

Pathogen Reduction Performance Standards Microbial Testing

I. Objective of Proposal

The objective of the proposed interim targets for pathogen reduction and daily microbial testing requirement is to establish a measure of accountability for adopting process controls in slaughter plants and plants producing raw ground product that effectively control and reduce harmful bacteria on raw products. Salmonella has been selected in the proposed rule to serve as both an indicator of process control and as the basis for a pathogen-reduction performance standard.

II. Description of Comments

The two issues most commonly addressed by the commenters concerning the proposed microbial testing requirements were the proposed selection of Salmonella as the indicator organism and the frequency of proposed testing. Commenters generally supported the concept of HACCP-based process control and the goal of reducing harmful bacteria on raw products.

Some commenters supported the proposed use of Salmonella as the indicator organism because it is a leading cause of foodborne illness, and, among common enteric pathogens, it is among the most prevalent and relatively simple tests are available to detect it.

Some commenters opposed the use of Salmonella as the indicator organism because its low incidence in beef makes it a poor indicator of pathogen reduction in that species; the yes/no test result is a weak measure of process control; and, compared to some non-pathogenic alternatives such as generic E. coli, Salmonella tests are more difficult, time-consuming and costly. Some commenters recommended FSIS consider an alternative indicator organism such as generic E. coli as a preferable process control indicator organism because it can serve effectively in all species as an indicator of fecal contamination.

Some commenters recommended retaining Salmonella as the target or performance standard for pathogen reduction but adding a requirement for E. coli testing because it is a preferable tool for verifying process control. Some commenters recommended requiring testing for additional pathogens in selected species or products based on the degree of public health risk posed by the pathogen.

With regard to sampling frequency, some commenters supported the one sample per day testing requirement as an efficient means of verifying process control.

The comments received on the frequency of testing centered upon suggestions on the sampling frequency of one test per day for each species and for raw ground product. A sampling protocol based on production volume or product risk was suggested as an alternative. Some commenters opposed the proposed testing requirement stating that it was inadequate to verify process control reliably and recommended more frequent testing that would be more representative of a plant's production. Some commenters recommended basing the frequency of testing on a plant's volume of production and argued that the proposed sampling frequency and moving sum statistical procedure would allow a lack of process control to go undetected for excessive periods.

Some commenters criticized the proposed frequency, noting the cost burden of the testing and its financial impact on businesses, especially for small volume plants and plants producing multiple species and multiple ground products that would require multiple tests. Some commenters recommended less than daily testing or other changes to minimize the financial impact on small business.

Some commenters objected to the proposed test sample collection methodology, including the sample size. Recommendations included adopting the same sample size for all species. Some commenters preferred swab samples to samples taken by knife cuts.

Some commenters stated that proposed end product testing is inconsistent with HACCP principles and that establishments should decide for themselves through hazard analysis whether testing is needed and at what frequency.

III. FSIS' Current Thinking on Selected Issues

The concepts of process control, microbiological testing to verify process control, and the establishment of practical measures of accountability for controlling and reducing harmful bacteria on raw products remain central to the FSIS food safety strategy. Based on the comments related to microbial testing, FSIS reviewed whether the pathogen reduction objectives of the rule can be accomplished without requiring near-term microbial testing. FSIS considers some appropriate approach to testing to be necessary as the means of ensuring that every establishment is working toward an acceptable level of pathogen control. The key issues raised by the comments involve how best to implement these concepts.

Relative to concerns about reducing the burden of testing, the Agency is reviewing: (1) the organism to be selected in testing; (2) the necessity for daily testing in every plant, including plants that grind raw meat and poultry obtained from other plants and (3) the necessity for testing each species slaughtered and each ground product produced.

The proposed rule relied on Salmonella as both a process control indicator and as the basis for a pathogen reduction performance standard applicable to all species.

Based on the comments, FSIS is seriously considering generic E. coli as the process control indicator organism and the adoption of a quantitative E. coli standard as a measure of process control with respect to the prevention and reduction of fecal contamination in slaughter plants.

If FSIS moves to a quantitative E. coli standard as the means of verifying process control, the Agency will also need to resolve what the standard should be (i.e., the number of organisms).

FSIS continues to regard microbiological testing to verify process control to be an establishment's responsibility. FSIS is reconsidering the proposed one test sample per day requirement based on comments questioning both its adequacy and its cost impact on small plants. FSIS is considering alternatives that are based on the volume of production. FSIS is also considering alternatives that would reduce the cost impact of testing on very small-volume plants producing multiple species and multiple products.

FSIS is considering the adoption of pathogen-specific performance standards as a direct measure of accountability for controlling and reducing harmful bacteria on raw meat and poultry products. For example, the proposed interim targets for pathogen reduction based on Salmonella (or possibly other pathogens for specific species) could be adopted as performance standards and enforced by FSIS through its own compliance monitoring. Establishments not consistently achieving the targets would be required to take corrective action and could be subject to other regulatory action, as appropriate.