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Winonah Hauter

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

Docket No : FSIS-2006-0028

Transmitted via facsimile: (202) 690-6519

Dear Ms. Blumberg:

On behalf of the consumer group Food & Water Watch, I welcome this opportunity to comment on the proposals on implementing risk-based inspection in processing being advanced by the Food Safety and Inspection Service (FSIS). While we make the following comments on the proposals, we do so even though we are unsure of what the final risk-based inspection system model will look like.

At the outset, I would like to express our displeasure over the Agency's lack of candor in this entire process. For example, Agency officials continually make the assertion that every processing plant is visited once per shift by an FSIS inspector. That is clearly not the case, as we have discovered through the Agency's own documents and comments made by Agency inspection personnel during the "employee feedback sessions" conducted earlier this year. We will discuss this point further below.

Agency management officials also assert that non-compliance reports (NRs) are written by inspection personnel for every regulatory violation. The actual number of NRs written is much lower for several reasons: First, due to inspector shortages, inspectors may not be able to visit all of the plants in their assignments, so inspectors may not be present to document violations. Second, due to extra workloads carried by some processing inspectors, they may not have the time to document all regulatory violations. Third, inspectors are often "gagged" into not writing NRs.

Agency officials were less than forthcoming about a USDA Inspector General audit report that they received on September 28, 2006 – some two weeks prior to the public meeting

on risk-based inspection – that was critical of the Agency's sampling procedures for *Salmonella*. We believe this report is crucial to this entire discussion of risk-based inspection.

Furthermore, we believe that the Agency has restricted the participation of inspection personnel in this entire process. The Agency claims that their employees are one of the "pillars" of food safety, yet this pillar has been conspicuously absent from the discussions. The Agency conducted "employee feedback sessions" using questionable methodology, convened "employee town hall" meetings at times when most inspection personnel could not participate, and provided very limited opportunity for employees to participate in the October 10-11, 2006 public meeting on this issue. We firmly believe that inspectors' input would provide invaluable information regarding improvements in the inspection process.

In these comments, we address the two foundational papers published by FSIS on July 19, 2006, regarding the Agency's proposal for Risk-Based Inspection: "Measuring Product Inherent Risk for Risk-Based Inspection" and "Measuring Establishment Risk Control for Risk-Based Inspection." The Agency has explained that the papers describe the Agency's approach to using current data to assess the two types of risk that will be considered when allocating resources under its RBI proposal.

A. Measuring Product Inherent Risk

The position paper "Measuring Product Inherent Risk for Risk-Based Inspection" makes it clear that there have been extensive deliberations and research efforts on RBI at the Agency since at least May 2001, from which consumers and frontline FSIS personnel have been excluded. Despite the fact that the Agency has discussed, in general terms, its intentions to pursue significant modifications to its inspection program with the National Advisory Committee on Meat and Poultry Inspection, these previous efforts had never been specifically described or presented to that group or publicly in any other forum.

The paper reports that internal Agency working groups worked with the Research Triangle Institute and Texas A & M to assess product risk, but does not describe the instruction or guidance presented to these groups. The paper also reports that the Agency conducted four "expert elicitations," but no information is provided about the experts involved, their professional affiliations, or the assumptions involved in doing the product risk rankings. The paper concludes by saying that analysis showed general agreement among the experts.

After consumer groups informed RESOLVE of our concerns, the Agency published several other papers at its website. Rather than clarifying, these papers raised even more serious concerns about the final expert elicitation. A September 2005 memo[1] identifies the experts involved. Four had primary ties to large corporations – Oscar Meyer, ConAgra, Keystone Foods, and Better Built Foods. Most of the rest were scientists from land grant universities with industry ties. Only two were affiliated with public health institutions, the Centers for Disease Control and FDA's Center for Food Safety and Applied Nutrition. This memo also identifies the results with some specificity, demonstrating that there seemed to be some serious disagreement

[1] http://www.fsis.usda.gov/PDF/Elicitation_Memo_092205.pdf

among the experts regarding some of the products. For example, while the median level of risk listed for ready-to-eat dried poultry was 2.0, the maximum assessed by one expert was 300,000,000.

The memo also includes the instructions to the experts, which include assumptions for estimating the level of risk of illness posed by each product, which seemed to be inappropriate, or which required knowledge experts might not have, including:

> "Do not account for products that are prepared (sliced, ground, cooked, etc.) at the retail or institutional level. Consider preparation only by the producing plant and the consumer.... The incoming source material comes from a ... firm with average or typical food safety controls....The consumers are healthy adults."

