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Michael Rybolt

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May 30, 2006

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW.
Room 102 Cotton Annex
Washington, DC 20250

Re: Docket 04-026N "*Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection"

Dear Sir or Madam:

We respectfully submit the following comments in response to the above Docket, published in the *Federal Register* on February 27, 2006. The National Turkey Federation is the advocate for all segments of the U.S. turkey industry, providing services and conducting activities, which increase demand for its members' products and protect and enhance the ability to effectively and profitably provide wholesome, high quality, nutritious turkey products.

In general, we support the agency's efforts to improve *Salmonella* control and its efforts to implement a risk-based allocation of resources. We are committed to working collectively with the agency as it develops the risk-based allocation system. However, we discuss below some inherent fallacies with the agency's *Salmonella* initiative.

Briefly, it is difficult to envision from the agency's publication how public health will be improved. The agency's goal is to reduce public exposure to *Salmonella* through poultry products, thereby decreasing the incidence of salmonellosis. We agree with this goal; however, we disagree that the current proposal meets that goal. Without proper risk attribution data, it is merely assumptive to conclude any reduction in poultry would have a measurable impact in human salmonellosis incidence.

Suite 400 • 1225 New York Avenue, NW • Washington, DC 20005 • TEL: (202)898-0100 • FAX: (202)898-0203

As the agency moves toward a risk-based allocation system, many variables should be considered rather than the incidence of *Salmonella* on raw poultry. The agency has previously developed a risk-based methodology for *Listeria monocytogenes*, which incorporated multiple factors. Likewise, the agency should not focus solely on the *Salmonella* incidence when attempting to categorize a poultry establishment. Rather, it should incorporate other risk factors as discussed herein.
That being said, we respectfully offer the following comments.

1. Reporting *Salmonella* Sample Results Individually

Announced agency action – FSIS will supply establishments with the results of individual samples as results become available. However, by so sharing, FSIS is prepared to waive the FOIA exemption for pre-decisional documents and release the individual establishment's set results.

Industry Comment:

We agree that sharing of individual test results can assist establishments by providing feedback during the sample set as to how the establishment is doing in meeting the standard. This can be especially useful during long sample sets.[1] We do note that many establishments conduct companion sampling so as to ascertain their performance during the set.

However, we respectfully disagree that the sharing of individual sample results would affect the pre-decisional character of the data. We believe individual results are pre-decisional – just as the complete sets are considered pre-decisional. It is especially confusing since the individual results are simply the precursor to the complete set results. Therefore, since the nature of the information has not changed, we request that the exemption from non-disclosure of individual establishment data likewise remain unchanged.

Moreover, we understand that FSIS will review the reporting to determine whether to continue sharing individual sample results after a year. We respectfully submit that it would be premature for the agency to change the FOIA status of the sample results during this pilot period.

2. Posting Results Quarterly

Announced agency action – FSIS will publish its *Salmonella* results on a quarterly not yearly basis.

[1] In the case of ground turkey with a 53-sample set, it can take over three months to complete.

Industry Comment:

Although we can see the value of posting results on a quarterly basis, we request that any quarterly posting be clearly explained and/or footnoted to indicate that the results should not be compared to the previously posted yearly results. First, unlike yearly postings, which normalize seasonal variations, quarterly reports will highlight such variances and will not permit accurate data comparisons to previous yearly results. Second, the criterion to select establishments for sampling will have been changed from "all plants every year" to "targeted plant sampling," rendering comparisons to previous yearly data misleading.

FSIS may consider further refining its quarterly posting by providing data on a geographic basis to determine whether there are variations based not merely on seasons, but the areas of the country where the samples were taken. The agency should also consider how it would address posting data obtained from targeted sampling.

3. Initiating Sampling of Turkey Carcasses

Announced agency action -- FSIS will initiate sampling of young turkey carcasses; the results will be measured against the recently completed national baseline. The "baseline guidance" (a/k/a "performance standard") will be 19.6%, or no more than 13 positives per 56 sample set.

Industry Comment:

As we begin this "performance standard," we request that the agency recognize the limitation of the baseline guidance. The "standard" is based on a national survey in 1996-1997 of approximately 1,200 samples. The agency simply does not have the years' worth of data for turkey carcasses as it has for the products covered by an existing performance standard. Accordingly, we respectfully request caution in taking any action, including classifying turkey slaughterers into categories, until the current validity of the "standard' has been demonstrated by the agency's sample sets. We would submit that the agency should delay setting a baseline guidance until there is sufficient data to be considered statistically valid across all contributing variables including plant size, seasonality, regional variation, and subtype variability.

4. Classifying Establishments by Performance

Announced agency action -- FSIS will establish three categories of establishments and take varying enforcement actions based on which group the establishment falls in. The three categories are Category 1 (incidence rate of 50% or less of the

standard); Category 2 (incidence rate from 51% to 100% of the standard); and Category 3 (incidence rate greater than the performance standard).

