food & water watch

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Mr. Keith Payne
United States Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 1175, South Building
Washington, DC 20250

Docket No. FSIS-2008-011

Transmitted via facsimile: (202) 690-6519

Dear Mr. Payne,

On behalf of the consumer group Food & Water Watch, I welcome this opportunity to comment on the two agency proposals presented by the agency at the "Shiga Toxin-Producing *E. coli* Public Meeting" on April 9-10, 2008. In general, and subject to our comments below, we support the agency's proposals to extend its policies pertaining to adulterated products to include:

1) intact beef, including primals and sub-primals; and
2) selected non-O157 Shiga toxin-producing *E. coli* (STECs).

FSIS held the public meeting, in part, to discuss the recent spike in illnesses and recalls related to *E. coli* O157:H7 and to solicit input about "possible solutions to address the challenges this pathogen presents."[1] In these comments we identify issues we believe may have contributed to the 2007 events and present our recommendations for actions we believe may improve the agency's control of this pathogen. We believe that the agency's previous and current regulatory policies related to the control of this pathogen violate the principle of prevention, which is central to its HACCP inspection system. Information that has been shared in connection with the public meeting clearly demonstrates that the agency continues to avoid involvement at a possibly significant source of the problem – the large slaughterhouses that produce a great majority of the raw beef.

The spike in *E. coli* recalls and outbreaks led one reporter to refer to "the recall-littered year of 2007."[2] In 2006, there were eight recalls of beef products, all of which were triggered by

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[1] "Shiga Toxin-Producing E. coli Public Meeting." Federal Register, Volume 73, Number 65, April 3, 2008
[2] "A Mystery Still – Researchers have many questions but few answers for this year's spike in E. coli outbreaks." Steve Bjerklie, Meat & Poultry, December 1, 2007.
http://am.sosland.com/ActiveMagazine/welcome/MP/MP_1207.asp

product testing. In 2007, there were 21 recalls and 10 were triggered by foodborne illness outbreaks.[3]

While we applaud the agency for responding to the recent evidence of significant problems, we hope the agency's resolve is not dependant on events that make headlines. Only 3 percent of foodborne illnesses are associated with outbreaks; the rest are "sporadic" or isolated cases, which are much less likely to have a food source identified.[4] Therefore, the agency cannot be confident that a lack of *E. coli* related outbreaks indicates that agency regulated products are not leading to tragedy for some consumers. We encourage the agency to pursue changes, such as its recent proposals, until it maximizes the public health results possible from exercise of its regulatory authorities, rather than using unreliable metrics such as relying on illness outbreaks.

Intact Beef

We agree that the agency should consider extending the definition of adulteration to primals and sub-primals, (subject to caveats we will discuss later) because it is clear that the current policies provide insufficient protection for public health. The most recognized raw product used by grinders to make ground beef is boneless "trim" – small pieces of meat collected and packaged by slaughterhouses – and this product is considered and treated as adulterated if contaminated with *E. coli* O157:H7. Inspectors have long informed us, however that there is a dangerous loophole in agency policy because many grinders also buy boxed beef, containing primals and subprimals, from large slaughterhouses, divide it into the smaller cuts such as steaks and roasts, and incorporate the small, excess pieces of meat that remain (called "bench trim") into ground beef. The danger exists because boxed beef is not considered or treated as adulterated when contaminated with the pathogen and the agency never prohibited the use of bench trim produced from this boxed beef.

At the April 9th public meeting, the agency presented evidence that revealed, for the first time, the extent of the use of bench trim. According to recently gathered data from grinders, the agency determined that while 62 percent of grinders use boneless trim, 75 percent use primal cuts and/or associated bench trim. Clearly, a policy, which fails to address contamination on the larger, intact pieces of beef, is inadequate.

We do not believe, however, that merely extending the definition of adulteration to include primals and subprimals will better protect the public health because we cannot assume that agency decisions necessary to implement such a policy will prioritize public health concerns. The agency's regulatory history regarding *E. coli* O157:H7, particularly the agency's use of microbial testing/sampling and the treatment of results, beginning from the introduction of HACCP in 1998 through the agency's current use of N-60 sampling, reveals a consistent practice of avoiding regulatory action at the large slaughterhouses where the contamination originates, holding the small, final grinders responsible for the contamination and compromising public health throughout. We present a short synopsis of this history with a recommendation that the agency seriously consider this history as it makes a final determination on the next steps it will take to deal with the challenge of *E. coli* O157:H7.

