Salmonella, based on what is achievable in the near term with available science and technology. FSIS may in the future adjust the interim targets for *Salmonella* downward, as experience warrants, and may consider adopting similar technology-based interim targets for other pathogens.

As explained earlier in this document, FSIS also intends to pursue over the long term development of science-based food safety performance standards that are based on what is necessary and appropriate to protect public health. This is the approach typically taken in the regulation of chemical residues in food: tolerances are established that limit the amount of residue that can be lawfully present based on an assessment of what limit is necessary to ensure the safety of the food. For certain cooked, ready-to-eat products, and more recently in the case of *E. coli* 0157:H7 in raw ground beef, FSIS has determined that pathogens at any level pose a safety concern and legally adulterate the product, in effect setting a zero tolerance for such pathogens.

Other than *E. coli* 0157:H7 in raw ground beef, a potential hazard that survives traditional cooking practices followed by many people, FSIS has not taken this approach with pathogenic microorganisms contaminating raw meat and poultry products. FSIS has relied in part on the fact that proper and generally accepted cooking practices kill most pathogens present in most raw products. It is also believed that for some important pathogens, such as *Salmonella, Staphylococcus aureus* and *Bacillus cereus*, some minimum number of organisms may be required to pose a significant threat of illness, although there is much scientific uncertainty in this area and susceptibility to illness varies among individuals.

The task of establishing science and public-health based food safety performance standards for meat and poultry products, such as by identifying levels of specific pathogens that pose a threat to public health and requiring that those levels not be exceeded, raises difficult scientific and public health policy issues. These include determining the nature of the hazard posed by particular pathogens and the actual threat to health posed under various conditions of exposure to the pathogen—an inquiry commonly referred to as risk assessment. In setting such standards, it also must be determined how protective the standard is to be: how strong must the assurance of safety be? Is any degree of risk acceptable? How can potential risks be managed by quantitative limits, labeling or some combination of measures? Addressing these public health policy issues is sometimes referred to as risk management.

FSIS invites public comment on the utility of health-based food safety performance standards and the issues involved in developing them. FSIS also intends to hold one or more public meetings to explore this topic with interested persons and experts in the industry, scientific, consumer and public health communities. Details on the time, place, and agenda for such meetings will be published in a future issue of the **Federal Register**. While the public health policy issues in this area are difficult and important, it is necessary first to consider the scientific basis for setting health-based food safety performance standards. The following paragraphs describe the current state of knowledge in this area and some of the scientific issues that need to be addressed.

Quantitative Risk Assessment for Microbial Pathogens

Integral to development of public health-based food safety performance standards is an understanding of the relationship between bacterial levels and the incidence of disease. The likelihood that an exposure to a foodborne pathogen will produce a disease response in an individual is dependent on the pathogenicity of the microorganism, the level of exposure (i.e., number of microorganisms ingested), and the susceptibility of the host. Qualitative and quantitative consideration of these factors is the basis for conducting a microbial risk assessment.

Pathogenicity describes the overall disease-causing capability of a microorganism. The inherent potential for a microorganism to cause disease is associated with one or more genetic characteristics (i.e., virulence factors). The virulence of a species is reflected in the levels of the microorganism that are needed to colonize a host and produce an infection or toxigenic response, as well as the severity (i.e., medical consequences) of the disease. However, pathogens must always be considered in the context of their host, since disease processes are dependent on host/pathogen interactions. In any population, individuals will have a varied response to any specific pathogen. This includes both the levels of the pathogen needed to elicit an infection or morbidity, and the extent and duration of symptoms. Typically, there will be a distribution of susceptibilities as a function of the levels of ingested pathogen.

This distribution of the host and pathogen characteristics means that the potential for infection must be treated as a probability function. This approach is replacing the older concept of minimum infectious dose, which fails to take into account the distribution of susceptibility within the host population. As the number of pathogen cells to which the host population is exposed increases, there is a corresponding increase in the probability of infection among the population.

The amount of data on the quantitative dose-response relations for human and various foodborne pathogens is severely limited. However, available data do allow estimation of infection rates for many foodborne pathogens. In many instances this may be sufficient since, barring exceptional pathogenic resistance or host susceptibility, the key data for a microbial risk assessment in foods are estimates of exposure (i.e., the numbers of pathogens ingested by consumers) and their correlation with infection rates.

A key limitation on the application of risk assessment techniques to microbial food safety issues has been that, unlike most chemical toxins, the levels of bacteria in food are not constant. They can change drastically as the result of growth or inactivation. The ability to run risk assessment scenarios to study the potential impact of changing food processing or food preparation protocols is dependent on acquiring a reasonable estimate of the levels of a pathogen consumers are ingesting. The ability to estimate exposure is, in turn, dependent on being able to estimate (1) The probability that the pathogen is present in the food ingredients, (2) the initial levels of the pathogen that can be expected if the microorganism is present, and (3) how these levels are likely to change as a result of operations associated with the processing, preparation, and storage of the food. While there are still methodological limitations, recent advances in predictive microbiology and the systematic collection of baseline data on the presence of pathogenic bacteria in foods have begun to allow the first quantitative microbial risk assessments.

In the case of some significant foodborne illness sources, such as contamination of raw poultry with *Salmonella* and *Campylobacter*, the illness is more often caused not by direct consumption of the contaminated food but by cross-contamination of other foods during handling and preparation. FSIS is not aware of research having been done to correlate levels of specific