experience in food preparation and knowledge of safe food handling and storage methods. These people include:

- Food service workers, many of whom receive inadequate training, are part-time and teenagers, who experience high-turnover;
- Men and women in the workplace, who have minimal time for food preparation and often little experience or interest in food preparation;
- Children, who are increasingly expected to shop and prepare their own meals;
- Immigrants, who might not be able to read food handling instructions, or whose cultural practices include eating raw or very rare meat and poultry products. Other vulnerable sectors of the population, more severely affected by foodborne illness, are also increasing in size;
- Immunocompromised persons (i.e., persons with diabetes, cancer, chronic intestinal diseases, organ transplants, and AIDS);
- Persons 65 years and older—a growing proportion of the population—who, due to the normal decline in immune response, are at increased risk.

In 1993, to increase awareness about pathogens, FSIS promulgated a regulation requiring safe handling labels on most raw meat and poultry products. The Agency's Meat and Poultry Hotline provides consumers with immediate responses to questions about food handling and safety. These steps are important but they are not a substitute for building into the food production and regulatory system measures to reduce to the maximum extent possible the presence of microbial pathogens in meat and poultry products purchased by U.S. consumers.

V. Costs Associated With HACCP

This section details the costs to the meat and poultry industry of the proposed measures to control pathogenic microorganisms and other biological, physical and chemical hazards. Unless otherwise stated, the figures used are three-year undiscounted costs. They have been estimated for:

• Four near-term initiatives that could be implemented shortly after promulgation of a final rule. These include the creation of Standard Operating Procedures (SOPs) for sanitation and three pathogen reduction and control interventions: antimicrobial treatment of carcasses, microbiological testing, and time and temperature requirements for all raw product received, held, and shipped by inspected establishments.

• The longer-term Hazard Analysis and Critical Control Point (HACCP) systems developed by establishments would be phased in over an approximate three-year period after the final rule is promulgated.

Total cost of the near-term initiatives and the three-year HACCP implementation is estimated at \$733.5 million. This includes \$552.8 million for federally inspected establishments and \$180.7 million for State establishments. The costs for small establishments, which make up about a third of the total establishments, are estimated at \$330.6 million, or just under 45 percent of the total. The Agency recognizes the problem these costs could present to small firms and has requested in the proposal public comments that will help it make appropriate adjustments to modify this burden.

A. Cost Analysis Procedures

In estimating the costs of the proposed rule, FSIS used data generated by various Agency operational and research components such as Total Quality Control (TQC), Partial Quality Control (PQC), and the various Baseline Microbiological Surveys. An especially important source was the cost information from the HACCP Pilot Program conducted from 1991 to 1993. The cost analysis also relied heavily on four of the Agency's main databases.

New databases were created by merging selected variables from the four FSIS databases and enhancing them with additional economic and financial data. The Enhanced Economic Analysis Database contains information on each of the slaughter and processing establishments active as of August 1994.

Described below as a prelude to the sections containing the estimated nearterm and long-term costs are the assumptions, criteria, and other factors underlying or used in this cost analysis. Details of cost methodology and estimations are available in an appendix.

1. Number of Establishments

There are 6,186 Federal slaughter, processing, and combination (performing both slaughter and processing operations) establishments. An additional 2,893 establishments fall under State inspection. For some cost analysis purposes, combination establishments (performing both slaughter and processing) were counted as two separate plants.

2. Establishment Size

For its cost analysis, FSIS defines a small establishment as one with less

than \$2.5 million in annual sales. (This definition does not coincide with the Small Business Association definition for a small business.) Using the FSIS criterion, 42.2 percent of processing plants (Federal and State) and 16.8 percent of slaughter plants would be considered small establishments. A medium establishment is defined as one with annual sales of more than \$2.5 million and less than \$50 million. A large establishment is one whose sales are greater than \$50 million per year.

State establishments are all considered to be small establishments. Since figures on these plants' sales volumes were not available, the size determination was based on amount of production, which was below the average for Federal establishments with sales less than \$2.5 million. FSIS invites comments on the State classifications.

3. Process Categories

In keeping with the process control principles inherent in HACCP, FSIS identified 14 process categories (see Table 6 at the end of this section.) There is a separate category for each of the nine actual slaughter and processing processes and for each of the five species slaughtered. FSIS believes the 14 categories encompass all the products of the regulated industry. Every plant must develop a HACCP plan for each applicable category. The estimated costs for plan development are based on the total number of processes in all plants.

4. Implementation Schedule

FSIS plans that the final rule will become effective. The near-term initiatives would go into effect three months after it is published in the **Federal Register** and remain in effect in each plant until that plant's HACCP program begins (except for the sanitation SOP's, which will continue with HACCP). HACCP implementation would be phased in by process over three years, from date of final rule promulgation, with each process category assigned a slot in that time frame when its HACCP plan would be implemented. Small plants would have the option of implementing the plans for all their processes three years from promulgation instead of implementing plans for individual processes according to the time frame for medium and large plants.

5. Compliance

Some establishments may find that their present process(es) cannot consistently produce product that meets the specified interim target. This target, although a new "measure" of safety, is