[3] Comments of Dr. Raymond. Public Meeting Transcript. April 9, 2008. pg. 17.
[4] Comments of Dr. Jones. Public Meeting Transcript. April 10, 2008, pg. 492.

The agency's previous approaches to the regulation of E. coli O157:H7

HACCP was originally developed specifically because sampling of product at the end of the production process in order to determine product safety was unfeasible. The manager of the original HACCP program reported:

> "We concluded after extensive evaluation that the only way we could succeed would be to establish control over the entire process, the raw materials, the processing environment and the people involved."[5] (emphasis not in the original).

When sampling is used in HACCP, it is used to determine if, or verify that, the production process is under control.

In 1998, the agency implemented HACCP and published the Backgrounder "Pathogen Reduction and HACCP Systems. . . and Beyond. The New Regulatory Approach for Meat and Poultry Safety", which described the agency commitment to a systems approach:

- prevention was the primary goal of the new program;
- "the eligibility of products to bear the marks of inspection [would be based on] the continuous demonstration that the plant sanitation and process control systems are working to prevent adulteration"; and
- the agency would "maintain vigorous and continuous inspection oversight to ensure [that] standards are met, and take enforcement action when standards are not met through system failures".[6]

It is important to recognize that knowledge of system failures at plants that were the source of problems would have necessitated agency action under this approach.

Pathogenic contamination of beef occurs at the slaughterhouse and therefore, the slaughterhouse is the *only* place in the production chain for ground beef that contamination can be prevented. Approximately 80 percent of the beef is slaughtered by plants owned by several large corporations that often also produce "coarse ground" beef. Many of the smallest grinders do no slaughter of their own and merely perform the final grinding operation on the beef that they buy from the largest packers. "Vigorous" inspection oversight and enforcement under HACCP, therefore, would necessarily entail the agency's involvement at the large slaughterhouses if the agency determined that there were process control problems at these plants. This has not occurred.

The agency initiated testing for *E. coli* O157:H7 in 1994 but quadrupled the number of tests once HACCP began. Between 1998 and 2003, however, it generally exempted all of the large

[5] Dr. Howard Bauman. 1990. HACCP: concept, development and application. *Food Technol.* 44(5):156-158 quoted in HACCP, A Systematic Approach to Food Safety. Ed. by Scott and Stevenson. 4th ed. 2006, pg 2.
[6] HACCP Backgrounder. http://www.fsis.usda.gov/oa/background/bkbeyond.htm

slaughter plants from FSIS *E. coli* O157:H7 testing[7] for at least one, and for as many as four of the five years.[8] In so doing, the agency avoided knowledge of problems that might have necessitated agency involvement and enforcement. Another agency policy mandated that inspectors ignore company tests that were positive for *E. coli*, demonstrating system failures, unless the company designated them as HACCP records.[9]

The agency could have compensated for some of this blindness at the large source plants if it engaged in aggressive traceback investigations when its testing program discovered contamination at a downline grinder. Instead, it adopted the position that small grinders who received contaminated product from the source slaughterhouses were capable of and responsible for forcing the large suppliers to take actions to protect public health[10] and the agency concentrated its enforcement actions at grinding facilities, even when they were only further processing supplies they had received from a separate slaughterhouse. This further enabled the agency to avoid knowledge of problems at the large source slaughterhouses.

The agency's testing databases and its online recall notices suggest that traceback efforts were minimal at best. Between 1998 and 2002, there were only 9 recalls of *E. coli* O157:H7 contamination on beef as a result of tracebacks to slaughterhouses, while the agency's testing program discovered the pathogen at 55 federal processing plants or retail facilities that could not have been the source of the problem because they did not slaughter animals themselves. Other studies suggest that the agency had an active antipathy towards traceback.[11] It appears that the agency has maintained this position – between 2003 and 2007, there were only 2 recalls as a result of such tracebacks.

In 2002, the ConAgra recall of nearly 19 million pounds of beef due to *E. coli* O157:H7 adulteration, and the report by USDA's Office of Inspector General about it, demonstrated the inadequacies of the agency's approach to sampling, and the fallacy of the assumption behind it – that the large plants and their innovative technologies could be relied on to protect public health, with little agency oversight. The agency ended the testing exemption for the largest plants, in

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[7] The agency did not specifically identify the large slaughterhouses in the exemption, but premised the exemption on practices that were then only feasible at the largest plants. Directive 10, 010.1 instructed inspectors not to take samples at an establishment if it: "(1) it conducts routine daily testing of raw ground beef products for E. coli O157:H7; (2) it requires suppliers of boneless beef to certify that each lot received has been tested and found negative for E. coli O157:H7; or (3) it uses validated pathogen reduction interventions on beef carcasses, routinely verifies the interventions' effectiveness through testing for E. coli O157:H7, and prevents the use of boneless beef or carcasses from outside sources." The only exception to the exemption was when there was a positive *E. coli* 0157:H7 finding in the plant's product by FSIS within the previous 6 months.

