

Sub-Committee Number 2
5 Feb 2008

The conceptual algorithm of public health risk ranking involves two components: magnitude and hazard: indicators of process control. The questions which this sub-committee was asked related to the hazard: indicators of process control. The sub-committee agreed that it was important to capture some indicator of the day to day activities of the establishment, which would include both verification testing and NR's including those which the Agency considers to be "health based".

1. What data analysis, in addition to those that have been done by FSIS, would the Committee view as helpful to the Agency in assessing the utility of the inclusion of inspection observations, including those recorded as NR's, in its public health risk-based inspection algorithm?

The sub-committee commented extensively on the variability inherent in NR's, including but not limited geographical location of the establishment, seasonal variations, variation attributable to the physical state of the establishment, and variability associated with the inspection process. The Carnegie-Mellon analysis was presented as a summary graph in slide 5 of the presentation entitled "Across Establishment Ranking Concept for Processing and Slaughter", with the intent of demonstrating that NR's were either a predictor or associated with the future presence of salmonellae on the product.

No one on the subcommittee had read appendix E in detail, but some specific issues were raised about the Carnegie-Mellon analysis. The questions included, in no particular order:

Were the NR's taken from all establishments across species lines? If so, is it reasonable to compare raw poultry slaughter with beef or pork slaughter?

What percentage of the total NR's are represented in the industry or FSIS public health groups during the time frame evaluated?

Are the NR's related? Do one or more NR's have a greater influence on the predictive value than others?

2. For the purpose of illustration, a thirty day time window was used for calculating NR rates in the proposed algorithm. What time window would the committee propose for calculating NR rates and/or what criteria should be considered in establishing the time window?

The subcommittee did not feel that it was qualified to make a recommendation on a specific time window for the evaluation of NR's.

There was a discussion of the relative merits of a "time period" in comparison to a "production volume" window, and the consensus was that a time window was appropriate.

There was further discussion of the variability inherent in NR's.

There was a suggestion that there needed to be a starting point, and that 30 days was a reasonable starting point. Several of the subcommittee members felt that it might be more appropriate to look at a longer time frame.

The subcommittee also raised the issue of how frequently the algorithm would be run by the Agency, once it was implemented.

FSIS staff indicated that the algorithm was currently being evaluated with existing data, and the subcommittee strongly encouraged the Agency to continue to do this. The Agency could, with sufficient data, conduct a sensitivity analysis of the time window, to indicate what reasonable time frames may be relevant.

3. What other recommendations does the committee have regarding how NR's can be used to establish levels of inspection?

The subcommittee supported the concept of attempting to capture the day to day activities within establishments, and generally agreed that NR's were part of that effort. The subcommittee noted that there were gaps in the data which needed to be filled, and that the Agency should also include this information in the indicators of process control. As an example, the results of the FSA's are not currently included in the algorithm, and this could be another potential predictor of future salmonella performance. It was also suggested that the establishment's response to an NR be captured in the system, as this could also provide insight into the conditions in the establishment.

4. What other recommendations does the committee have regarding the use of process control indicators included in the algorithm for establishing levels of inspection?

The other process control indicators include the criteria used to identify LOI level 3 establishments. These are heavily weighted towards microbiological test results, but also include associations with recalls or food borne disease outbreaks. FSIS staff also commented on the *Escherichia coli* Biotypes I/II process control indicators, and noted that unusual trends in the current criteria would result in directed activities by the inspection personnel.

There was a general sense that other information that might be available within a specific establishment, such as the presence of external quality assurance programs mandated by customers of the establishment, could be captured within the algorithm. However, there was not consensus on this point, and some felt that this might not be relevant. It was suggested that this could be part of the establishment's profile, but not part of the algorithm.

FSIS staff also discussed the Management Control System, which captures not only NR's, but also the decision making process employed by the inspector. This information could also be incorporated as an indicator of process control in the algorithm.

Additional Comments:

The ultimate outcome of this algorithm will have to "make sense" at the establishment level. It is recommended that preliminary results developed by the exercising the algorithm be evaluated by inspectors in the field, to determine if the results do in fact reflect conditions at the establishment level.