered contravenes the spirit of the Federal Meat Inspection Act and imperils consumers. It also unnecessarily exposes the industry to continued adverse public recall announcements because the agency intentionally avoided enforcement actions at the true source plants, and no effective corrective actions transpired.

However, a new attitude seems to be emerging at FSIS which seems to presage an agency desire to address contamination at the source. On February 24, 2006 FSIS conducted a public hearing entitled "*Advances in Post-Harvest Interventions To Reduce Salmonella in Poultry"*. Dr. Daniel Engeljohn stated "*And then importantly with the ground products – because the highest prevalence or at least the percent positives that we're finding is in the ground products. And it's the source materials that we want to focus on first* (emphasis added)*, and then we'll focus on those ground products"*. FSIS Dr. Patricia

Bennett likewise stated "*Now, the first focus of the Agency will be on the control of Salmonella in slaughter establishments* (emphasis added). *But that doesn't mean that the Agency is disinterested in the ground-product classes. But we do realize that you first need to control what's going on with the source materials before you're going to control what's going on with the ground-product classes"* (emphasis added).

This refreshing candor in the agency's willingness to admit that Salmonella emanates in slaughter establishments has not been publicly observed in agency discussions of E.coli issues, although both pathogens emanate from the same source, which is animal intestines and hides which are plentiful at slaughter plants but non-existent in down line, further processing plants which do not slaughter. These agency admissions pose additional questions, the answers to which could reveal FSIS future decisions.

1. Will FSIS likewise focus on slaughter establishments as likely sources of E.coli 0157:H7 contamination?
2. How can FSIS focus on slaughter establishments unless it embraces the need for sampling at the slaughter plants, as well as down line further processing plants?
3. Will FSIS continue to place sole liability for the presence of detected Salmonella and E.coli 0157:H7 at down line, further processing non-slaughter plants?

A conclusion to this discussion of the usefulness of "Commerce Findings" in establishing risk mandates that the agency leave no stone unturned in a scientific attempt to clearly delineate the true source plant which introduced contamination into products which are shipped into commerce. In the absence of unrestricted investigations into the true source of pathogen-laced products, true risk cannot be scientifically determined and assigned to allegedly deficient plants. Any discussion of "unrestricted investigations" requires an agency stance on the authority of field personnel to thoroughly document evidence necessary to conduct expedited tracebacks. HACCP has imposed artificial restrictions which limit inspector actions in plants, an integral component in HACCP mentality. Therefore, any attempt to liberate inspectors in their oversight of plant production actions constitutes an assault on the very heart of HACCP. Likewise, what is the agency's stance on the validity of company-generated records? Agency refusal to accept copious evidence collected and presented by agency field personnel as well as plant management should be classified as destruction of documentary evidence. Furthermore, when field-generated evidence is rejected by the agency, and agency headquarters personnel assume the right to rewrite history from their remote locations, this must constitute falsification of records. Until this variety of potential problems is addressed by the agency and official policies are issued which provide answers, "Commerce Findings" present limited usefulness if any in establishing risk by plant.

Another Performance Indicator listed in the agency's technical paper is "*System Tracking E.coli 0157:H7 (STEPS) Results*". The agency states "*An establishment that produces intact beef products (e.g. beef trim) and appears on the supplier list of one or more producers of raw ground beef products that have tested positive for E.coli 0157:H7. The agency* ***should*** (emphasis added) *take a closer look at establishments identified in this*

way". Realizing the enforcement tenacity the agency utilizes at down line further processing plants which experience positive microbial lab results, an unbiased agency should exhibit the same tenacity at plants which supply raw materials to these down line plants. Whenever a plant which produces intact beef products which ultimately result in adverse lab results at two or more down line plants, the agency **must** (not "should") initiate an immediate FSA investigation into production activities and HACCP design and implementation at the supplier plants. This investigation must not only monitor production lines, but also review results of all plant-conducted microbial test results (both presumptive and confirmed) as well as daily HACCP/SSOP records. If FSIS takes its legislative mandate seriously to protect the public from food borne outbreaks, the agency must aggressively conduct intensive investigations at such supplier plants.

Another Performance Indicator identified by the agency is *"Agricultural Marketing Service Laboratory Results"*. The agency technical paper further states *"An establishment that has one or more products test positive for E.coli 0157:H7 in the AMS school lunch testing program **may*** (emphasis added) *warrant enhanced inspection*". The fact that FSIS does not **mandate** enhanced inspection, even temporarily, at plants which have produced contaminated product for consumption by school children is without merit. Young people are in the category of consumers who are more at risk when consuming contaminated meat, justifying enhanced inspection via a mandated substantial increase of agency-conducted microbial tests at such processing plants. Young, elderly and immune-compromised people are at more risk. Some plants dedicate a substantial portion of their production to one or more of these three at-risk groups. In conclusion, plants which target one or more of these at-risk groups in their production and marketing efforts should be classified as higher risk, and FSIS must utilize a higher degree of oversight at these plants.

