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Via Electronic Mail

Mr. Keith Payne
USDA, FSIS
1400 Independence Avenue, SW
Room 1175, South Building
Washington DC 20250

Re: Docket No. FSIS-2008-0011

Dear Mr. Payne:

We respectfully submit these comments to the Food Safety and Inspection Service (FSIS), on behalf of our clients that produce raw beef, in response to: the Federal Register Notice entitled: "Shiga Toxin-Producing *E. coli* Public Meeting," Docket No. FSIS-2008-0011, the public meeting agenda items, and comments made throughout the public meeting.

Intact Products

We ***oppose*** any Agency determination that intact raw beef products, such as primal cuts and boxed whole muscle beef, are adulterated if they bear *E. coli* O157:H7. As FSIS conceded at the public meeting, it has no evidence that intact products present an increased risk to public heath. Indeed, no illness has ever been linked to consumption of intact product bearing *E. coli* O157:H7.[1]

[1] During the public meeting, a speaker indicated that he knew of one case where intact product caused illness (generally referred to as the "Sizzler" outbreak). What that speaker failed to mention was no one got ill from eating meat, even assuming the meat actually did bear *E. coli* O157:H7. Instead, the food product implicated was watermelon from the salad bar which was sliced using the same knife used to cut raw meat and other products. Relying on illness caused by clear cross-contamination during preparation to support a decision that a raw product is adulterated would be a dangerous precedent which would open the door to all raw meat and poultry being deemed adulterated, regardless of how consumers ordinarily cook the product. We have also heard of a recent *E. coli* O157:H7 outbreak in Nebraska (April 2008) involving intact beef flats. There, the preparer compromised the surface integrity by inserting cloves, thereby

The Agency's interest in intact cuts does not relate to these products. The Agency's interest relates to what these products may be used for – non-intact products (such as needle tenderized product) and trimmings made from the intact cuts (*e.g.*, "bench trim"). We respectfully submit that the Agency, and public health, would be better served by addressing non-intact product and bench trim directly, not by focusing on their raw materials.

Looking first to non-intact products, the current FSIS risk assessment estimates that the risks of illnesses due to intact and non-intact products is significantly low - this is without the use of any intervention in the non-intact process. For example, the estimate for illness for non-intact steaks is only 1 in 14.2 million servings, significantly less than the 1 in 600,000 servings of ground beef in the summer months. Given the fact that the current FSIS risk assessment does not support a determination that intact beef should be deemed adulterated, we understand FSIS will be re-doing this risk assessment, but that it will not be completed for over a year. We submit FSIS should not proceed on expanding the products covered by the *E. coli* O157:H7 adulteration determination prior to the completion of the risk assessment, especially given the lack of any supporting illness data on intact products, as mentioned above.

We do not mean to suggest that the Agency should not take measures to address non-intact and bench trim. We recommend that FSIS should proceed, but proceed in a manner that is based on the evidence. A brief review of all four reported outbreaks (2000, 2003, 2004, 2007) involving non-intact products demonstrated that the cause was not high incidence frequency or level on incoming raw materials, but was attributable to sanitation challenges. The sanitation of the equipment is the most critical step in the production of these products. Moreover, if marinades are utilized on these products, they should be changed daily, unless treated with a validated intervention. Therefore, we recommend that FSIS focus on the design and implementation of these validated practices in facilities that produce non-intact products from intact cuts, rather than testing for pathogens on a product that is unlikely to be contaminated and which has not caused illness.

As FSIS moves forward on non-intact products, the Agency should encourage, but not require, the use of an intervention on intact products before needle tenderization and/or marination. The Agency should explore such an initiative through its recently created Office of Outreach, Employee Education and Training (OOEET). Many of the small and very small establishments may not even be aware of the interventions that can be applied as described in FSIS Directive 7120.1, which would require minimal additional validation at the in-plant level.

