(2) HACCP Plans

(a) Basis of Required Elements

The question of adherence to the seven principles of HACCP as defined by the NACMCF has been considered by FSIS since it began HACCP activities.

FSIS has determined that the scientific and conceptual integrity of HACCP as articulated by NACMCF is critical to its success and to public acceptance of inspection systems based on it. FSIS believes that each principle is important to achieving the objectives of HACCP and that the support of the scientific, technical, and industry communities for HACCP rests on its overall integrity. Furthermore, the external advice from such bodies as NAS and GAO recommending HACCP implementation assumed adoption of all seven principles. Therefore, the Agency has determined that its regulatory requirements will be founded on HACCP principles as articulated by NACMCF. Comments are invited on this fundamental premise of the FSIS proposed regulation.

(b) Required Elements

FSIS is proposing to require that inspected establishments develop HACCP plans that include: identification of the processing steps that present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit, which may not be exceeded at the CCP and, if appropriate, a target limit; description of the establishment monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded and the individual responsible for taking corrective action; description of the records that will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits currently a part of FSIS regulation or other requirements must be met. FSIS invites comment on permitting approval of alternative procedures if sound scientific reasons and data are provided.

FSIS is proposing that the HACCP plan be signed by the responsible establishment official as an indication of his or her accountability for the plan. Comment is invited on the merits of such a requirement as a method of ensuring and demonstrating establishment commitment to, and formal adoption of, the plan.

(3) Overview of Plan Content and Format; Consistency With FDA

FSIS is aware that a large number of food producing companies are regulated by both FDA and USDA. Earlier this year, FDA proposed to mandate HACCP for seafood processors (59 FR 4142, January 28, 1994). In formulating the proposal presented in this document, FSIS has tried to assure conceptual uniformity and consistency with FDA on the practical details to the greatest extent possible. However, differing statutes are administered by the two agencies and each species—livestock, birds and fish and shellfish—differ significantly.

In many important respects, the FSIS and FDA HACCP programs are fully consistent. The same underlying principles of HACCP form the foundation of the two programs. Both programs have the goal of improving the microbial profile of regulated food products and, thereby, reducing the incidence of foodborne illness that might be associated with these foods.

Both programs require that establishments: develop HACCP plans that address the health and safety aspects of their processes; have access to at least one HACCP-trained individual; and recognize and carry out their responsibility to control sanitation as a prerequisite to HACCP.

In addition, both regulatory programs are similar in that operational success is the mechanism for acceptance of establishment HACCP plans; verification tasks of all types will be conducted by regulatory officials; and FSIS and FDA will attempt to provide assistance to establishments through the development of guidance materials or generic models from which industry efforts can begin.

FSIS is recommending that the format used in its generic models and those of the NACMCF be followed by all establishments; however, Agency personnel will be flexible in this matter and consider alternative formats that ensure that both establishment and inspection personnel can readily identify the hazards, the CCP's and the specific critical limits, plus actions and records that should be associated with each. The generic models are to provide guidance, not serve as blueprints, and not substitute for process controls. FSIS proposes to publish and make widely available both its generic models and the NACMCF models. Comments are invited on this approach.

FSIS is proposing to require that each inspected establishment have and implement a HACCP plan that is specific to each kind of meat or poultry

processing activity conducted in that establishment. Establishments coming under inspection after the implementation date appropriate for the process(es) to be conducted will be required to develop their HACCP plans in conjunction with the application for the grant of inspection. FSIS acknowledges that such establishments may need some practical experience operating under their HACCP plan to finalize their plans. FSIS invites comments on whether new establishments coming under inspection should be granted a reasonable amount of time, for example, six months, to finalize their HACCP plans under commercial conditions.

(4) Sanitation as a Prerequisite to HACCP Plan Development

FSIS believes that there are certain prerequisites that must be met before successful HACCP plan development can be accomplished. An important foundation is the successful control of the cleanliness and sanitation of the facilities and equipment, and adequacy of employee sanitation and hygienic practices necessary in producing meat and poultry products. FSIS is proposing that this be accomplished through Standard Operating Procedures for sanitation. (See "Near-term Interventions" section of "DISCUSSION OF REGULATORY PROPOSALS," above).

These proposed regulations reflect the decision that HACCP plans should address food safety factors only. FSIS invites comment on this approach.

(5) Participation of HACCP-Trained Individuals

The Agency believes that establishments will vary widely in their familiarity and experience with HACCP. All establishments will need to have access to persons who have been trained in HACCP and its application to meat and poultry production processes. Some establishments have already chosen to secure HACCP training for their staff or to secure consulting services. Others must accomplish this before they begin the hazard analysis that will initiate their plan development process. FSIS will consider an individual who has successfully completed a recognized HACCP training course, as defined in §§ 326.1 and 381.601, to be a HACCPtrained individual.

A recognized HACCP course would consist of at least three days: one day devoted to understanding the seven principles of HACCP; one day devoted to meshing these concepts with this and other regulatory requirements of FSIS; and one day devoted to development of