and producing safe, wholesome, unadulterated products.

FSIS is proposing these regulations because a system of preventive controls with documentation and verification of successful operation is the most effective approach available for producing safe food. Emphasis by the regulated industry on improving the control of microbiological hazards in raw and cooked products in conjunction with process control will reduce the risk of disease resulting from the presence of pathogenic microorganisms in meat and

poultry products.

HACCP is a conceptually simple system by which meat and poultry establishments can identify and evaluate the hazards that could affect the safety of their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine. The HACCP systems mandated in these proposed regulations will be limited to attributes affecting product safety, as opposed to economic adulteration and quality parameters. If these regulations are adopted, FSIS will verify HACCP system operations as part

of its program of continuous inspection. FSIS is proposing to make HACCP mandatory for the meat and poultry industry for the following reasons:

(1) Adoption of HACCP controls by the meat and poultry industry, coupled with FSIS inspection activities designed to verify the successful operation of the HACCP system, will produce a more effective and more efficient system for ensuring the safety of meat and poultry products than currently exists. HACCP appropriately places responsibility on meat and poultry establishments to demonstrate an understanding of hazards and risks associated with their products and an ability to control the processes they use.

(2) A federally mandated HACCP system will provide the basis for a modernized process control system capable of dealing with all the hazards that might be associated with meat and poultry products currently and in the future—biological, physical, and

(3) The expertise for applying HACCP to meat and poultry processes and products is in an advanced state of development. Considerable progress in applying HACCP to meat and poultry processes has already been achieved by FSIS and other USDA agencies (e.g., the Extension Service). Work has also been done by other Federal agencies, several States, by academic institutions, by industry trade associations and independent industry members.

(4) HACCP has a broad base of support. In March 1994, a variety of constituent interest groups including consumers, the regulated industry, scientists and other professionals, producers, employee representatives, and other Federal and State governmental representatives endorsed the HACCP approach as embodied in the seven principles set forth by the NACMCF

Meat and poultry industry representatives have urged the Federal government to institute the mandatory use of a HACCP-based production system for their products. In a recent letter, the American Meat Institute (AMI) has petitioned the Agency to begin rulemaking to mandate HACCP.

Members of the International Meat and Poultry HACCP Alliance strongly support implementation of a mandatory HACCP program. The Alliance consists of approximately 30 industry associations, 10 professional associations, 32 university affiliates, 6 service groups, 6 Government representatives and 5 foreign government representatives.

In its 1993 report, Creating a Government That Works Better and Costs Less, Vice President Gore's National Performance Review recommended that: "[USDA] require all food processing establishments to identify the danger points in their processes on which safety inspections would focus * * * also [to] develop rigorous, scientifically based systems for conducting inspections. * *

(5) A federally mandated HACCP system of preventive process controls appears to be a prerequisite to continued access to world markets. For example, the United States' largest trading partner, Canada, has announced its intention to implement HACCP for meat and poultry processes by 1996. Australia and New Zealand are also implementing HACCP-based programs.

(6) Use of the limited public resources available to assure the wholesomeness of the meat and poultry supply can be significantly more effective if all meat and poultry establishments are controlling their processes through HACCP systems. HACCP systems focus attention on hazards to product safety and steps critical for their effective control. HACCP systems generate data that can be used to continuously assess whether the process is in control, and, when deviations occur, what was done to correct the problem. These two characteristics of HACCP systems will mean that inspector attention can be directed to the safety related elements of the process and that inspector review

can utilize objective measures of how well the controls have been working.

(7) Implementation of mandatory HACCP systems in inspected establishments permits separation and clarification of the differing roles of establishment and inspection personnel. HACCP is an industry process control system. Holding the industry responsible for the development and effective operation of HACCP systems makes it clear that production of wholesome meat and poultry products is industry's responsibility, not the responsibility of the inspection service. The role of the regulatory agency under HACCP is verification that the establishment is controlling its processes and consistently producing

complying products.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food and the products made from it unavoidably entail some risk of pathogen exposure and foodborne illness to consumers. However, since pathogens are not visible to the naked eye, consumers have no way to determine whether the food they buy is safe to handle and eat. When foodborne illness does occur. consumers often cannot relate the symptoms they experience to a specific food—or any food—because symptoms may appear after some time has passed. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. When consumers cannot trace an illness to any particular food or even be certain it was caused by food, food retailers and restaurateurs are not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors may have little incentive to incur costs for more than minimal pathogen and other hazard controls. The Agency believes that today about as much process control exists as current market incentives are likely to generate. The existence of significant foodborne illness demonstrates the inadequacy of the status quo. Thus, if foodborne illness is to be reduced, there must be