[8] *E. coli* O157:H7 test data received from the agency by Food & Water Watch through the Freedom of Information Act.

[9] "Food Safety and Inspection Service Oversight of Production and Recall at ConAgra (Establishment 969)." USDA/OIG Great Plains Region Audit Report. Report No. 24601-22-KC. September 2003.

[10] "The best way to regulate the whole supply chain is to put pressure at the end of the chain and then rely on the end user or the final processor to put pressure on upstream suppliers for safe input." Dr. Elise Golan, USDA's Economic Research Service. Presentation at "Pathogen Reduction: A Scientific Dialogue". May 7, 2002. Transcript at http://www.fsis.usda.gov/oppde/rdad/frpubs/Docs_02-006N.htm.

[11] "Food Safety and Inspection Service Oversight of Production and Recall at ConAgra (Establishment 969)." USDA/OIG Great Plains Region Audit Report. Report No. 24601-22-KC. September 2003. see also "Shielding the Giant." Tom Devine. Government Accountability Project. July 2003.

March 2004,[12] but in conjunction with industry insiders adopted a new policy, based on increased industry testing, that continued to facilitate the agency's plausible deniability regarding conditions at the largest slaughterhouses. Under this new policy, the agency would not test a plant's beef until the plant had *pre-tested* the product and found it to be free of the pathogen.[13] Further, the agency now agency collects roughly the same number of samples at plants that produce 250 pounds of beef per day as those that produce more than 2.5 million pounds per day. With such a protocol, the agency could obviously continue to pursue ignorance of the true extent of contaminated beef coming off of these slaughter floors. The agency continued this policy[14] until the end of September, 2007 just as the Topps recall was expanding its recall of contaminated beef from under a half a million pounds to 21.7 million pounds, and only after Food & Water Watch, brought this policy to the attention of Congress.

The agency's current approach to the regulation of E. coli O157:H7

The approach discussed here began around 2003 or 2004, when the industry increased its own testing of product coming off of its slaughter floors, and continues today. The increased pre-testing by plants, using the N-60 protocol described below, was not without some benefits – it probably prevented some contaminated product from reaching consumers. But information provided in connection with the public meeting indicates that the agency's approach has been, again, to distance itself from knowledge of the company test procedures and results. We believe that this continued ignorance and inaction is partially to blame for the events in 2007.

N-60

The validity of the agency's approach and use of N-60 is critical because, in the last several years, the agency has used or continues to use it as the basis for:

- its baseline testing program for *E. coli* O157:H7 in trim;
- follow-up testing when the agency's *E. coli* O157:H7 testing program finds a positive; and
- sampling imported products at the border.

Most importantly with respect to our comments, the agency has used it since 2003 or 2004 to determine which "combos" (containers that hold 2, 000 pounds of beef) may carry the USDA seal of approval. The agency is effectively using company N-60 results for what is commonly referred to as "lot acceptance." Based on information provided by the agency and others, we believe that the agency has done so without sufficient scientific justification.

The N-60 testing protocol, which was described by the International Commission on Microbiological Specifications for Foods (IC-MSF), is so named because it involves taking 60 units from a "lot" and testing them for contamination, to indicate whether there is any

[12] FSIS Directive 10, 010.1 Rev. 1. March 31, 2004.
[13] The agency justified this omission on the rationale that the agency wanted to determine the microbial profile of products that were sold as raw product.
[14] FSIS Notice 62-07. September 28, 2007.

contamination in the lot.[15] If analysis of the 60 unit sample indicates contamination, the lot is declared to be contaminated; if there is no contamination found in the analysis, the entire lot is treated as if it were free of contamination. At the meeting, the agency indicated that N-60 was "recommended by ICMSF where the hazard is severe and where conditions may increase the hazard."[16] As we will discuss later, we do not believe that ICMSF "recommended" this approach, but note here that, although N-60 was the most stringent of 15 sampling protocols discussed by ICMSF, it is not the upper limit contemplated by the Commission. The IC-MSF made clear that "[t]he stringency of any of the sampling plans can be increased by adjusting . . . [the number of units taken]."[17] More importantly, the ICMSF and other experts caution against the use of N-60 for lot acceptance, which we discuss later.

