National Advisory Committee on Meat and Poultry Inspection
January 16 – 17, 2013
Washington, DC

Subcommittee on
Review of Criteria for Public Health Related Non Compliance Records (NRs)

Report and Recommendations

The Data Analysis Subcommittee recognizes the work of the agency in updating the regulatory criteria by which focused inspection activities (such as FSAs) are prioritized. This type of data-driven, science-based approach is critical for addressing risk. The issues delineated below represent additional areas for consideration or issues of concern to the subcommittee.

What comments does the Committee have regarding the approach used to select the PHR list?

- **Data dilution is a concern. The mixing of performance-based and public health criteria may misclassify items and their significance.**
- **It may not be reasonable that all the data is randomly distributed—positives may suggest clusters or links, so relegating it all to the larger data sphere and assuming randomness does a disservice to the data. May require secondary sampling to tease out this additional data.**
- **FSIS has made an assumption that there's a link between NRs and pathogen findings, even though there may not always be cause and effect (e.g. specified risk materials). Notwithstanding the recognition that an NR is indicative of a general loss of control, the agency may need to provide a better foundation for the use of NRs as an 'indicator' sufficient to trigger an FSA (e.g., if the overall NR count was high enough above the cut point, even without LM or E coli positives, that could be enough to trigger it).**
- **FSIS still needs to clarify its intentions in process control and public health control/protection: statistical significance does not necessarily equal practical significance. Agency may be missing the public health benefit by focusing on the process NRs. The agency should provide its reasoning on this issue, including whether it intends for PHR monitoring to be a performance based, evaluative tool, whereas the FSAs that result from that monitoring are the public health risk analysis.**
    - **Thus, on a continuous basis, the data gathered from those FSAs should be reviewed for relevance to public health (i.e., was the agency looking for the right things) and should inform the development of the PHR list going forward. Similarly, the agency should consider which of the candidate elements may be showing up later in FSAs and should thus be added to the list.**
- **The information gained through ongoing data analysis should be shared with Extension and used to update training for industry, regulators, and others as appropriate.**

Does the Committee have any comments on the four criteria used to select the candidate PHR list?

The Committee agrees that the four criteria used to establish the PHR are the correct areas to be considered, provided they are appropriately used. With regard to Hazard Analysis specifically:

- **Within the frame of continuous process improvement, the Agency should clarify its intention with regard to HACCP. The agency needs to identify areas within the framework of HACCP systems that are still not fully being controlled—the agency needs to identify gaps in the existing practices (early adopters sharing with capable learners) to more fully realize the goals of HACCP. Once those gaps are closed, the agency can continue to make improvements in their HACCP regulatory system.**
    - **CDC National Center for Environmental Health's methodology for doing environmental assessments (systems approach) is an example of the type of assessment that could provide additional data for decision-making.**
- **On an annual basis, FSIS should reassess the validity of PHR and sampling data to evaluate the degree of correlation between the two. In addition, FSIS should analyze and update the PHR list annually based on all available information collected by the agency.**
- **FSIS should issue Notices and Directives to explain the process.**
- **The Agency should consider the regulations that triggered noncompliance increases when determining the scope of for-cause HAVs.**

Does the Committee have any comments on the public health outcomes (pathogen test results) analyzed to select the final list of PHR's?

- **FSIS should include the non-0157 STECS and Campylobacter for analysis.**
- **FSIS' sampling program may not be robust enough to serve as the only data source underpinning this determination. It is the understanding of the committee that not every important public health activity can be linked with its impact on microbial levels. As the agency moves forward with the PHR analysis, it should seek to expand the pool of available data to ensure confidence in the decisions being made. The agency should consider, for example, gathering and accessing total plate count data, serotype data, and other sources of data for use in data analysis, scheduling, enforcement, etc.**
- **FSIS should look closely at the timing of how data is transmitted to decision-makers and ensure that the data is used contemporaneously for risk reduction activities. Delays in the transfer of data may weaken its usefulness.**

Other Issues

Data

- **Data should be available for IPP personnel whereby they can easily determine whether noncompliance is trending upward so that they can use PHR analyses to be proactive rather than reactive. Facilities should similarly be able to review that data so that they can react internally. Consideration should be taken to ensure that this data does not lead to selectivity wherein compliance activity is calibrated to remain below the cut point or, alternatively, push above a cut point (to trigger an FSA).**
- **Prior to implementing the data posting plan, the agency should convene stakeholders to identify methods for sharing PHR data that serve the goal of rapid and effective risk mitigation and process transparency while remaining contextually appropriate and not providing disincentives.**