Industry Comment:

We agree that FSIS should allocate resources (testing and personnel) on the basis of risk. However, the proposed category system may be overly simplistic and could actually result in a misallocation of resources.

If FSIS wishes to dedicate resources based on public health, an establishment's *Salmonella* incident rate may not be the best measure. Incidence does not take into account the level of organisms on the product and this "load" has a bearing on the likelihood of illness due to cross contamination or improper cooking. Incidence does not take into account whether the *Salmonella* present on the product even poses a risk of illness. Incidence does not take into account whether particular products have actually caused illness, either in general (attribution data on *Salmonella* is lacking) or in particular (has an establishment previously been linked or suspected of being implicated in an outbreak). Incidence does not take into account whether the products are normally processed into RTE items before being sold to consumers. By relying solely on incidence, the agency could focus resources on an establishment which is at 51% of the performance standard. However, we do not see that focus as enhancing public safety if that establishment has low levels of *Salmonella*, the *Salmonella* serotype(s) found does not pose a risk of illness, or the majority of the establishment's raw products are sold for processing into RTE items under inspection.

Alternatively, FSIS may consider waiting until it completes its *Salmonella* Risk Assessment due to begin later this year. The agency used the *Listeria monocytogenes* Risk assessment to develop the multivariate equation to rank establishment by individual plant risk profile.[2]

Should the agency's preference remain with *Salmonella* incidence, an alternative but simple method to allocate resources would be to prepare a single list of all establishments subject to a performance standard and rank according to the incidence rate of *Salmonella* serotypes of human health concern. The agency could then focus resources on those establishments with the highest rates.

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[2] "Risk-Based Methodology"
The Agency will utilize a risk-ranking of establishments producing post-lethality exposed RTE meat and poultry product to determine the scheduling of Lm testing. This risk ranking is a multivariate equation (algorithm) that is formed by previously developed peer-reviewed risk assessments (FDA-FSIS 2003; FSIS 2003) and the ongoing results from FSIS tests of RTE meat and poultry products. By using the multivariate risk-ranking methodology the agency ensures that the establishments scheduled for this risk-based sampling program are those with the greatest probability of producing RTE meat and poultry products contaminated by Lm. Attachment 5, FSIS Directive 10,240.5

One point of clarification: according to the Notice, FSIS will focus primarily on slaughter, not grinding. How will this be implemented in terms of allocation of testing? The large majority of ground and mechanically-separated turkey moves into commerce for further processing. These products are considered for levels of *Salmonella* in HACCP plans when performing " cook validation" for pathogens of concern for RTE items. We would propose that all ground and mechanically-separated turkey destined for use in further processing (cooked) should be exempt from the performance standard and separated from ground turkey for the purposed sampling.

5. Scheduling *Salmonella* Sampling Frequency by Category

Announced agency action – FSIS will move away from a once per year sample set for all establishments and adjust frequency based on the plants' category with more frequent testing in the higher categories.

Industry Comment:

As discussed above, we believe scheduling based solely upon an establishment's "category" is not a true risk-based sampling scheme. Once again, if incidence is the sole attribute to be relied upon, we suggest ranking all establishments and focusing on the ones with the highest incident rate and/or those which have exceeded the performance standard. Again, we would support less or no sampling for turkey items intended for cooking by an FSIS regulated establishment.

6. Instituting Food Safety Assessments at Establishments with Poor Performance

Announced agency action -- Category 2 and 3 plants may be subject to additional bio-mapping sampling, expedited serotyping, and Food Safety Assessments, especially, if the establishment's *Salmonella* serotypes are associated with human illnesses.

Industry Comment:

As indicated above, we support allocating resources based on risk. However, we would suggest either a more public health based criteria or focusing on those establishments exceeding the current standard rather than the simple incidence of *Salmonella* on raw poultry products. Again, as mentioned previously, a true risk-based allocation of resources should incorporate other variables such as the product's intended use, attribution data, and the *Salmonella* load on product. In essence, a scientific risk assessment is needed.

7. Issuing *Salmonella* Compliance Guidelines

Announced agency action -- FSIS will make available a new compliance guideline for broiler slaughter.

Industry Comment:

Industry welcomes FSIS guidance. However, there has always been a tendency on the part of Consumer Safety Inspectors to treat the guidance as if it was regulation – seeking to impose the guidance on the establishment. Likewise, Enforcement, Investigation, and Analysis Officers (EIAO) tend to use the guidance as a checklist. The EIAO will then question any deviation from the recommendations regardless of the establishment's justification for its program. We recognize this can happen with any agency guidance, so we request the agency make as clear as it possibly can that the guidance contains suggestions for consideration, not prescriptive requirements.

In addition, we strongly request that the guidance be first issued in draft form to allow industry to comment and make suggestions to better ensure its practicality. We would also suggest that language be incorporated that indicates that the guidance is not static and that scientific information could provide for new technologies. Likewise, the agency could provide routine updates to ensure the most current information is made available.