If the results of analyzing the 60 samples are positive, the statistically valid conclusion that can be drawn is that there is a 95 percent chance that *at least* 5 percent of the "units" in that lot are contaminated.[18] Put another way, if 5 percent or more of the units are contaminated, there is a 95 percent chance that testing 60 samples will reveal the contamination. However, this high degree of confidence (95 percent) in finding the pathogen is dependent on the integrity of the sampling procedure, including the following factors:

- there is at least a 5 percent contamination rate (prevalence) in the tested lot;
- the contamination is distributed uniformly throughout the lot so that the sample is representative of the whole lot; and
- collection of units for the sample is not biased to avoid detecting the contamination.

It is clear to us that none of these conditions have been met.

Prevalence

There is insufficient data on the prevalence of *E. coli* O157:H7 in combos of trim to provide a reliable prevalence estimate on which to determine if N-60 is sufficient. It is apparent, however, that the agency assumes it is much less than the requisite 5 percent contamination rate necessary for a 95 percent confidence level. At the meeting, the agency announced that its trim baseline determined the average contamination rate to be 0.68 percent. (This was likely an underestimate because, again, the agency tested primarily pre-tested beef.) In subsequent discussions the agency reported that anecdotal evidence suggests the prevalence in trim fluctuates between 1 percent and 2 percent throughout the year.[19] The impact of a lower prevalence rate would have a significant impact on the efficacy of the N-60 test, as indicated in the chart below.

[15] *Microorganisms in Foods 7 – Microbiological Testing in Food Safety Management.* ICMSF. Klewar Academic/Plenum Publishers. 2002.
[16] Slide 8. "Beef Trim Baseline Results and How FSIS Will Use Them." Loren Lange. Presentation at the April 9, 2008 public meeting.
[17] *Microorganisms in Foods* 7. Pg 162.
[18] *Microorganisms in Foods* 7. Pg 162.
[19] "Verification sampling using N60 sampling plans: FSIS's expectations." FSIS discussion paper. April 21, 2008.

Prevalence Rate	Confidence Level
5%	95%
2%	70%
1.5%	60%
1%	45%

This means that when the prevalence rate is 1 percent, N-60 testing is more likely to indicate that a contaminated lot is not contaminated.

Uniform distribution of the contamination

The units used in N-60 for trim testing are individual pieces of trim. The validity of the statistical conclusions is also dependant on whether the 60 selected pieces of trim are representative of the contamination level throughout the lot. This is where the agency's use of N-60 is internally inconsistent.

Prior to the industry's adoption of N-60, the agency mandated that all product produced "from clean-up to clean-up" be treated as a single lot when considering if product was adulterated. This was based on the fact that contamination on one piece of meat can cross-contaminate equipment, workers, and other pieces of meat with which it comes in contact. If pathogenic contamination was found on any of the product produced during the "clean-up to clean-up" period, which was typically one day, then all of the product produced on that day was considered adulterated and had to be destroyed or diverted to cooking to destroy the pathogen. In effect, the agency adopted the position that, because of the virulence of the pathogen and lack of certainty about the extent of cross-contamination, any contamination was representative of the condition of an entire day's production. Continuation of this position, however, would have discouraged companies from doing more sampling.

In conjunction with the advent of N-60 sampling by the plants, agency policy embraced the opposite assumption. We assume the agency's change of position was a result of information provided by industry and are interested in a fuller explanation of the position changed. In a discussion drafted distributed to stakeholders after the meeting, the agency stated:

> "FSIS assumes that contamination of the carcass, and consequently the primal cuts and trim, is a point-source contamination event (i.e., contamination is limited to a point of contamination on the carcass rather than being spread out over large areas of the carcass during slaughter/dressing). Thus, the contaminant transfers to individual combo bins and generally is localized within the combo bin)(sic)."

As a result of this change in its position, the agency also allowed plants to determine lot size on their own. The most common protocol used by the industry, and by the agency, is to consider 5 combos (10, 000 pounds) as one independent lot, despite the fact that no clean-up takes place before the next lot is produced. Twelve samples are collected from the top of each combo, for a total of 60 pieces necessary for an N-60 sample. The plant benefits because a finding of contamination no longer requires the destruction of a full day's worth of production – only the one five combo lot is treated as adulterated.