Commentary from the public at the October 10 and 11 public meeting on RBI was so critical of this expert elicitation that FSIS officials suggested that they would consider doing another one and would include some independent experts on the panel. Therefore, we assume that more extensive comment on this paper is unnecessary at this time.

B. Measuring Establishment Risk Control

In its position paper, "Measuring Establishment Risk Control for Risk-Based Inspection," the Agency identifies five "realms" it will consider as it decreases inspection in certain plants: food safety system design, food safety system implementation, pathogen control, in-commerce performance, and other performance indicators. (At the October 10 and 11, 2006 public meeting on RBI, the Agency identified food defense plans as an additional realm, but public comment was largely negative and Agency statements at the NACMPI meeting indicated that the Agency has dropped this from consideration. Therefore, we offer no comments on food defense plans at this time.)

According to the Measuring Establishment Risk paper, the Agency will use these factors for assessing risk at "approximately 5,200 federally-inspected meat and poultry processing establishments for which risk control effectiveness must somehow be measured and monitored for RBI." The Agency also makes clear that assessing risk must be a continual process:

> "[F]ood safety system process control effectiveness can significantly change in an establishment over the course of weeks. This means we need to *re*-measure risk control effectiveness frequently.
>
> FSIS plans to regularly – perhaps monthly – retrieve data for the five factors for every meat and poultry processing establishment for a recent period of time - or "window."

There are significant data gaps in the information the Agency maintains in each of the five realms which make the Agency's plan to use the data to approximate a real-time risk assessment for each of the 5, 200 plants unrealistic.

Food Safety System Design

This realm will consist of the results of Food Safety Assessments (FSAs), which are periodic reviews performed by the Agency's Enforcement, Investigation, and Analysis Officers (EIAOs). The following problems with the data decrease the Agency's ability to use this realm effectively to make real time assessments.

FSAs are conducted so infrequently that the Agency should not rely on them to provide an up-to-date picture of an establishment's food safety system. At the public meeting on RBI, Dr. Barbara Masters reported that FSAs are performed in each establishment every three years, on average. One inspector told us recently that it is not unusual for plants to change their HACCP plans, and that one plant he covers routinely changes at least one of its HACCP plans each month. Because establishments are free to change their food safety systems whenever and as frequently as they choose, the results of an FSA may be a reliable indicator of risk for only a very short time.

Additionally, FSAs are often a catalyst for establishment management to change its food safety systems. Therefore, by design, FSAs may trigger their own irrelevance in estimating the risk posed by the establishment even several weeks later. Before FSIS relies on an FSA to determine risk, the Agency must determine that the findings are still relevant.

We also have concerns, however, about even those FSAs that *do* reflect an establishment's systems. Many processing plants have an individual HACCP plan for each of the many products they produce. For example, one inspector recently told us of a plant that has over 20 HACCP plans. Although the Measuring Establishment Risk paper quotes the directive for EIAOs, which instructs that they consider "all food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment,"[2] another inspector told us that in a recent review, an EIAO examined only three of the establishment's many HACCP plans. At the recent public meeting on RBI, Dr. Barbara Masters acknowledged that EIAOs only review a "representative sample" of an establishment's programs. Obviously, under RBI, the Agency will schedule one level of inspection for the whole establishment, and will not limit any decrease to only those particular products that have been reviewed. Therefore we are concerned about the potential threats to public health that may result as a result of relying on this type of sampling, which may overlook product lines that pose additional risk, to decrease inspection in some processing plants.

[2] FSIS Directive 5100.1 "Enforcement, Investigation, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology" 9/30/05 pg. 1. http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.1.pdf

FSAs are a relatively new assessment tool used by the Agency and have not been reviewed for consistency by the Office of Inspector General or Government Accountability Office. We've heard from several inspectors and small plant owners, however, about plant managers who have changed their HACCP plans in response to one EIAO review, only to have those same plans rejected by the next EIAOs sent to the plant. We are concerned that this indicates that FSAs may not have a reliable scientific basis. We've also been told by FSIS supervisory officials that the EIAO training is not yet capable of ensuring consistent determinations. Until all of these difficulties are squarely faced, the Agency may be putting consumers at risk by relying on current FSAs to decrease inspection at a particular establishment.

Finally, FSIS has experienced serious budgetary problems since at least the spring of 2006. We have been informed that one result of this shortfall is that EIAOs were temporarily "grounded" to avoid the travel expenses incurred in conducting an FSA. Therefore, the acknowledged average of one FSA per plant every three years, has been even more attenuated and the value of this realm of information decreased.