In our final comment on intact product, we wish to direct the Agency's attention to *Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994). In that case, the District Court found that the Agency had justified its decision that *E. coli* O157:H7 was an adulterant in raw ground beef because the Agency could demonstrate that consumers were becoming ill even after cooking the

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rendering the beef non-intact. This was compounded when the preparer so undercooked the product that some flats could not even be served.

product. For intact product, FSIS has not demonstrated it can meet this burden of proof. Hence, any adulteration decision involving intact product would be without any legal support.

On the issue of bench trim, we respectfully submit that there should be no real controversy surrounding this product because it is simply trim. Since 1999, trim is adulterated if it bears *E. coli* O157:H7. *See* 64 Fed Reg 2,803 (January 19, 1999). In general, industry should be either testing product, using a robust methodology, or sending the product for "cooking only." There has been a reluctance on the part of some to conduct testing of bench trim, given the potential implications to non-intact products (and now potentially the intact products) from which the bench trim was derived. We would encourage the Agency to consider a policy that bench trim would not implicate the products from which it is derived if the establishment maintains sound sanitation to address significant cross contamination. Further, the Agency should explore including information, in an outreach initiative through its recently created OOEET office, that bench trim needs to be considered as trim by all parties.

Note on FSIS sampling practices with intact product – We are concerned that FSIS has already begun to implement a policy that intact product is adulterated if it bears *E. coli* O157:H7. Beginning with FSIS Notice 17-07, FSIS has conducted upstream sampling of intact cuts when it hasbeen used in raw ground products, regardless of whether the product was packaged individually in cryovac, and regardless of whether the producing establishment knew of the purchaser's intended use of the product. Since the issuance of FSIS Notice 17-07, we have seen an increase in sampling of individual cryovaced subprimals, both domestically and with imports, merely because a FSIS program employee has asserted that such products were "intended" for raw, non-intact use.[2] This approach of assigning "intended use" will implement the policy that intact products are adulterated with *E. coli* O157:H7 by the back door, contrary to the FSIS assertion of transparency.

Non-O157 STEC

We recognize FSIS needs to gather scientific data on the issue of non-O157 shiga toxin producing *E. coli* (STEC). We encourage FSIS to use sound science in determining future actions. That said, we have serious concerns with the Agency's proposed implementation of a sampling program to generate data. We hope FSIS will consider and address our concerns before it initiates the sampling program and give notice before the program starts.

Even though there are outstanding issues regarding laboratory methodology and rapid methods, FSIS has expressed its intention to initiate a sampling program for non-O157 STEC. Under this program, all samples submitted for *E. coli* O157:H7 sampling will be tested for each of the six major non-O157 STEC serogroups. Such testing will occur immediately after a positive *E. coli* O157:H7 sample. In the event the sample is negative, it will be analyzed for non-O157 STEC "later." If the

[2] We admit that certain non-individually packaged subprimals may be presumed to be intended for raw ground use, such as "two piece chucks" sold in "naked" combos. These products are already treated in the industry as if they were trim. It is the individually packaged product, which is most frequently sent to retail stores, that poses the concern.

sample is negative for *E. coli* O157:H7, FSIS has stated that: "At this time, production lots [shipped] will not be recalled, seized, or detained" based on a positive non-O157 STEC result. (Emphasis in original).

This approach to sampling *E. coli* O157:H7 negative product for non-O157 STEC poses a significant risk to inspected establishments. Even if the FSIS statement did not include the qualifier "at this time", a prudent establishment must seriously consider holding[3] (or sending to cooking) product which tested negative for *E. coli* O157:H7 until the non-O157 STEC results are reported. FSIS will conduct a PFGE analysis of any non-O157 STEC positive and post the result on PulseNet. If it matches an illness, and the released product was sold in the outbreak area, we can envision a recall based primarily on this "non-regulatory" sample. FSIS would have no option in such a situation but to require a recall. Accordingly, an establishment exposes itself to potential liability if it ships *E. coli* O157:H7 negative product before the FSIS non-O157 STEC analyses are reported negative to the establishment.

