prohibit distribution of products exceeding such levels. The acceptable level of pathogens would be effectively zero (<1 per 25 grams) in at least some cases. The establishment of such standards is the approach generally taken for the regulation of chemical additives in food. It provides a very direct means of controlling and avoiding substances in food that present a public health concern.

FSIS has not taken this approach in the past with respect to pathogenic microorganisms on raw meat and poultry. FSIS has been constrained by the lack of a scientific basis for determining the levels at which specific pathogens do or do not present a safety hazard, particularly in regard to the potential for pathogens to increase or decrease during distribution, marketing and consumption. FSIS also has relied in part on the fact that proper cooking kills pathogens present on raw product. The closest FSIS has come to this approach is its recent decision to treat raw ground beef contaminated with any amount of E. coli O157:H7 as adulterated within the meaning of the FMIA, but this was based on the fact that traditional and accepted cooking methods for raw ground beef (such as in a "medium rare" hamburger) do not kill this dangerous pathogen.

FSIS believes that determining the levels of specific pathogens that pose a public health risk and using those levels for regulatory purposes is a desirable goal because it provides a very direct means of defining an acceptable level of food safety performance by a meat or poultry establishment and for holding the establishment accountable for achieving it. As a general matter, however, this approach currently is not available to FSIS to deal with the broad array of pathogens in raw meat and poultry. There are large gaps in the scientific knowledge required to determine levels of specific pathogens that do and do not pose a hazard. For example, with certain infectious pathogens where the primary mode of transmission involves crosscontamination, it is currently not possible to correlate pathogen levels with risk of disease (e.g., Campylobacter jejuni in raw poultry).

FSIS intends to continue to work with the scientific and public health communities and the meat and poultry industry toward determining what levels of specific pathogens on specific products pose public health concerns requiring regulatory action and to reduce pathogens below those levels to the maximum extent possible. However, the scientific and public health policy issues involved are complex and their resolution will require a concerted, long-term effort. Some of the issues and FSIS's plans for public meetings to begin addressing them are described below in Part III.

For the present, FSIS has decided to pursue an alternative strategy for pathogen reduction that is based on the same principle of articulating an acceptable level of food safety performance and holding establishments accountable for meeting it, but that also takes account of what is achievable today. Specifically, FSIS is proposing interim targets for reducing the incidence of contamination of meat and poultry carcasses and ground meat and poultry products with Salmonella, coupled with requirements for all affected establishments to conduct microbial testing to determine whether their targets are being achieved. FSIS believes that significant progress can be made in pathogen reduction by taking advantage of current technologies and industry capabilities, even as the Agency's HACCP program develops and the scientific basis for setting more definitive targets, guidelines or standards evolves.

The proposed *Salmonella* testing program is an important element of FSIS's food safety strategy because it will:

(1) reduce the prevalence of pathogens of public health concern;

(2) induce process changes by some establishments that are needed to achieve both the target for *Salmonella* and a reduction in the frequency and level of contamination of raw meat and poultry with other pathogens;

(3) establish the principle that the FSIS's inspection program and establishment process control programs must begin directly targeting and reducing pathogenic microorganisms of public health concern;

(4) begin building the foundation for HACCP, which will rely on microbial targets, guidelines, and standards to help define the process controls that will be needed to achieve the desired level of food safety performance; and

(5) begin building a database on the prevalence of *Salmonella* contamination, which will be used for national trend analysis and as an essential tool for setting future pathogen reduction goals.

The Agency's interim target and microbial testing proposal includes the following major elements:

(1) selection of *Salmonella* as the target pathogen;

(2) identification of a national baseline occurrence of *Salmonella* contamination for each major species and for ground meat and poultry; (3) adoption of, as an interim target for pathogen reduction, the requirement that within two years, or some other period specified by FSIS through this rulemaking, each establishment achieve an incidence of contamination below the current mean national baseline;

(4) a requirement that each establishment conduct daily testing for *Salmonella* to determine whether the establishment's process controls are, over a specified period of time, achieving the interim target; and

(5) prompt development and implementation of remedial plans by establishments not meeting the target within a specified period.

The Agency invites public comment on its proposal to establish interim targets for pathogen reduction and require microbial testing. The proposal's major elements are outlined below following a brief discussion of the public health rationale for targeting reduction in incidence of a specific pathogen as a step toward reducing the risk of foodborne illness associated with meat and poultry products.

## 3. Public Health Benefit of Interim Pathogen Reduction

As noted in earlier portions of this document, Salmonella, Campylobacter, E. coli O157:H7, Listeria monocytogenes, Staphylococcus aureus, and Clostridium perfringens constitute the major bacterial pathogens associated with foodborne illness. Healthy People 2000 outlines goals for reducing the incidence of each of these pathogens. Salmonella, Campylobacter, E. coli O157:H7, and *Clostridium perfringens* appear to be introduced into meat and poultry primarily at the time of slaughter. Public health concerns arise from this initial contamination. in combination with other variables including subsequent handling by industry and the consumer, opportunities for cross-contamination, cooking practices, and the like. These variables have been described in detail in the 1987 National Academy of Sciences report, Poultry Inspection: The Basis for a Risk Assessment Approach.

While FSIS cannot quantify the reduction in disease incidence which will occur with specific interim reductions in bacterial contamination of raw product, simply reducing the percentage of product containing a pathogen should result in a reduction in disease incidence, although mishandling may still occur.

Each pathogen has a somewhat different epidemiology, and responds to different interventions in different ways; for example, some interventions may be very effective for *Salmonella*, but have