Food Safety System Implementation

This realm will consist of the Agency's inspection data recorded in its Performance Based Inspection System and noncompliance records (NRs). The following problems with the data decrease the Agency's ability to use this realm effectively to make real time assessments.

At the present time, there are problems with FSIS' use of its PBIS database. The USDA Inspector General, in a November 2004 audit report, stated the following about the PBIS database:

> "Due to the lack of controls noted during our audit, FSIS cannot be assured that PBIS is complete, accurate, and reliable. As a result, FSIS management may not have the information it needs to effectively manage its inspection activities. Without effective controls over data integrity, the PBIS system may be an unreliable repository that gives FSIS management a false sense that inspection activities are adequately carried out and sanitation of plant operations is accurately reported."[3]

According to the Measuring Establishment Risk paper, NRs are records of instances in which:

> "establishments fail to implement documented features of their own systems or fail to meet explicit regulatory requirements. [They] document in the Agency's Performance Based Inspection System (PBIS) the time, date, and nature of *any* [emphasis not in original] regulatory noncompliance. PBIS is consequently one of the most important sources of information with which the Agency can assess how well establishments

[3] http://www.usda.gov/oig/webdocs/24501-01-FM.pdf

> control food safety risks. NRs – at least some NRs – indicate how consistently establishments comply with food safety regulatory requirements."

A footnote to the last sentence explains the qualification:

> "Some NRs document noncompliance with non-food safety requirements. . . . Still other NRs document noncompliance with recordkeeping or other requirements believed to have little bearing on food safety."

If, as the paper claims, NRs documented the details of *any* regulatory noncompliance, the Agency would have a much more accurate picture of an establishment's implementation of its food safety controls than, in reality, it does. There are numerous gaps in the data concerning plant performance that NRs should represent, because many violations are either not witnessed by government inspectors, or even when they are witnessed, they are not documented on an NR.

Inspection in processing plants has been interpreted to mean "daily" inspection. Many processing plants are part of "patrol" assignments – a group of plants that will be covered by one inspector who travels between them during the shift. The majority of these patrols include more than two establishments (we are aware of some that include up to seven, but some assignments may include more) so inspectors will be there for less than half of the production day, but the Agency views even the briefest appearance as satisfying the mandate of daily inspection. Obviously, any violations that occur during the inspector's absence are not recorded. Additionally, even violations that *are* observed may not be recorded because of the time it takes to accurately complete the NR form. Inspectors say that, on average, it takes about an hour to complete one NR because of the research of the regulations and the establishment's food safety plans that are required. When inspectors notice several problems in a plant, they may determine that the best way to protect public health is to verbally inform plant management, get them to agree to an acceptable corrective action, and then move on to inspect other plants on his or her patrol that may also routinely have problems complying with the regulations.

This problem is exacerbated by the chronic inspector shortages that occur throughout the country. During the summer of 2006, Agency records revealed significant vacancies in every district from which we were able to get records. We got partial information from inspector whistleblowers after the Agency failed to release this information publicly.[4] The vacancy rate was 9% for the Jackson District, 10% for the Atlanta District, 11% for the Raleigh District, and 13% for the Denver District. One Agency official recently admitted that the New York City area typically has a 25% vacancy rate. For patrol assignments covering 59 plants in the Chicago District, records showed a vacancy rate of 70%!

When one inspection position is vacant, other inspectors have to assume responsibility for those plants, resulting in inspectors being "doubled or tripled up." This summer we learned

[4] This evidence is not exhaustive – we've learned of most of it from inspectors who require that we protect their anonymity because they fear retaliation and reprisal from Agency officials who do not want this information to be made public.

of one inspector in the Albany District who was covering 18 plants for many weeks. Recently we learned of an inspector in the Philadelphia District who has been covering 26 plants for several weeks, at least. Obviously, when inspectors are doubled or tripled up they don't have enough time even to visit all of the plants they are supposed to cover that day. They are therefore even less likely, and it would arguably be irresponsible for them, to instead spend an hour documenting one violation at one plant.

