day, both before operations commence and during operation. In the GMP area, certain important food safety-related practices that have emerged in recent years have become recognized by the majority of the industry as appropriate GMPs, but they have not been made part of the basic regulatory requirement all establishments must meet.

FSIS believes it is important, especially for the near term, to codify certain minimum practices all establishments must observe to produce safe meat and poultry products and to improve the Agency's ability to hold establishments accountable for following those practices. Thus, FSIS is proposing: (1) to require that all establishments develop and adopt standard operating procedures for their sanitation programs, (2) to require that all slaughter establishments incorporate at least one effective antimicrobial treatment to reduce the levels of microorganisms on carcasses before they enter the chilling step, and (3) to codify specific time and temperature requirements for cooling of carcasses post-slaughter.

The majority of meat and poultry establishments already observe some or all of the practices FSIS is proposing to require. They are basic to producing a safe product, and FSIS believes all establishments should observe them. By codifying these practices in the Agency's regulations, FSIS will have an effective means to hold all establishments accountable for meeting them. Codifying these basic requirements is by no means a complete or long-term solution to the food safety problem but rather is part of the Agency's effort to ensure, as more fundamental improvements are being developed, that readily available improvements are incorporated into the system in the near term. FSIS invites comment on whether elements of current GMP's should be mandated by the Agency.

2. FSIS must stimulate improvement in food safety practices by setting public health-oriented targets, guidelines, or standards all establishments must meet. This is the centerpiece of the FSIS food safety strategy and the most important departure from the Agency's current regulatory approach. In its past regulation of the slaughter process and of raw, ready-to-cook meat and poultry products, FSIS has not clearly defined what safety means or set public health targets, guidelines, or standards for reducing the incidence of contamination of these products with human pathogens (pathogens that cause illness in humans). Consequently, there has been no basis for evaluating from an

objective, public health standpoint whether the measures establishments have taken to prevent harmful contamination are adequate or should be deemed acceptable. FSIS has instead focused on managing its current system of visual inspection and encouraging industry efforts to reduce pathogens, but without an effective tool for requiring or evaluating those efforts.

FSIS believes that setting public health targets, guidelines, or standards is the most powerful and effective tool available for bringing about changes in FSIS-inspected establishments, especially slaughter establishments, that will reduce levels of pathogenic microorganisms and improve the safety of meat and poultry products. The concept is simply that, by establishing targets, guidelines, or standards establishments are required to meet, FSIS can stimulate the innovation and change needed to reduce risk from all sources of foodborne hazards-whether biological, chemical, or physical—and, at the same time, have a tool for holding all establishments accountable for achieving an acceptable level of food safety performance.

FSIS realizes that this new approach raises some new and difficult scientific and policy issues and thus may be controversial in some quarters. The most important issues concern the basis upon which the targets, guidelines, or standards (hereafter referred to generally as "microbial limits") will be set and the consequences for an establishment that does not meet them.

There are many possible approaches for setting and using microbial limits. One approach is to set specific quantitative limits for each significant pathogenic microorganism on the basis of a scientific risk assessment, and to use this limit as the basis for excluding from commerce any raw product that exceeds the limit. This is the approach typically taken in the regulation of food additives, chemical contaminants, and physical defects, and provides the most direct and perhaps most effective means of ensuring that standards necessary to protect public health are being met. One difficulty with this approach to pathogenic microorganisms is that the scientific data and understanding concerning the link between specific levels of many pathogens and the risk of foodborne illness that would be needed to set such limits based solely on considerations of public health are not currently available. A second, perhaps more significant difficulty is the fact that the levels of additives and other chemicals generally remain stable, whereas levels of microorganisms can change over time, due to growth and

destruction. As explained in a later section of this document, FSIS intends to work with the scientific and public health communities to develop the scientific basis for setting quantitative limits for specific pathogens.

Another approach to pathogen reduction is to set targets for reduction based on what is judged achievable with available science and technology, and to require individual establishments to meet such targets on a consistent basis, by adoption of appropriate process controls. Even with this approach, there are difficult issues concerning the basis upon which such targets should be set. FSIS believes, however, that enough is known today and can be learned during the course of this rulemaking to make this approach viable and very useful in the near term.

Later in this document, FSIS is proposing to set interim targets for pathogen reduction, using as the starting point the current baseline incidence of Salmonella contamination of finished carcasses in all raw meat and poultry slaughter operations and in raw ground meat or poultry products, and requiring reductions in *Salmonella* in relation to the current baseline. FSIS believes that significant reductions in the incidence of contamination with this human pathogen are achievable in the relatively near term, and that the process improvements some establishments will have to make to reach the goal will also reduce the levels of other pathogens.

Key to the FSIS strategy for using public health-based microbial limits to reduce pathogens is the recognition that what is scientifically supportable and appropriate will evolve over time. FSIS believes the interim step it is proposing in this new area to target and reduce the incidence of Salmonella is feasible and can be effective in the near term, but it is just a first step. As knowledge and methodologies improve, additional pathogens could be targeted, targets could be lowered, and the use of the targets could expand eventually to include their use in some cases as legal standards for products.

FSIS will be working closely in the coming years with the scientific and public health communities, the industry, and public interest groups to consider how microbial limits can best be used to reduce the risk of foodborne illness. Later in this document, FSIS discusses some of the difficult scientific issues that need to be resolved to make the fullest use of microbial limits.

3. FSIS must make meat and poultry establishments responsible for microbial testing of their products to ensure proper process control and verify achievement of microbial limits. To