While we recognize the potential benefits of increased industry testing, there are a number of problems with the agency's radical change of position. First, we know of no agency or industry study which demonstrates that the "point-source" theory is correct and is being correctly applied, or of any evidence that cross-contamination no longer poses any public health threats under the current practices. It is possible that contamination in one 5-combo lot extends into other lots, that the limits of N-60 testing prevent detection of that contamination, and consequently adulterated product is being released into commerce.

Second, the agency allows the 60 samples to be collected from the top layer of each of the five combos. This would be valid only if contamination is distributed evenly throughout the five combos, which would implicate the concerns mentioned in the paragraph above. On the other hand, and to the extent that the agency's point-source theory is correct, each combo (perhaps even each layer in the combo) is independent of the next and the agency's reliance on testing of five separate combos as one "lot" for an N-60 test is invalid. If the contamination level of one combo has no bearing on the contamination level of the next combo, then the 12 pieces taken from the top of each combo represent one lot and the confidence level for test results would be limited to the confidence level provided by N-12 testing. Confidence levels of N-12 with the following prevalence rate estimates are as follows:

Prevalence Rate	Confidence Level
5%	46%
2%	22%
1.5%	17%
1	11%

Therefore, at the agency's assumed 1.5 percent contamination rate, and for arguments sake, making the illogical assumption that point-source operates such that contamination in one combo has no significance for other combos *but* that the top layer *is* representative of the associated combo, there is only a 17percent chance that N-60 will identify a contaminated lot. This provides the large supplier with quite an advantage because the USDA will apply the seal of approval to more than 4 out of 5 contaminated lots produced. If this is the case, and we believe it may be at least to some extent, it may also be a source of some of the problems that became evident with the 2007 events because it creates an incentive for a slaughter plant to spend less resources maintaining process control on the slaughter floor. None of the boxed beef going out will be tested because it is not subject to adulteration policies. Even if it were found to be adulterated, there would be no repercussions because it violates no standards. Most of the trim that is contaminated will go undetected by testing only 12 pieces from each combo. And finally, when contamination is found, it will necessitate treating as adulterated only 10, 000 of the more than 3 million pounds produced daily in the many large plants.

Circumstances warrant consideration of one final variation. At least one company, which owns several large slaughterhouses, began designating one, rather than five, combos as a lot in the beginning of 2007.[20] The benefit of this is that it increases the possibility of finding

[20] Public Meeting Transcript. April 10, 2007. Pg. 449.

contamination to the confidence levels of N-60 rather than N-12. However, to the extent that this protocol still fails to detect the effects of cross-contamination, a positive test result would be followed by treating only one combo as adulterated. It is possible that the 5-combo protocol detects less contamination but results in the diversion of more contaminated product because each positive test results in 5 combos being treated as adulterated. The agency should be collecting data on an on-going basis to determine how these factors interact.

The Beef Industry Food Safety Council apparently recognizes that cross-contamination is still an issue. It advised plants:

> "On days when there are multiple *E. coli* O157:H7 positives, it may be wise to consider diverting all trimmings from associated lots, even those that tested negative, to a cook operation. This recommendation is made based on the limitations of testing and an increased likelihood of undetected contamination from product that tested negative."[21]

In response to one of our questions at the meeting, the agency said that its considers whether positives for one production lot are related to other production lots, on a plant-by-plant basis, based on the plant's history.[22] However, we are not aware of any training provided to in-plant inspectors to enable them to make such determinations or instructions that they should consistently be monitoring this. Perhaps agency officials conducting Food Safety Assessments have been trained and instructed to make such determinations. However, given the difficulty that all agency officials had in answering questions about this at the meeting, we are not convinced that this is a policy that can be effectively managed by the agency at this point. Further, we have serious concerns about holding one plant to a lower food safety standard merely because its performance has historically been worse than other plants. A variable standard may be appropriate for other statistical process control situations but must be considered carefully before using it in a situation when a pathogen as virulent as *E. coli* O157:H7 is at issue. This approach also decreases incentives for plants to make improvements because the agency is apparently only holding them to a level of performance they have previously demonstrated – excellent performance would only lock the plant into higher expectations in the future.

Bias in the sampling method

Another factor that could diminish the reliability of an N-60 sample result is if the sampling techniques introduce bias into the sample. At the meeting, a food microbiologist discussed evidence of such bias. His company audited samples submitted by a plant to see if 1) an N-60 sample submission really contained 60 samples and 2) whether the samples included tissues from the outside of the carcass, which are more likely to be contaminated. The audit demonstrated that in a month and a half period beginning at the end of August 2007, no "N-60" sample submission actually contained 60 units, and 2/3 of the submissions contained less than 30 units.