Lack of sufficient time to complete documentation occurs not only in small processing plants but also in some of the largest slaughter and processing establishments in the nation. Processing inspectors in those facilities are often pulled from their own inspection tasks to fill in vacant slaughter inspection assignments at the same plant. During those days, the processing inspection tasks will not be performed. Agency policy exacerbates the problem by prohibiting processing inspectors from documenting any violations they see while they are covering a slaughter position, even though they would be able to document the identical violation if they observed it while performing their processing inspection duties. So, no NRs will be written for violations that are observed by processing inspectors who are filling in vacant slaughter assignments. During the summer of 2006, the slaughter vacancy rate was 8% for the Philadelphia District, 9% for the Atlanta District, 10% for the Jackson District, 11% for the Chicago District, 12% for the Denver District, 14% for the Raleigh District, and 16% for the Minneapolis District. Processing inspectors would be diverted from their tasks to fill in for these missing slaughter inspectors.

As a result of the aforementioned, absence of evidence cannot legitimately be construed as evidence of absence. That is, a lack of NRs documenting violations at an establishment should not be interpreted, for purposes of measuring establishment risk, to be evidence of historical compliance with the regulations. At a minimum, the Agency would at least have to be able to determine which establishments received less than standard inspection coverage and interpret the dearth of findings appropriately. Although USDA's Office of Inspector General has repeatedly recommended that the Agency keep records of instances when inspection tasks are not performed, for example, specifically because of lack of inspector time, the Agency has failed to do so. (The Agency did keep such records until 1997, and the PBIS system is capable of recording the information.) Therefore, the Agency will not accurately be able to determine systematically where a lack of NRs clearly indicates a history of compliance and where it may, instead, signal an establishment that has received decreased oversight. If the Agency interprets the current data without controlling for these factors, it might, ironically, decrease inspection at an establishment that has been without adequate inspection oversight for sometime and consequently has few NRs, in order to increase inspection at an establishment that has been improving its operations under a more constant and watchful inspection presence. If the Agency seeks local anecdotal information or establishes some other system to identify establishments that have few NRs because of a history of decreased inspection, the Agency should take a precautionary approach which prioritizes public health, while extrapolating for the missing information.

The Agency plans to isolate NRs that deal with food safety issues. As previously mentioned, it may determine that classes of NRs are not food-safety related, and mentioned NRs for recordkeeping violations as an example. Although the Agency has yet to be specific about

its analytic parameters, at the public meeting, officials indicated that some Sanitation Standard Operating Procedures (SSOP) and HACCP NRs would be presumed to be food safety. It would be a mistake for the Agency to disregard whole classes of NRs on the mistaken assumption that they all have no impact on food safety. We offer the following two examples of NRs written when inspectors discovered and prevented prohibited tissues from cattle over 30 months old from entering the food supply, which could pose a BSE risk to the public. The following "recordkeeping" NR was written at one of the largest beef slaughter facilities in the world:

> "At approximately 3:15 on 10/14/2004, Inspectors [redacted] witnessed 5 beef heads presented for inspection with the third and fourth incisor's present. These heads were not identified with the appropriate markings indicating that the carcasses (sic) age was 30 months plus. SSOP monitoring employee [redacted] and slaughter floor supervisor [redacted] were notified immediately and took action by identifying carcass's (sic) as 30 months plus and condemning affected offal and heads. . . A check of the establishments (sic) generated SSOP and HACCP records showed that corrective and preventive actions had been addressed. At 09:20 on 10/15/2004, [redacted] observed a head presented for inspection with the third and fourth incisor's (sic) present not identified as a 30 month or older carcass. [Redacted] slaughter supervisor, was notified and affected carcass and parts were appropriately identified and/or disposed of.
>
> [Additional information is provided which demonstrates that the plant was responsible for identifying and segregating these 30 + animals which is required under the regulations to prevent "specified risk materials" which could transmit Mad Cow disease, from reaching the public].[5]

The following "Product – Misbranding" NR was written at another of the largest beef slaughter facilities in the world:

> "At 0015 on 2-06-04 I went to the production floor to observe end of shift operations. As I passed by the [plant location details redacted] I noticed that an employee was emptying the contents of a cardboard combo into the auger that takes product to the edible rendering area. I noticed that a large portion of the contents of this combo were vertebral columns and that the columns were painted with blue ink. The vertebral columns where (sic)being co-mingled with other bones and edible product. Several of the painted vertebral columns were approximately halfway up the incline of the auger [redacted] which is an auger that takes product directly up to the edible rendering room."
>
> [The NR continues by stating that products with blue ink were to be diverted by company employees from edible rendering in one of several

[5] Noncompliance Record 11-2004-7698 at Establishment #235, a large beef slaughter plant. Obtained *via* Freedom of Information Act request.

ways. The inspector investigated and confirmed that these were not so diverted and would have been incorporated in products which could reach the human food chain, had he not intervened.][6]

The Agency has implemented new data analysis methods that might enable it to identify anomalies such as these NR pertaining to BSE, rather than grouping them with all others so coded. The Agency implemented these new methods when an OIG audit demonstrated that the Agency's data analysis abilities were completely unable to locate all NRs pertaining to BSE. It is unclear whether the Agency, with its improved system is now capable of identifying all potential food safety NRs that might be categorized under a code that the Agency may classify as non-food safety related. The Agency should not disregard categories of NRs or any individual NR without the ability to perform an accurate and thorough analysis of whether there was a potential food safety impact.

