required to take affirmative measures to reduce or eliminate contamination.

One concern regarding the use of antimicrobial treatments is that such treatments will be relied on as a substitute for careful sanitary dressing techniques which provide the best opportunity to prevent contamination from occurring in the establishment. Other concerns are that some treatments are ineffective at least for certain organisms, and certain treatments, such as carcass washes or soaks, might make matters worse by spreading contamination and can cause economic adulteration.

FSIS agrees that antimicrobial treatments must not be allowed to substitute for careful sanitary dressing procedures, and that any interventions must be effective and not result in economic adulteration. FSIS also agrees that no one treatment will be effective for all pathogens of possible public health concern. FSIS believes that the best way to prevent harmful contamination of meat and poultry products is by adopting multiple approaches throughout production, slaughter, and processing that will contribute to preventing or reducing the likelihood and degree of microbial contamination, especially by pathogens.

FSIS believes that mandating at least one antimicrobial treatment prior to the chilling process is an integral part—but only one part—of the strategy for reducing pathogens on meat and poultry proposed in this document. Product not properly treated with at least one antimicrobial treatment would be retained; the Inspector in Charge would determine its disposition. FSIS invites public comment on this approach, as well as on the issues raised in the discussion below concerning what treatments are effective and appropriate.

Past and Current Agency Policy

Despite establishment's best efforts to reduce or eliminate contamination during slaughter and dressing procedures, livestock and poultry carcasses still may harbor pathogenic microorganisms. The sources of these organisms, most of which are associated with the living livestock and poultry, are not fully understood, and fully effective preharvest preventive measures, while under study, are not currently available. Thus, introduction of pathogenic microorganisms into establishments along with the animals cannot be absolutely prevented at this time. The use of the best slaughter and sanitary dressing procedures and technologies can reduce the likelihood that product will be contaminated by these invisible pathogens, but they

cannot guarantee the absence of pathogenic bacteria on raw meat or poultry product.

FSIS recognizes that the technologies now available for reducing bacterial contamination on raw carcasses are limited. Indeed, the inspection regulations currently have no listings for antimicrobial agents as such. However, FSIS has over the years permitted a number of such treatments to be used in inspected establishments on a case-bycase basis, and is proposing to include some of these in the regulations through this rulemaking. Some currently available treatment methods are described below.

New antimicrobial procedures, including variations on those listed below, will be approved for use by FSIS to meet the proposed requirement for an antimicrobial treatment, provided data are submitted demonstrating they are safe and effective for that purpose. Current interventions generally provide at least a one order of magnitude (i.e., a 90-percent) reduction in the numbers of bacteria of concern on treated carcasses.

Antimicrobial treatments are interventions that decrease microorganisms present on the surfaces of meat and poultry carcasses. Antimicrobial treatments are not designed to compensate for sloppy sanitary dressing procedures on the slaughter floor, and under this proposal, will not be permitted to be used for that purpose.

Thus, the proposed use of antimicrobial treatments does not imply a change in current FSIS policy regarding removal of physical contaminants from meat and poultry carcasses. Fecal, ingesta, or milk contamination on cattle carcasses must be removed by trimming. Wash/trim studies are underway to determine the best way to remove these visible contaminants. Public comment and discussion, including peer review, of the data from these studies will be solicited and reviewed as part of the Agency's evaluation and decisionmaking process on this issue.

FSIS policy concerning visible contaminants on poultry continues to require carcasses to be free of fecal contamination before entering the chillers. The process control program set forth in the current regulations provides Finished Product Standards (FPS) for poultry where feces are one of the "nonconformances" that are summed with other nonconformances to determine compliance with the standard (9 CFR 381.76). This is only a measure of the presence of this nonconformance, not a tolerance. Finished poultry carcasses are subject to the same requirements as are finished livestock carcasses, with no visible fecal matter permitted. Because of confusion on this point, FSIS is proposing to remove feces from the FPS for poultry to make clear the current policy that there is no tolerance for feces.

The Agency's proposal to codify the zero tolerance policy for fecal contamination was one of a number of recently proposed changes to its poultry inspection regulations, designed primarily to address concerns about pathogens (July 13, 1994, 59 FR 35639). The proposal drew more than 400 comments. Although many critical comments were received, a great majority of the comments on point supported the use of antimicrobial treatments and removal of feces from the Finished Product Standards. Because these two elements of the July 13 proposal are incorporated in this proposal, comments are again being solicited. This does not, however, preclude completion of the July rulemaking on these two issues and the issuance of final rules based on that proposal.

One part of the July proposal that was criticized in the comments is the requirement that the antimicrobial treatment be limited to application prior to the chilling or cooling system. Some commenters indicated that certain antimicrobial treatments for use in the chilling or cooling systems are more effective than treatments applied before this point. Additionally, some held that certain post-chill treatments, such as irradiation, may provide a more effective treatment option. FSIS's intent was, and is, that poultry entering chill tanks be as clean as possible. However, FSIS invites comments on whether mandated antimicrobial treatments should be restricted to pre-chill application, as proposed above.

Irradiation is another issue related to this proposal on antimicrobial treatments. Irradiation is statutorily defined as a "food additive" under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thus its safety is evaluated by FDA, which must approve its use as a food additive in a regulation specifying safe and lawful conditions of use. FDA has approved irradiation for use in controlling foodborne pathogens on uncooked poultry (21 CFR 179.26), and FSIS has promulgated regulations under the PPIA specifying inspection requirements for establishments using that process (9 CFR 181.149). FDA currently is considering a petition to permit use of irradiation to control pathogens on uncooked meat. Irradiation is not being considered an