Therefore, we strongly urge FSIS to only sample product that tests positive for *E. coli* O157:H7 until such time a test is available that provides industry with the viable option to hold product while the non-O157 STEC test is being conducted. This approach would be consistent with the Agency statement made at the October 2007 public meeting on non-O157 STEC, when the Under Secretary publicly commented that the science (epidemiology and laboratory methods) is simply not sufficiently advanced to make a sound and practical policy determination of how to proceed with these organisms.

On the issue of Non-O157 STEC generally, we do wish to remind the Agency that at the October 2007 public meeting, and again at the February *E. coli* O157:H7 public meeting, both the Centers for Disease Control and FSIS admitted that ***none*** of the twenty-three non-O157 STEC outbreaks in the U.S. have involved meat. Although these organisms should not be ignored, it is not as if there is a demonstrated danger. The evidence presented at the October 2007 public meeting on this topic demonstrated that the interventions currently in use in the beef industry are effective on these organisms, a conclusion supported by the lack of a meat-related outbreak. Moreover, acting before the science (epidemiology and laboratory methods) is sufficiently advanced to make a sound and practical policy determination of how to proceed with these organisms will not provide true food safety. Until practical issues, such as laboratory methods and products implicated, are resolved, no true progress will be made; making Non-O157 STECs adulterants only advance political goals, not public health.

We also urge FSIS to provide sufficient advance notification to the industry before any testing of non-O157 STEC begins. This notification should also include any policy considerations related to testing of imported products.

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[3] FSIS has not indicated how long the test would take, as well as whether and how the Agency would notify establishments of test results. Holding product would be a significant cost to establishments. Sending product to cooking is also a significant cost to establishments.

Mandatory Verification Testing for *E. coli* O157:H7

In its presentation on "Sampling," FSIS officials stated: "Testing for *E. coli* O157:H7 in raw beef at all points [in the chain] is an essential part of any food safety system."

We are concerned that this statement, taken to its logical conclusion, would mean that any establishment's HACCP plan for raw beef would be *per se* inadequate if the plan did not include some provision for verification testing of product for *E. coli* O157:H7. Without commenting on the advisability of such a new policy, we respectfully submit that FSIS cannot adopt this *per se* rule in the absence of rulemaking.

Existing HACCP regulations specify certain ongoing verification activities. See 9 CFR § 417.4(a)(2). However, ongoing microbiological testing is not specified. Indeed, according to the preamble to this regulation, FSIS noted: "for *E. coli* O157:H7 on going verification is unlikely to include in-plant testing for the pathogen due to its relatively infrequent occurrence." See 61 Fed. Reg. 38827, col. 1 (July 25, 1996).[4] Accordingly, mandatory verification testing for *E. coli* O157:H7 would be a "new" requirement not currently covered by existing regulation.

If it is a new requirement, FSIS cannot adopt such a policy by simply issuing a Notice or Directive. FSIS Notices and Directives are designed to provide guidance to Agency personnel, and are not subject to the rulemaking requirements of the Administrative Procedure Act (APA). See 5 USC § 553(b)(3). However, a mandatory requirement placed on industry to conduct *E. coli* O157:H7 verification sampling is not guidance to Agency personnel; rather it would have a direct application on inspected establishments by prescribing a course of conduct, and subjecting the establishments to sanctions for failing to comply.[5] Such a requirement would be a substantive rule.[6] The APA requires all agencies to conduct notice and comment rulemaking before adopting a substantive rule. Unless and until FSIS proceeds with rulemaking, it cannot mandate testing for *E. coli* O157:H7.

Although the APA clearly mandates the initiation of rulemaking, we submit that § 21 of the Federal Meat Inspection Act, 21 USC § 621, also requires the same procedure. This section provides that "all inspections and examinations made under this Act shall be such and made in such manner as

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[4] Even in the October 2002 Federal Register Notice addressing on-going testing for *E. coli* O157:H7, the Agency only "recommends" testing as one possible verification and then only as a verification of grinder purchase specifications, not at every point along the chain. See 67 Fed. Reg. 62,331, col. 1 (October 7, 2002). A "recommendation" is not enforceable across all plants, therefore the October 2002 Federal Register Notice would not constitute the rulemaking required to mandate this one specific verification method.