Pathogen Testing

This realm will consist of findings from the Agency's several pathogen testing programs. The following problems with the data decrease the Agency's ability to use this realm effectively to make real time assessments

The September 28, 2006 USDA Inspector General audit report entitled, "Review of Pathogen Reduction Enforcement Program Sampling Procedures," clearly illustrated that the Agency has an incomplete data base for its *Salmonella* testing program. The Inspector General identified as many as 865 establishments nationwide under FSIS jurisdiction that have no testing data for *Salmonella* and might be subject to regulatory sampling for this pathogen.[7] This represents a possible understatement of sampling sets of over 58 percent. While the Inspector General conceded that some of these establishments might be excluded from testing requirements due to regulatory exemptions (as they found in the Chicago District), there nonetheless seems to be a significant data gap that the Agency needs to address. The Inspector General also pointed out that the Agency lacks written justifications for the regulatory exemptions for pathogen testing it has adopted. We believe that the Agency also needs to address those omissions.

Some processing establishments are subject to no Agency microbial testing program. The Agency conducts a series of tests under its *Salmonella* compliance program in processing establishments that produce ground beef, chicken or turkey. It conducts *E. coli* O157:H7 tests in establishments that produce ground beef. It conducts *Listeria* sampling in establishments that make ready-to-eat products. Therefore, according to statements at the October 2006 public meeting, approximately a quarter to a third of establishments will not be tested, and consequently the Agency will have no information about them from this realm.

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[6] Noncompliance Record 15-2004-1556 at Establishment #9268, a large beef slaughter plant. Obtained *via* Freedom of Information Act request.

[7] USDA Office of Inspector General Report No. 24601-0007-Ch "Audit Report: Review of Pathogen Reduction Enforcement Program Sampling Procedures" September 2006, p. 20. http://www.usda.gov/oig/webdocs/24601-07-CH.pdf

Even at establishments that are tested, testing occurs only sporadically and the most recent results in the database may not accurately reflect the current level of process control. The Agency conducts *Salmonella* compliance sets in plants approximately once per year. Once the last in the series is completed, the establishment might not be tested again for a year or more. Microbial testing results demonstrate that process control can be lost very quickly, and under the Agency's current testing scheme, a public health threat could exist at a plant for quite some time, while the Agency is still operating on the previous acceptable results. Consumers have advocated for more testing but the Agency's program is still conducted in this sporadic fashion.

The Agency has recently increased its *E coli* O157:H7 testing at ground beef plants, but still does not average even one test per month. Even assuming that the Agency's program would discover any plant producing contaminated product (an assumption which exceeds the current capabilities of the testing program) a public health threat could arise which would not be reflected in this realm for quite some time. The largest processing plants produce over a million pounds of ground beef and ground beef components daily and even a temporary lapse of process control could result in scores of injuries and death.

In Commerce Findings

While the information in this realm would not be irrelevant, it is not collected on a systematic basis and therefore would not be suitable for making comparative assessments of establishments' relative risks. Given current traceback measures, conclusively identifying establishments that produce dangerous product is a very rare and fortuitous occurrence at best.

Other Performance Indicators

The information in this realm will include information, "not captured elsewhere" about enforcement actions at particular establishments, as well as other indicators of lack of pathogen control. Again, this data would not be irrelevant but, without more information, we don't anticipate that this realm will contain much additional data.

Given the information currently available to us, we anticipate that even the sum total of all data available to the Agency in all of these realms, will not be adequate to make sound decisions about an establishment's risk and decreasing inspection in plants for the purposes of implementing a radical new inspection regime nationwide. Although the Agency asserts in the "Measuring Establishment Risk" paper that there is "a large amount of data for our five factors,"[8] there are significant gaps in each of the realms. As a result, we assume that for many, if not most, establishments, FSIS will not have enough current information to approximate the risk posed. These gaps are due to everything from systemic flaws (like chronic shortages of inspectors resulting in a lack of documentation), to time lags (resulting in establishment reviews that are years old), to inadequate science (preventing the identification of connections between human illnesses and their source).