The agency technical paper entitled "*Measuring Product Inherent Risk for Risk-Based Inspection"* makes numerous references to volume of production as criteria to justify enhanced inspection. FSIS is to be commended for concluding that its initial volume variable requires a revision. The technical paper states "*….the volume multiplier and how it could be improved* (emphasis added) *to account for actual volumes of production of different products within a single establishment"*. Earlier in the agency's technical paper, the agency suggested a volume variable of 1.0 for very small plants, and a volume variable of only 2.0 for large establishments. This formative definition of volume variables lacks scientific credibility, presumably the reason for the agency's admission that improvement is required in defining risk involved with volume of production. Assigning only a 2.0 risk variable to a plant which processes thousands of beef daily while assigning a 1.0 variable to very small plants which do not process a thousand pounds a day constitutes a major bias in initial agency thinking, totally divorced from rational scientific protocol.

Insurance companies selling automotive insurance provide premium discounts for car owners which experience small annual mileage. Their reasoning is obvious: the lower volume mileage directly translates into lower potential risk. The same is abundantly true for meat plants with dramatically different production volumes.

Which plant constitutes more risk to the consuming public? A small spinach producer which markets to local consumers, or huge spinach production entities which ship their products both nationally and internationally? The current outbreak of E.Coli-contaminated spinach has now sickened 199 consumers in 26 states, and possibly more in Canada. 21% of these sicknesses have developed hemolytic uremic syndrome, a potentially lethal kidney disease. Some small meat plants don't have 199 total customers! Several meat recalls have also produced multiple sicknesses in dozens of states. We cannot deny that huge volume plants pose a much greater risk to the consuming public when compared to small and very small plants' production.

A major reevaluation of the agency's volume variables of 1.0, 1.5 and 2.0 must be accomplished if the agency places any credibility on the impact production volume represents when considering risk to the public.

In summary: RBI excludes slaughter-only facilities. However, if the agency (1) increases agency-conducted sampling, (2) demands and obtains access to all company sampling results (including prematurely truncated presumptive positive test results), and (3) be willing to utilize stringent enforcement actions at plants where pathogen contamination **originates**, non-compliant plants will not be insulated from RBI public health imperatives. This will require FSIS to voluntarily and aggressively embrace a legitimate, science based and unbiased commitment to trace backs to the true origin of contamination. A truly science based meat inspection system would mandate that no plants be considered immune from liability for the production of contaminated meat. While the agency is limiting RBI to processing plants and combined slaughter/processing plants, the advantages derived from an effective RBI system must have the authority to trace back to originating slaughter-only plants. FSIS must not be allowed to truncate trace backs to the source of contamination derived from evidence generated by an effective RBI system based on the definition that slaughter plants are not covered by RBI protocol. FSIS originally described HACCP as "Farm to Fork"; therefore, RBI must by necessity include trace backs to slaughter-only facilities when RBI evidence exposes that slaughter-only plants have shipped contaminated product into commerce. RBI must not be viewed as an attempt to insulate slaughter plants from accountability merely because FSIS has excluded these slaughter plants from RBI involvement. This fact must be clearly stated by the agency during these formative months of RBI design, long before RBI implementation.

FSIS has identified numerous components which have a direct impact on risk associated with individual plants' production of specific meat products. Some of these components such as production volume, product type such as RTE products, and historical results of microbial lab testing have unquestionable impacts on product safety, and by extension, potential risk to consumers. FSIS must refine and justify its definition and assignment of relative values to these various components. This paper has exposed numerous shortcomings with the agency's initial statements, many of which must be publicly addressed and a consensus reached prior to implementation of a science based RBI system. Because of the potential that a biased RBI system could be implemented, thereby

increasing risk to consumers, FSIS should utilize a deliberate and publicly debated environment prior to RBI implementation. Some variables such as microbial test results must experience additional agency base line studies to earn credibility for inclusion in establishment of risk assessments. All variables must focus on the true origin of contamination, rather than focus on further processing plants which inherit other plants' failures. Failure to identify the true origins of contamination virtually guarantees future recurrences, imperiling the consuming public.

Lastly, FSIS should create a committee to publicly debate the various components with perceived relevance to a RBI system. This broad based coalition should include but not be limited to FSIS personnel, equal representation from large, small and very small plants, unbiased scientists, consumer representatives, and microbiologists. Although the term of this committee will be brief, probably two years or less, the committee will dedicate substantial time to this issue and receive enormous input from various segments of the production to consumption continuum in America. Another advantage to a truly unbiased, science based RBI system would be increased confidence in American products from international customers who have been disillusioned with our products and closed their borders to our exports in recent years. Therefore, the conclusions of this committee, coupled with effective FSIS implementation, will benefit not only public health, but improve our Balance of Trade.

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