[5] Under the Rules of Practice, 9 CFR § 500.4(a), inspection can be suspended or withheld at an establishment with a inadequate HACCP system.

[6] This *per se* rule is not an interpretive rule, also exempt from rulemaking. An interpretive rule merely explains adoption of a specific requirement, not currently listed in the regulation (and previously excluded in the preamble language) is more than an explanation.

described in the rules and regulations prescribed by said Secretary. . . ." Since FSIS inspectors use the HACCP regulations to conduct inspections, and verification is one of the requirements, the *per se* verification requirement would need to be adopted as a "rule and regulation" through notice and comment rulemaking.

n=60 Sampling Issues

During the April 2008meeting, several attendees questioned the validity of the n=60 sampling method that is used by both the vast majority of the industry and FSIS. We would state for the record that each establishment is responsible for using supportable sampling methods for testing raw ground beef components. In addition, we wish to reaffirm that sampling and testing programs are merely verification tools to develop confidence that interventions and sanitary dressing practices are controlling contamination. Recent discussions seem to indicate that some are now viewing testing as a *per se* intervention. Industry does not consider it so. It must be recognized that a verification sampling program needs to be adequate for that purpose and historically, the n=60 program adopted by industry has proven to be an adequate verification to assess performance of interventions.

That said, we note that there have been situations where FSIS program employees have questioned the validity of an establishment's n=60 sampling method because it did not mirror the method used by FSIS (such as a sample size of two pounds for FSIS and 375 grams sample and analytical sample for industry, even though the FSIS laboratory only analyzes 325 grams, *i.e.*, five 65 gram samples for a total of 325 grams). We anticipate, given the challenges at the April 2008 public meeting, more questions will arise as to what constitutes a n=60 sampling program. Accordingly, we wish to insert into the record the industry's views of what constitutes a n=60 sampling program, since this sampling method was developed by industry and only adopted subsequently by FSIS.

We would note that with the growing use of n = 60, variations have developed. There are however, generally recognized features of the traditional n = 60 sampling method.[7]

n=60 Attributes:

Statistically, any lot which has been sampled and tested is represented using n=60 samples, whether tested as a composite or tested individually, has a 95% probability of detecting the target if the target of the testing is present at a level of 5% or greater. While there are several caveats associated with this, including sensitivity of testing methodology, employing appropriate sampling techniques, etc. Even in cases where all assumptions regarding testing methods and distribution of target are equal, test results for any lot not represented by 60 samples, will have a different probability statement associated with the results of testing.

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[7] There have been modifications to n = 60. As discussed below, modifications are acceptable provided the modified method has been validated to achieve at least the same level of detection as the traditional n = 60.

Key features of a traditional n=60 sampling program include the following criteria:

- A total of at least sixty separate pieces have been selected with equal representation from each of the units (*e.g.*, combo bins or boxes) represented as a "lot."

- A thin strip of the outside surface of the individual pieces is excised. Pieces representing external tissue of the carcass must be targeted. The likelihood of detecting microbial contaminants when testing internal tissues is considered to be minimal.

- The total net weight of the excised pieces for analysis when using a knife and hook to harvest the samples should be at approximately 375 grams.

- The thickness of any of the sixty excised pieces should be approximately 1/8th of an inch.

Based on this criteria, an analysis from a sampled product lot using the above criteria and found negative could be represented as a 95% confidence outcome from the traditional n=60 sampling, either on a certificate of analysis or otherwise.

n=60 Modifications

Modification of the above conventional n=60 sampling procedure is possible and acceptable if validation data and support analysis, including 3rd party procedure verification, is available to support an equivalent or better confidence statement.

We urge FSIS to continue to recognize n=60 as a robust sampling program, but not seek to impose the specific FSIS method as the only "true" n=60.

Additional Concerns

There were a variety of issues raised at the April 2008 public meeting which deserve comment.

FSIS Checklist Review – As part of FSIS Notice 65-07, establishment inspection personnel were instructed to complete a checklist so that FSIS could gain an understanding of the practices employed by industry to control *E. coli* O157:H7.

