burden for the development of a HACCP plan and hazard analysis would not have been as great for these establishments due to past experience. This option would initially have phased-in processes such as Thermally Processed/Commercially Sterile and end with Raw, Ground; Raw, Other, and Slaughter processes. Phase-in would occur in an inverse order from the first option considered.

The third phase-in scenario considered by the Agency utilized an evaluation of the number of establishments producing products covered by a process and the known volumes of industry production for each of these processes. In this option, process category Raw, Other would have been implemented first since this comprises a large sector of industry production both by volume and the number of producing establishments. The second process for phase-in would have been slaughter, since again, this comprises a large portion of the regulated industry both in the number of establishments and the volume of product produced. Thermally Processed/Commercially Sterile would have been the final process phased-in under this option since this process constitutes a small segment of the regulated industry both in the number of producing establishments and the volume of production.

The fourth option for phase-in, and the one proposed by the Agency, incorporates considerations from each of the above-discussed options, beginning with the processes that constitute the greatest public health risks, combining some other processes where the volume of production in the regulated industry is lower, using the option for processes where a large body of experience and regulatory criteria presently exist, and combining these for the existing time frame of total implementation over a 1-to-3-year period from the publication of a final HACCP regulation. In all options considered, the category encompassing small establishments will be phased-in last. FSIS selected the fourth option because it takes into consideration production, experience with process control, and public health risk. FSIS invites comments on the proposed phase-in schedule.

The Agency envisions that, upon the required implementation date for phasein, establishments will be completely ready to operate their HACCP system and that FSIS will conduct inspection activities according to HACCP principles, including verification and validation, to ensure that the HACCP system as operating is acceptable. The proposed phase-in schedule 4 is as follows:

Final rule plus 12 months: Raw Ground; Thermally Processed/ Commercially Sterile; and all Other Shelf Stable, Heat Treated Products.

Final rule plus 18 months: All Non Shelf Stable, Heat Treated, Not Fully Cooked; all Other Shelf Stable, Non Heat Treated.

Final rule plus 24 months: Fully Cooked, Non Shelf Stable; all Non Shelf Stable with Secondary Inhibitors.

Final rule plus 30 months: All

Slaughter; all Raw Other Product. Final rule plus 36 months: Small Establishments.

Special Consideration for Small Establishments

FSIS believes that planned technical assistance activities offer benefits to small establishments. Among these are the provision of generic models from which to begin HACCP plan development and the provision of other guidance material. Additionally, FSIS is proposing that small establishments, regardless of the processes performed and products produced, be permitted 36 months from the date of publication of the final rule in the **Federal Register** to complete plan development. In determining which establishments should be eligible for this implementation schedule, FSIS considered three ways of defining "small." The object was to distribute the economic burden equitably among various segments of the industry.

(1) Defining "small" on the basis of units produced (number of head slaughtered, number of birds slaughtered, or pounds of product produced). Because of the difficulty of making meaningful economic comparisons among unlike species and processes, the Agency decided against defining small establishments on the basis of production volume.

(2) Defining "small" according to the number of establishment employees. The Agency rejected this approach because the number of employees is not a good indicator of the ability of the establishment to undertake additional financial burdens.

(3) Definitions based on annual sales in dollars. This simple, across-the board measure appears both reasonable, simple, and fair. For this reason, the Agency selected this approach, rather than either of the others discussed, alone or in combination.

For the purposes of HACCP implementation scheduling, FSIS is proposing that small establishments be defined as those with annual production valued at or below \$2.5 million.

Defining a small business as one with a maximum of \$2.5 million in annual sales allows the maximum time for compliance with the HACCP requirement for a significant number of establishments, with approximately one-third of all establishments falling into the "small" category. Further, using the amount of \$2.5 million the percentage of slaughter establishments considered small is roughly the same as the percentage of processing establishments falling into this category. The proposed definition of a small establishment will not significantly affect achievement of the Agency's food safety objectives, because slaughter and processing establishments in this category together account for less than one percent of annual meat and poultry production in the United States.

FSIS invites comment on its approach to defining small establishments.

Regulatory Oversight of the HACCP System

The NACMCF has specifically addressed the subject of the roles of regulatory agencies with respect to establishments in which HACCP is the system of process control for food safety ("The Role of Regulatory Agencies and Industry in HACCP"). FSIS is in general agreement with that discussion, especially the part that emphasizes that, with respect to food safety, establishments must operate effective HACCP systems and the government role should focus on verification that HACCP plans are working as intended. If the regulatory agency were to take on hazard identification, determination of CCP's or critical limits, responsibility for corrective actions or monitoring responsibilities, it would be undermining the need for the establishment to assume full responsibility for the processing of safe product through the HACCP system of process control.

Verification procedures the Agency might use include:

- (1) Review of the HACCP plan;
- (2) Review of CCP records;
- (3) Review of deviations and responses to deviations;
- (4) Visual inspections of operations to see if CCP's are under control;
- (5) Random sample collection and analysis (including microbial testing);
- (6) Review of critical limits;
- (7) Review of written records of establishment verification tasks;
- (8) Revalidation of HACCP plans including on-site observations and complete records review.

FSIS intends to review and revise existing inspection tasks to assure that