

Although this proposal directly affects only FSIS-inspected establishments, FSIS encourages adherence to the proposed time/temperature requirements by all who handle or store raw meat and poultry products. At the end of this preamble, the Agency discusses plans to consider increasing oversight of the commercial handling of meat and poultry at locations outside inspected establishments, including during transportation, distribution and storage to the retail level. FSIS will be considering measures to ensure proper handling and cooking of raw and poultry products throughout the food safety continuum.

B. Microbial Testing; Interim Pathogen Reduction Targets

As discussed earlier, the centerpiece of the FSIS food safety strategy is to articulate what constitutes an acceptable level of food safety performance by a meat or poultry establishment and hold the establishment accountable for achieving that level of performance. In the case of pathogenic microorganisms on raw product, this means establishing targets, guidelines, or standards and requiring establishments to conduct regular microbial testing to verify current processes and practices are achieving those targets, guidelines, or standards, or whether further measures are required.

FSIS is proposing interim targets for pathogen reduction and microbial testing in slaughter establishments. This is an initial step toward measurable reductions in the incidence of contamination of meat and poultry products with pathogenic microorganisms. It also is a first step toward the eventual incorporation of microbial testing as an integral part of process control and verification in facilities operating under the HACCP approach proposed later in this document.

Before describing the proposal for interim targets and microbial testing, a brief description of the Agency's current use of microbial testing is provided.

1. Current Testing Program

FSIS's current regulatory use of microbial testing is generally directed at detecting product that is contaminated with bacteria of particular public health concern.

FSIS has made and will continue to make, on a case-by-case basis, determinations that a meat or poultry product presents an unacceptable public health risk, and is adulterated, due to the presence of specific pathogenic microorganisms in or on the product. Affected product may be processed or

raw. The discretionary authority to take immediate action in such cases to protect public health is an essential part of the Agency's food safety mandate.

Processed products that purport to be fully cooked and/or ready-to-eat have been and will continue to be deemed adulterated if found to contain pathogenic bacteria or toxic metabolites. These are products that consumers are likely to eat without further cooking. Consumers should be able to rely on processor's claims, implicit or explicit, that the product is fully cooked and/or ready-to-eat. Such product should in fact be ready to eat; further cooking should not be required to protect the consumer from pathogens.

FSIS currently operates programs to test various products for specified pathogens. Before establishing microbial testing programs, and if there is evidence of a potential public health risk from a pathogen being in or on a particular processed, ready-to-eat product, FSIS performs a risk evaluation that focuses primarily on the pathogenicity of the organism and the seriousness of the resulting disease.

If it is determined that there is a public health threat due to the risk of serious illness from consumption of a contaminated product, the Agency undertakes three related actions. First, product tested and found positive for the prohibited organism or toxin is retained and any implicated product in commerce is recalled voluntarily by the producing establishment. Second, the Agency undertakes a testing program to detect other products similarly contaminated and acquires data to decide if further actions are required. FSIS works with the manufacturer and distributors to return all implicated products to the inspected establishment. Appropriate public notices are given. Recalled product is destroyed or, if appropriate, reprocessed to destroy the contaminant, under FSIS oversight. Third, FSIS works with the establishment to determine the cause(s) of the contamination and to ensure that appropriate processing or other changes are made by the establishment to prevent a recurrence.

FSIS has made numerous determinations in the past that particular pathogens will, if found on a particular processed, fully cooked and/or ready-to-eat product, cause that product to be considered adulterated under the law, and has instituted testing programs accordingly. The following ready-to-eat products are tested for the presence of the microorganisms or their toxins, which, if found, will cause the product to be deemed adulterated, as indicated:

- Cooked beef: *Listeria monocytogenes*, *Salmonella*
- Sliced ham: *Listeria monocytogenes*, *Salmonella*
- Cooked meat patties: *E. coli* O157:H7
- Dry and semi-dry fermented sausages: Staphylococcal enterotoxin
- Jerky: *Listeria monocytogenes*, *Salmonella*
- Large diameter cooked sausages (e.g., bologna, salami): *Listeria monocytogenes*, *Salmonella*
- Small diameter cooked sausages (e.g., hot dogs, kielbasa, bratwurst): *Listeria monocytogenes*, *Salmonella*
- Meat and poultry salads and spreads: *Listeria monocytogenes*, *Salmonella*
- Cooked poultry products: *Listeria monocytogenes*, *Salmonella*

Most recently, FSIS determined that raw ground beef found to contain *Escherichia coli* O157:H7 is considered adulterated. This determination was made based on several factors. First, only small numbers of the O157:H7 strain of *E. coli* are required to cause serious illness or death, especially among children and the elderly. Second, traditional and accepted cooking practices for raw ground beef (e.g., a medium rare or slightly pink hamburger) do not kill *E. coli* O157:H7. Third, the illness caused by the bacteria can be transmitted to others (especially among highly susceptible small children). FSIS is conducting limited sampling and testing of raw ground beef in establishments and in the marketplace for the presence of *E. coli* O157:H7.

The key characteristic of current FSIS microbial testing programs is that sampling and testing is conducted by FSIS to detect violations and dangerous product contamination and to stimulate preventive measures by industry. Current programs do not involve microbial testing by establishments as part of an effort to verify process control and evaluate the adequacy of an establishment's efforts to control and reduce pathogens. FSIS believes its current testing programs serve a useful purpose but are not adequate by themselves to protect consumers. Microbial testing by companies to verify process control and demonstrate progress toward pathogen reduction is an integral part of FSIS's food safety strategy.

2. Proposed Targets and Testing

One approach to regulating pathogenic microorganisms in meat and poultry slaughter operations would be to determine, based on risk assessments, the levels of specific pathogens on raw meat and poultry products that do not pose a significant risk of illness and