Although we believe it is important for FSIS to ascertain what is being done by various establishments, we are concerned that FSIS may read too much into the survey responses and base public health policy decisions on the results.

First, there were 118 questions total, some of which could lead to inconsistent answers.

Second, notwithstanding the number of questions, there were times when the answer did not reflect accurately on the establishment's program from a process control perspective. For example, several of our clients (and dozens of small and very small slaughter establishments) do not buy any outside trim; rather they are their own and only supplier. Since it is a "sole source" operation, the establishment would not have purchase specifications. However, FSIS, based on the comments at the April 2008 public meeting, is concerned with the number of establishments without supplier specifications. Yet for the sole source establishments mentioned above, the absence of purchase specifications would be meaningless.

Third, the questions centered solely on design, not implementation. It is incongruous that an establishment with three interventions would "rate" higher than an establishment with one intervention, even if the establishment with three did not use the intervention according to its operating parameters.

Fourth, the Agency is considering the differences in establishments that had recalls last year and those that did not have recalls, and is trying to draw inferences from the data. We strongly encourage the Agency to recognize that the number of establishments that had recalls was small, and that the data may or may not have relevance as to what actually caused the recall. We encourage the Agency to consider the data as a source of input into an equation, but not the only source, as they consider how to move forward in solving the equation.

Turning Prerequisite Programs into HACCP plans – In one presentation, FSIS implied that, in certain situations, the Agency may no longer respect an establishment's negatives and could expect diversion for products testing negative and, possibly, products not tested (such as intact products, which could be used, but not intended to be used, for non-intact product). This could be based on the number of positive findings or, more troubling, on the Agency's review of sanitary dressing practices. Many sanitary dressing practices are governed by prerequisite programs since a single failure or random, low incidence level failure does not automatically result in adulterated product given downstream interventions.

Recently, FSIS has begun looking at such programs, (for example, knife dipping between carcasses) as an indication of whether an establishment is out of control because of a low level non-compliance rate with such prerequisite specifications. Sanitary dressing is important, but deviations from such programs should not rise to the level of failing to operate an intervention properly. We are concerned when an Enforcement, Investigation and Analysis Officer asks during a Food Safety Assessment whether an establishment has ever had a deviation from a pre-requisite program, and, if so, whether the plant "*reassessed*" its program. This is an appropriate question for a HACCP deviation, but an over-reaction in the case of a low-level non-conformance with a prerequisite program.

FSIS Interference with Business Relationships – One presentation noted that FSIS has heard that suppliers may refuse to sell product to customers who test the product. This is a concern since the supplier has relinquished control of the lots produced that day, therefore a downstream customer product positive could trigger a recall. "FSIS will be following up with industry to see how the conflict is resolved." If the conflict is not resolved, "FSIS will step in." From our legal perspective, we believe such blatant interference and involvement in business dealings is far beyond any Agency authority.

Purge Sampling – FSIS will sample purge (if possible) in conjunction with regulatory *E. coli* O157:H7 sampling so as to determine whether purge is a valid or superior detection method. Although we do not object should the Agency wish to explore this option, we do wish to advise FSIS that not all products generate purge, especially those higher in fat, therefore purge will be virtually non-existent at time of sampling trim at packing plants. Moreover, purge is difficult to collect aseptically.

Review of Financial Records – In an alarming and insulting statement, FSIS indicated that during a review of testing records, should it see an unexplainable trend downward, the Agency would look at corporate financial information to see if the reduction is attributable to financial pressure. The implication, unintended or not, is that a company would modify its testing due to business considerations so as not to find positive product and thereby minimize the loss attributed to positive findings. Given that all of the advances in controlling *E. coli* O157:H7 have occurred as a result of industry efforts since 2002, we find such lack of faith disturbing.[8]

Consequently, we have advised all our clients of our legal position - that FSIS lacks even a colorable argument to justify access to financial records. Accordingly, FSIS cannot compel access to such records under any circumstances.

Are We Moving Forward With Real Solutions?