8. Obtaining Serotyping Information in a more timely manner

Announced agency action – FSIS will obtain serotyping information more quickly and may take additional action based on the results (the serotype information will be made available to plants when available and will be published on an annual basis).

Industry Comment:

We concur with the agency that not all *Salmonella* is created equal; that some serotypes have human health implications, while others do not. Further, we agree that one serotype is not an indicator of another. Our only issue relates to dissemination of the serotyping results. We submit that the agency's reaction to a *Salmonella* set would depend, to some degree, on the serotype information. Therefore, this data should be deemed pre-decisional and not subject to public dissemination.

9. Maintaining an On-Going Baseline, including Serotype Patterns

Announced agency action -- FSIS will conduct *Salmonella* baseline studies for specific product classes.

Industry Comment:

We support continuing baselines studies to provide a better picture of the *Salmonella* levels across all products. We hope that in conjunction with these baselines, FSIS work with its public health partners on developing attribution data.

10. Subtyping *Salmonella* with PFGE or Phage

Announced agency action – FSIS sub-type *Salmonella* positives and also assess phage-typing.

Industry Comment:

Although PFGE has been successfully used with other microorganisms, such as *L. monocytogenes* and *E. coli* O157:H7, there is not the same general recognition of PFGE for *Salmonella*. Indeed, there are those who assert that phage typing is actually more useful in linking positive results. Accordingly, we recommend that FSIS engage in further dialogue on this issue before putting too much credence (or before taking regulatory action) based primarily on PFGE results.

11. Review of 2006 Data

Announced agency action -- FSIS will monitor the 2006 results and should the great majority of establishments (*e.g.*, 90%) in a specific product class be over half of the performance standard/baseline guidance, FSIS will take additional, unspecified enforcement-type actions.

Industry Comment:

We do not oppose and indeed support working with the agency to reduce *Salmonella* incidence. We also appreciate the agency's recognition that as we work to reduce incidence, there will be a time lag as improvements are developed and implemented.

Nevertheless, we are concerned with the agency's willingness to ignore the regulatory performance standard. If the performance standard is the maximum acceptable industry incidence rate, FSIS should not take action against the industry if ***one-half*** of the performance standard is exceeded. If FSIS wishes, it has the authority to amend the *Salmonella* performance regulation. It should not choose to ignore a regulation in favor of an informal enforcement policy. Further, a failure of

90% of the industry to reach one half of the performance standard would be an indication of process capability, not a lack of commitment. In such case, industry and the agency would need to work more closely at developing positive approaches and technologies for improvement rather than imposing implied punitive sanctions. A science-based approach would be much more productive.

Further, without the appropriate attribution data, the agency's suggestion that if 90% of the industry is meeting the mark, there will be an effect on public health, is without merit. It is also presumptive that any additional actions, which are unclear, would likewise have a positive effect on public health. What specific additional actions would the agency consider?

12. Future Agency Options

Announced agency action -- FSIS has identified certain incentives, including, but not limited to: "Negative Incentives," such as publication of the agency's results, identifying the establishment name and number, and "Positive Incentives," such as modification of the agency's approach to inspection.

Industry Comments:

We applaud FSIS for recognizing the value of incentives. Incentives have proven effective in controlling *L. monocytogenes* and *E. coli* O157:H7. Incentives are even more appropriate in the context of *Salmonella* given the organism is not an adulterant in raw product.

As regards negative incentives, we are concerned with the misleading impression that posting of results may generate. FSIS will post the results of all establishments. Customers would be confused with the postings, either because the posting would be without a framework of what the incident rate means (with the presumption then that any positive number is "bad") or because the results are posted by the agency categories which could be misleading as to whether one establishment is more likely to pose a true public health risk than another.

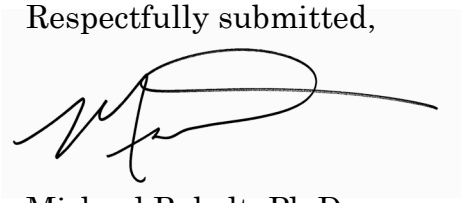
As regards positive incentives, we believe that establishments, which have demonstrated process control, as measured by public health criteria should be granted more control over their operations, subject to agency verification. FSIS should acknowledge that establishments operating with a very low *Salmonella* incidence rate are responsible for their operations and should eliminate any disruptions and distractions caused by inappropriate command and control or by unnecessary and unneeded food safety review of the establishment's programs. The recognition of outstanding establishments would also permit FSIS to better allocate

inspection resources to establishments that have not demonstrated control as measured against food safety standards.

Conclusion

We appreciate the opportunity to comment on the agency's *Salmonella* initiative. We look forward to working together with the agency on improving *Salmonella* control and reducing incidence.

Respectfully submitted,



Michael Rybolt, Ph.D.
Manager, Scientific and Technical Affairs
National Turkey Federation