When his company informed the plant about this inadequacy, the plant began sending in the correct number of samples, but then consistently sent in less than 40 percent external samples,

[21] "Best Practices for Using Microbiological Sampling." BIFSCo. Facilitated by Kerri B. Harris. International HACCP Alliance. November 2007.
[22] "Public Meeting Transcript. April 9, 2008. Pgs. 360-1.

which is where contamination is more likely to be found.[23] It is irrelevant whether these discrepancies were intentional or inadvertent – they demonstrate real world departures from an established protocol, which can impact the reliability of the result. We are not aware that the agency exercises any oversight to guard against such departures from protocol. The agency does not instruct inspectors to monitor whether plants are choosing samples in a biased fashion or whether they are sending in the appropriate number of samples and we know of no mandates for labs to monitor submissions. Given this, we have little confidence that company N-60 sampling procedures are consistently reliable.

Based on the aforementioned, we have serious concerns about the agency's use of N-60, as it has been recently described. It would be reasonable to assume that current use of the N-60 method, assuming all of the mitigating factors identified above (contamination rate of 1.5 percent or less, rather than 5 percent; a heterogeneous distribution of the pathogen throughout the combos; taking samples only from the top; and taking samples of internal tissue rather than external tissue), may provide significantly less than a 17 percent probability of detecting combos that are contaminated. Given these odds, the agency must reconsider its use of N-60.

In general, the agency has relied on end product microbial sampling as a method of determining which product carries its seal of approval. (We reject any argument that maintains that it is the industry, not the agency that is using sampling to make these determinations – only the agency makes the final determination to approve product and apply the government seal for release to consumers.) The agency has no data to demonstrate the effectiveness of the variations of N-60 upon which it has relied. When we asked about this at the meeting, one agency official reported that the agency had been presented with industry evidence that demonstrated that N-60 was "pretty effective" but not "perfect."[24] Of more concern for us is the fact that the agency has used N-60 for "lot acceptance" despite the pervasive expert concerns about this practice, of which the agency is surely aware.

The limitations of sampling to detect contamination in food is a fundamental issue for food microbiologists, who frequently pair discussions about it with reminders that sampling should be used to trigger process control improvements. As it presented its various sampling plants, the IC-MSF warned

> "that the sampling plans . . . may not provide the desired stringency required to come to a reliable decision for lot acceptance . . . The poor performance of the sampling plans in detecting lots with low concentrations of pathogens demonstrates that lot acceptance testing is an unreliable approach to ensure consumer safety. It is for this and other reasons. . . that greater emphasis should be placed on control systems, such as GHP and HACCP." (emphasis not in the original).

Similarly, the Beef Industry Food Safety Council (BIFSCo) cautioned sampling practitioners that:

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[23] "A Microbiologist's Perspectives." Mansour Samadpour. Presentation on April 9, 2008. Slide 8. http://www.fsis.usda.gov/News_&_Events/Agenda_Ecoli_040908/index.asp

[24] Public Meeting Transcript. April 9, 2008. pg. 355.

> "If microbiological sampling is not properly used, it can give a false sense of security that the process is in control when it is not. . . Microbiological testing is not designed to test safety of the product . . . It is important to remember that HACCP was initially developed as a preventive process control system for food safety hazards, because end-product testing was not capable of determining product safety. . . .When using this type of sampling plan, it is expected that some level of positives will be detected. Each positive sample requires an evaluation of the process to determine if changes are needed to ensure process control. . . [25]

Unfortunately for consumers, evidence suggests that, with respect to N-60 testing by establishments, the agency focused little, if at all, on whether or how companies were using N-60 results to improve slaughter procedures to prevent contamination. In the last several months, Felicia Nestor, our Senior Policy Analyst, has heard from inspectors, FSIS officials, industry consultants, extension agents, plant owners, and HACCP trainers that to the best of their knowledge, the agency allowed the industry to use N-60 primarily to determine which lots were contaminated – process control modifications have been a secondary concern, at best. Additionally, agency officials have admitted that they have no knowledge or records of how many lots each plant, or the industry as a whole, has found to be contaminated over the course of the last several years. Such data may have helped the agency detect problems before there was a rise in foodborne illness outbreaks. We are encouraged, however, by the agency's statement at the meeting that:

> "We do have an inspector in charge in these facilities who does have the opportunity to look at both what's happening at slaughter and at processing, and so we are looking to see what more do we need to be doing in terms of looking at the data in both operations and then questioning the management as to how they are reacting to the findings that they have."[26]