In the press release announcing the April 2008public meeting, FSIS stated that the purpose of the meeting was "to discuss challenges and proposed solutions in moving forward to address recalls and illnesses related to *E. coli* O157:H7."

Much was discussed at the meeting, including certain proffered solutions, but we respectfully submit that only on the second day of the meeting was there any meaningful discussion on what may have occurred in 2007 and how all stakeholders can move forward with effective preventive and pro-active measures. We did not hear an explanation on why declaring *E. coli* O157:H7 an adulterant on intact raw beef, or declaring Non-O157 STEC an adulterant, would have had any impact on the state of *E. coli* O157:H7 in 2007. If these were not causative factors, focusing attention on these issues

[8] If one questions whether it was industry voluntary testing that resulted in the advances, please compare FSIS' progress from 1994 (when it declared *E. coli* O157:H7 as an adulterant) to 2002-2003 when industry adopted a 100% trim testing "policy", resulting in the advances since that time period, even including 2007.

will only divert attention away from the true underlying causes. We need to be ever mindful of the truism – those that do not learn from the past are doomed to repeat it.

In this regard, we hope FSIS will use the thought process it expects establishments to use when there are HACCP deviations – a root cause analysis of what occurred so that effective preventive measures can be identified and implemented.

Our clients represent a significant segment of the industry. Based on our clients' experiences and those of others we have visited, many of the recalls and illnesses could be linked to certain potential causes, which have existing measures that can be used to minimize recurrence.

First, the effectiveness of supplier's sampling programs. The true advancement in reducing rates has not been in removing potentially positive product from commerce (though that is a benefit), it has been in how the establishments improve the total food safety system in response to positives. Merely because an establishment is using a n=60 sampling method does not mean the establishment is testing in a robust manner. FSIS could instruct its inspectors to verify that if a plant chooses to conduct a n=60 (or other validated method of sampling), it is conducting it in a robust manner. Obviously, this is not to say an establishment must conduct a n=60 (or that it even need to test its trim), it is just that if the establishment chooses to do so, it does so correctly. There have been occasions when establishments change ownership and once the sampling method is employed correctly, the true effectiveness (or lack thereof) of the total food safety program is shown. In this regard, the problem of "do-overs" (which caused one if not two recalls last year) also must be addressed.

Second, as a corollary to the above, FSIS should focus its sampling not merely on the basis of volume (which, in reality, is occurring). FSIS should increase its focus on trim sampling given the higher incidence rate in trim than in grind (based on both FSIS and industry data). Although we understand more trim samples are being taken in 2008 than in 2007, there are approximately 10 times more ground samples than trim samples. Also, by focusing on trim, the Agency results would provide feedback directly to the slaughter establishment for system improvement.

Third, the effectiveness of interventions. This simply asks whether the intervention is being used consistent with validated operating parameters. For example, lactic acid should be applied uniformly at a concentration of 2.5 to 5%; hot water should raise the carcass surface temperature to an adequate temperature and time to achieve the desired level of kill of pathogenic microorganisms. If this is not being done correctly, there is more cause for concern, than with other issues the Agency currently seems to be focusing on, such as infrequent non-conformances with a prerequisite program. Interventions to control *E. coli* O157:H7 may be the single largest control factor the industry has at this point (while pre-harvest controls are being further developed).

Finally, we would re-emphasize the recommendation in the January 29, 2008 Office of Inspector General Report, Food Safety and Inspection Service Sampling and Testing for *E. coli*, that suggests that FSIS needs to formalize its campaign for educating industry on best practices and encouraging their implementation. The report specifically refers to: CCPs for controlling food safety hazards at the supplier (*E. coli* O157:H7 interventions as described above), supplier sampling, and audits at suppliers.

We believe there are various other options which should be explored, but the short term (and do-able) solution is to improve the basics across the board, not seek to take on new or advanced challenges.

Conclusion

We appreciate the opportunity to express our views on this important issue. We look forward to continuing this dialogue and to the cooperative, professional relationship we have enjoyed with FSIS.

Respectfully submitted,

Dennis R. Johnson

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