they are focused on the CCP's for each of the processes that will be controlled by HACCP plans. These revised tasks will be incorporated into the PBIS and become part of regular assignments for program personnel.

Public Access to Records

There is a broad policy question about public access to establishment records generated under HACCP. Some groups believe that any records used by regulatory agencies for making a determination about the safety of meat and poultry products produced should be made public to the maximum extent possible. Others take the position that such broad-scale access compromises establishments' rights to protect sensitive commercial information from business competitors.

FSIS believes that public access to any records which it generates itself and any establishment records copied by FSIS as part of its verification tasks would be governed by the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the implementing regulations of USDA (7 CFR Part 1, Subpart A). FOIA exempts particular commercial and financial information from mandatory release by government agencies. As a preliminary matter, it appears that at least some elements of HACCP plans and monitoring records would be considered commercial information of the kind exempt from disclosure. FSIS is committed to meeting fully the public disclosure objectives and requirements of the Freedom of Information Act.

It should be noted that the FOIA presumes that the governmental agency has both possession and control of the record. Therefore, when information is obtained from an establishment and is maintained by FSIS, that information becomes an agency record subject to FOIA. As previously discussed, the Agency is not proposing that HACCP plans be submitted for approval. HACCP plans which have been accepted by virtue of successful process controls will be on file in the establishment and available for review by FSIS program personnel. Therefore, the information maintained by the establishments, including monitoring records, would not be subject to a FOIA request. However, if during validation of an establishment's HACCP plan, or during an investigation of an alleged violation, HACCP records are obtained from an establishment, those records become agency records subject to FOIA.

FSIS invites public comment on the issue of whether broader public accessibility to an establishment's records is in the public interest, and, if so, to what extent the records should be required to be disclosed.

Relationship to Other Process Control Systems

To eliminate duplication, redundancy, and confusion, FSIS is considering proposing that the mandatory HACCP plan become the only Agency recognized process control system for health and safety aspects of the processes/products of each establishment. Those portions of existing TQC systems or PQC programs that address health and safety issues would be encompassed within the mandatory HACCP plan. Those aspects of an establishments operations that are not health-and-safety related and, therefore, not covered by the HACCP plan would be monitored by tasks assigned through PBIS at frequencies determined by the demands of HACCP verification activities. Comments are invited on this approach.

Enforcement

The enforcement provisions would require that establishments have verified HACCP plans for their processing operations by the dates specified for the establishment and process. As noted, the HACCP requirements would be phased in by having different effective dates—12 months, 18 months, 24 months, 30 months, or 36 months from the date the final rule is published, depending on the establishment and the product(s) being produced.

Establishments that fail to have a verified HACCP plan in place for a processing operation by the date required for that operation would have its inspection for that process suspended. Similarly, new establishments and establishments applying for inspection of new processing operations would be denied inspection services after those dates unless and until a HACCP plan is in place for that process.

The enforcement provisions also provide that, once adopted, HACCP plans would still be subject to verification by FSIS. If a HACCP plan is found by FSIS to be invalid, inspection would be suspended from existing operations, pending correction of the HACCP plan.

A HACCP plan might be found invalid for one or more of three reasons: (1) The HACCP plan does not meet the essential requirements set forth in the regulation; (2) HACCP records are not being maintained as required by the regulation and/or the plan, preventing validation of the plan and/or verification of process controls as may

be required, and (3) a processing failure results in the production of adulterated product.

Suspension of all or a part of an establishment's inspection services will be made under rules of practice, proposed in Part 335 of the Federal meat inspection regulations and Subpart W of the poultry products inspection regulations, requiring notice by FSIS to the establishment of the reasons for the suspension. The notice also would specify the processing operations affected (if not the entire establishment) and the corrective action(s) required before inspection service would be resumed.

While inspection is suspended, the facilities identified in the suspension notice could not be used for the production of meat or poultry products. Furthermore, if product produced prior to the suspension were suspected of being adulterated, such product would be retained at the establishment pending disposition by the Program, and if already shipped, such product would be subject to recall as necessary to protect public health.

A suspension would be lifted and inspection service restored upon the designated Program official providing written acknowledgement of receipt of a modified plan, coupled with a detailed validation of that plan by a HACCPtrained individual. The modified plan must have been developed in consultation with that HACCP-trained individual. In the case of suspension caused by a processing deficiency resulting in production of adulterated product, a written testing plan would also be required. The plan must provide for the testing of finished product produced under the modified plan for chemical or microbial characteristics, as appropriate, to demonstrate that the process under the modified plan would correct the identified problem.

Failure to prepare a valid HACCP plan as specified in the notice, by the time specified in the notice, will result in service on the establishment of a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service will be refused or withdrawn pending resolution of any hearing.

Failure to adhere to a modified HACCP plan, and, if applicable, testing plan, resulting in a repeat of the suspension for the same or a related deficiency, would in addition to the requirement for another modified plan, require a Program review of the establishment's performance under other provisions of the inspection laws before inspection would be restored.