In addition to agency oversight of whether N-60 test results are leading to a plant's review of its process control, positive N-60 test results should be triggering action on the primals and subprimals produced at the same time. The trim and the primals/subprimals from which it is cut, are all handled at the same time, on the same tables and by the same people. Contaminated trim would indicate likely contamination on the associated primals/subprimals. The agency admitted at the meeting that this is not happening.[27] If extending the definition of adulteration would

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25 "Best Practices for Using Microbiological Sampling." BIFSCo. Facilitated by Kerri B. Harris. International HACCP Alliance. November 2007.
see also "Sampling Techniques" Lagen and Vandeven, in *Detecting Pathogens in Food.* Ed. by Thomas A. McMeekin. CRC Press. 2003. Pg 36. "Even the most stringent practical sampling plan (case 15; n=60. . .) will accept a defect rate of 2 percent on 30 percent of sampling occasions. In this case defective means containing an unacceptably high concentration of the pathogen of concern, . . . yet the sampling plan would indicate acceptance of the batch nearly one time in three! In the context of an ongoing relationship, a rejection rate of two in three would create pressure that rapidly leads to an improvement in future performance, but in the short term the acceptance rate of one in three may not provide the protection we require."

[26] Public Meeting Transcript. April 9, 2008. Pg. 213.

[27] Public Meeting Transcript. April 9, 2008. Pg. 214.

require plants to take action to prevent those primals from entering commerce in an adulterated state, it may be sufficient reason alone to extend the definition.

Next Steps

Based on the aforementioned considerations our support for the agency's proposal to extend the definition of adulteration to primals/subprimals is qualified. Merely treating *E. coli* O157:H7 as an adulterant in larger cuts of meat will not protect public health if the agency continues to focus its attention and resources on the smallest plants and avoid regulatory oversight at the source plants. This decade-long pattern, despite numerous *apparent* policy changes, is evidence of a stubborn resistance to what, we believe, is the agency's proper role. We agree with the American Association of Meat Processors (AAMP) comments to this docket that "[t]he Agency has failed to properly and appropriately trace back the source of *E. coli* O157:H7 contamination in ground beef to meat suppliers for years."[28] Like AAMP, we do "not want to see the lack of accountability on the suppliers behalf continued."[29]

Unfortunately, the agency still seems to want to deflect attention away from the suppliers. At the meeting, one slide presented by the agency indicated that 10 of the 11 establishments "producing implicated beef products" in 2007 were small plants.[30] It was misleading for several reasons. Nine of these small 10 plants were processing plants, that is – they slaughtered no animals themselves but merely further processed beef that they received from other slaughterhouses. The only reason they are the plants "implicated" by these recalls is because FSIS, by choice, left these plants alone in the spotlight by failing to trace back to the source slaughter plants. Further, 2 of these 9 plants are owned by corporations with large slaughter facilities that were likely source plants for the smaller plants. Finally, the only small plant of the 10 that was also a slaughter plant is owned by the largest corporate producer, Tyson. We believe this slide demonstrates that the agency continues to not only avoid focusing on the largest companies, it will also actively direct the public's attention away from these plants.

At the meeting, the agency discussed a survey it had done at beef plants, just after the 2007 Topps recall. In that survey (Checklist) the agency asked whether small grinders were using certain activities to control *E. coli* O157:H7 in their beef products.[31] The agency will be considering actions in response to this survey in conjunction with the proposal discussed here. For these reasons we offer a few comments on Notice 65-07 for consideration along with our other comments.

In the Checklist, the agency asks whether grinders and other downline processors test incoming products from suppliers. We believe this expectation is unreasonable. First, the agency is well aware that some suppliers will refuse to sell to downline processors who intend to test incoming product. Second, if more testing needs to be done to ensure product safety, the costs should be

[28] Comments to Docket No. FSIS-2008-0011. American Association of Meat Processors. Andrea Brown. April 17, 2008. http://www.fsis.usda.gov/OPPDE/Comments/2008-0011/2008-0011-1.pdf
[29] Ibid.
[30] "Shiga Toxin-Producing *E. coli*: Addressing the Challenges, Moving Forward with the Solutions." Dr. David Goldman. FSIS. April 9, 2008. Slide 11.
[31] FSIS Notice 65-07. Revised Checklist. October 12, 2007.

borne by the plant that causes the contamination. Third, testing at the end of the line is inefficient because downline processors often only have a fraction of the original contaminated lot, and FSIS does not traceback to identify and contain the full contaminated lot. Fourth, if testing were done at the source plant, and FSIS kept records of the results, FSIS would be more accountable for taking action at the source plants. Finally, FSIS applies the seal of approval to products leaving the source plants and should assume its responsibility to "ensure" the safety of those products – the agency has been wholly neglecting this responsibility as described in the previous section.