[8] Measuring, pg. 7.

Even for establishments for which FSIS has the most data, much of it will be largely duplicative of information recorded in the other realms. For example, if Agency testing detects E. coli 0157:H7 in ground beef at an establishment, this will be recorded in the Pathogen Control realm. Or if a consumer gets sick from E. coli O157:H7, notifies the Agency, and the Agency verifies that the illness is linked to a particular establishment (which will be a very unusual event), that information will be recorded in the In Commerce realm. In either case, a NR will likely be written as a result, which will be recorded in the Food Safety System Implementation realm. This E. coli O157:H7 finding is also likely to trigger an FSA, which will be recorded in the Food Safety System Design realm. While the Agency will have data for the one establishment in a number of realms, the gravamen will be the same for each and may be limited to a single event.

We believe the Agency will have to make significant improvements to its on-going data collection efforts, and then collect data for some time, in order to make reliable estimates of the relative risks posed by particular establishments. It remains to be seen whether the Agency can develop systems capable of accurately and frequently updating an establishment profile. Currently, however, it is very clear that the Agency does not have the necessary data to pursue its plans to decrease inspection at numerous plants on a risk-based theory.

Other Concerns about the Agency's Proposals

We view the Agency's current proposals as an opening salvo to attack the "continuous inspection" standard that has been in effect for over 100 years. We believe that the Agency lacks the statutory authority to eliminate daily inspection in processing. The Under Secretary for Food Safety has been quoted in the media as advocating "virtual" inspection whereby plant management can merely e-mail or fax daily production records to FSIS inspection personnel rather than require official on-site visits on a daily basis.[9] We have also learned that the Agency was exploring allowing Canadian meat and poultry products into U.S. commerce that had been subjected to less-than-daily-inspection, which we view as a back-door attempt to eliminate daily inspection in the United States.

The Agency has also been covertly altering inspection assignments by instituting "team inspection" as a way to prepare for the implementation of risk-based inspection in processing.[10] The Agency has not shared its complete plan on team inspection with stakeholders and we believe that it is "placing the cart before the horse" since its risk-based inspection proposals are so flawed.

Even though there are serious flaws with its risk-based inspection proposals for processing, the Agency has already begun the process of discussing implementing risk-based

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[9] Morton, Joseph "USDA Looks at 'Virtual' Inspections" *Omaha World-Herald,* October 23, 2006.

[10] USDA Food Safety and Inspection Service "2007 Explanatory Notes: Hearings before the United States House of Representatives Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations, Part 1" March 8, 2006. p. 315.

inspection for poultry slaughter. We believe that this is premature and we contend that the Agency lacks the statutory authority to do so.

We also believe that the Agency has missed opportunities to communicate with Congress about the need for additional funding for inspection resources. We can only surmise that since the Agency has not requested the necessary resources to meets its statutory obligations, it will use inspector shortages as an excuse to implement a risk-based inspection scheme which we will believe will diminish consumer protections against contaminated food.

Finally, it appears that the only opportunity for the public's involvement with this process will be through this stakeholder process and comment period, as at least one news article indicates that FSIS plans to roll out its RBI system sometime during the first quarter of 2007. The article also indicates that this change would be in the form of an internal directive or notice to inspection personnel, without providing notice in the *Federal Register* and opportunity for public comment.[11] This is unacceptable. As noted, we have not has adequate opportunity to provide comments on RBI because we do not know what the final program will entail. As the Agency is surely aware, insofar as RBI is likely to be inconsistent with its current approach for conducting inspections or encodes a substantive value judgment on what products and product types are to be deemed adulterated, the Agency is required under the Administrative Procedures Act to engage in notice and comment rulemaking. We therefore request the agency engage in such rulemaking as required under the law.

For all of the reasons stated above, Food & Water Watch vehemently opposes all of the Agency's risk-based inspection proposals. To follow Dr. Raymond's pattern of using sports analogies to describe this program, and in recognition of the all Midwest World Series: This RBI is a strikeout.

In light of the recent announcement regarding an extension to the deadline for the submission of comments on this issue, we reserve the right to submit supplementary comments should additional information become available in the future.

Should you have any questions regarding our comments, please feel free to contact me at (202) 797-6550.

Sincerely,

Wenonah Hauter
Executive Director

[11] Sugarman, Carol "USDA Food Safety Chief and Union Leader Spar at Congressional Event" *Food Chemical News*, September 18, 2006.