There was broad support for incorporating the seven HACCP principles into HACCP plans. Different perspectives were expressed concerning the means by which this might be achieved. These perspectives ranged from having plans developed by certified experts, to the use of objective baseline data from industry operations, and to the use of generic models. Having and applying generic models and guidelines to plant specific situations was considered desirable.

Training/Certification: What should be the role of FSIS with regard to industry HACCP training?

This question generated discussion on three components: (1) HACCP curricula, (2) training approaches, and (3) certification requirements. The centrality of training to successful implementation of HACCP is reflected in the broad range of perspectives offered. Curricula concerns ranged from the need for uniform training on principles, to the need for specific training on application of the principles within a particular establishment operation, to the need for joint training between inspectors and industry employees. Training approaches touched on the need for training to be both available and affordable, and the potential for training development and delivery to occur within various private sector organizations as well as academia. Certification requirements addressed the alternatives of having HACCP-trained personnel in establishments, having HACCP consultants available on-call, and having some type of certification process for such individuals.

Phase-in: Should the mandatory HACCP requirement be phased-in and, if so, how?

There was broad support for the notion of phasing-in HACCP requirements, since allowing enough time for the HACCP program to develop and grow is deemed critical for its success. Proceeding on a deliberate schedule allows for an orderly transition within the industry and permits adjustments of the regulatory infrastructure to suit the HACCP structure within inspected establishments. A variety of approaches to phase-in and timing were offered. A second point raised was that the phasein should take advantage of existing HACCP knowledge and expertise, advancing first those industry segments whose process control operations are more closely aligned with HACCP. A third point offered was that the phasein should provide for a transition or trial period as application of HACCP occurs within a particular establishment.

Measures of Effectiveness: How can it be determined initially, and on a continuing basis, that HACCP plans are working effectively?

Participants discussed the need to develop measures of effectiveness for HACCP plans. These ranged from the use of baseline data on the process, establishment, and product level; to the use of microbial, physical, and chemical guidelines; to the use of in-process, as well as end-product testing; to the openness and accessibility of data and records on selected measures of effectiveness. There was considerable discussion concerning the need for finished product testing to support verification of a HACCP program. The area of greatest controversy was the need for microbial testing and the development of microbial guidelines in conjunction with the need for finished product testing. Different perspectives were offered on these issues, on how such testing could be accomplished, and on the practical limits of detection, sample collection, and testing

Compliance/Enforcement: What are the best ways to adequately enforce and ensure compliance with HACCP requirements?

Participants presented views on the types of regulatory authority that would be appropriate in a mandatory HACCP system. Viewpoints ranged from those who believed that current enforcement authorities are adequate, to those who stated a need for new authorities (e.g., civil penalties) and those who believed a review of enforcement authorities should be undertaken to reflect the changes in roles and responsibilities between the industry and the inspection service. There was significant discussion concerning deviations from HACCP requirements and how these deviations should be handled, including appropriate enforcement responses to repeated deviations from the HACCP plan. Here, two major points of view were articulated. The first view was that any deviation from a HACCP plan could result in a regulatory remedy (rather than criminal remedy) and that a deviation from a CCP, while a food safety concern, should result in a regulatory response related to the level of severity (in terms of risk to human health) of the deviation. The second view was that any deviation from the HACCP plan constitutes adulteration, hence a violation of law subject to enforcement action. This view holds that, since HACCP is intended to address potentially serious food safety hazards, a deviation is a violation. A final point of discussion on this issue was employee protection from reprisals for reporting food safety hazards (e.g.,

whistleblower protection for industry employees).

Relationship and Effect of HACCP on Current Inspection Procedures: To what extent will the possible changes in the regulated industry impact on possible changes in the current inspection system?

Discussion on this issue centered on five points: Modification of inspection procedures to take advantage of HACCP plans; advantages and disadvantages of continuing current regulatory programs until HACCP is fully implemented; ways to combine HACCP and the current inspection system; the extent to which changes in industry will affect changes in inspection; and the potential effects of HACCP on small establishments. Modification of inspection procedures to take advantage of HACCP plans generally follow NACMCF recommendations that regulatory verification of HACCP plans can be accomplished in lieu of, rather than adding to, existing procedures. This would permit reallocation of inspection resources to food safety concerns and away from quality attributes and aesthetic concerns. HACCP should not invite an arbitrary reduction in the inspection force and the numbers of inspectors should not be tied to HACCP implementation. The potential effects of HACCP on small establishments were noted, along with the view that some accommodation during implementation should be afforded to these establishments.

All issues raised and discussed during the HACCP Round Table were taken into account in formulating this proposal.

FSIS Experience With Process Control

(1) Current Application of Hazard Analysis to Meat and Poultry Processing.

The principle of hazard analysis has been utilized to prevent foodborne illness associated with specific meat and poultry products and to support regulatory process control for certain voluntary procedures. The examples discussed below represent FSIS's early efforts using hazard analysis to identify CCP's in a production process and to establish stringent regulatory requirements for controlling production processes. Whereas the earlier regulations were prescriptive, the current proposal is performance based, and holds the industry fully responsible for conducting the hazard analysis and identifying the CCP's and critical limits associated with producing products that minimize the risk of foodborne illness.