The Checklist asks whether grinders and other downline processors have third-party audits done at supplier plants. We believe this expectation is unreasonable. FSIS has inspectors in plants every day and throughout the entire slaughter process. If the agency were to give them ample time and authorities, they are in the best position to audit whether plants are conducting food safety activities that meet regulations, which should be sufficient to ensure food safety. We believe that if an auditor can go into a plant and discover problems missed by the agency, the agency has not done its job. Further, the Hallmark beef recall, which occurred after the plant passed several third party audits and an audit by the USDA, demonstrates how ineffective these can be. This was confirmed by one speaker at the public meeting, familiar with recalls, who that he had never seen a plant subject to recall that had not passed all third party audits with scores above 96 percent.[32]

At the meeting, the agency said that some downline processors are relying on the USDA seal of approval to ensure that products are safe. We do not believe that this is unreasonable. Under the current circumstances, it is evident that that reliance is unwarranted, but we believe that the agency's goal as it moves forward should be to establish policies that make the USDA seal something worthy of relying upon. This will mean adopting its proper regulatory role at the slaughterhouses. It will also mean committing to its proper role with respect to public health. We firmly believe that the agency's approach, thus far, has been harmful and perhaps even deadly for consumers.

Non-O157 STEC

We support, without qualification, the proposal to extend the definition of adulteration to cover the six non-O157 Shiga-toxin producing *E. coli* serogroups identified by the agency at the meeting. Whether the recent increasing incidence rate is because of a proliferation of the organisms or due to better reporting, we believe the numbers are significant enough to begin addressing these pathogens. Several presenters at the public meeting said that in certain locations, non-O157 STECs are being found more frequently than O175:H7.

We are especially concerned by the fact that the medical community may not be as vigilant as it should be with respect to these additional serogroups. Previous history suggests that agency recognition of the non-0157 STECs as a public health threat may lead to an increasing recognition in the medical community. As the agency pointed out at the meeting, declaring the additional serogroups as adulterants will also trigger the necessary methodologies so that they are detected and reported on an adequate basis.

[32] Public Meeting Transcript. April 9, 2008. Pg. 112.

Several presenters at the public meeting pointed out that the additional serogroups are capable of causing illnesses as severe as those caused by O157:H7, as well as death. For this reason, we believe the agency must include them in its regulation of adulteration.

Recommendations

We recommend that the agency:

1. Fully document the reasoning for any actions it takes as it moves forward. Lack of transparency will only lead to a decrease in public confidence.

2. Develop a computerized database into which inspectors record aspects of any establishment's N-60 sampling program, including: 1) lot size, 2) number of lots on a given day, 3) number of lots that tested positive, 4) which lots tested positive, and 5) any sanitation procedures which might impact the possibility for cross-contamination. The agency is applying the USDA seal of approval based on N-60 results and must have data to support those decisions. Additionally, this data is necessary for the agency to understand whether and what changes should be made to its treatment of establishment N-60 results.

3. Immediately establish a number of positive N-60 samples that, irrespective of an establishment's previous performance, triggers a requirement that the establishment reassess its processes and documents that reassessment.

4. Instruct inspectors to monitor when establishment employees collect N-60 samples to ensure that enough samples are being used and that they are being collected in a way that does not introduce bias.

5. Strengthen rules pertaining to whether any visible fecal material can be sent through chemical interventions.

6. Pursue aggressive traceback investigations whenever testing discovers contamination at a downline processing plant. Merely treating *E. coli* O157:H7 as an adulterant in larger cuts of meat will not protect public health if the agency continues to focus its attention and resources on the smallest plants and avoid regulatory oversight at the source plants.

7. Impose no mandate on downline processors to test incoming products that bear the USDA seal of approval or require third-party audits of suppliers. These have proven to be inadequate substitutes for food safety systems that prevent contamination. The problem of *E. coli* starts in slaughter plants, not downline processors. Therefore it cannot be solved by focusing excessively on processing plants.

8. Conduct a public meeting to discuss the agency's use of microbial sampling. We are aware that Safe Tables Our Priority (STOP) will be making a recommendation for a public meeting, and we are in full support of this idea.

Should you have any questions regarding our comments, please feel free to contact me at (202) 683-2550.

Sincerely,

Wen Hau

Wenonah Hauter
Executive Director