under which animals are held in the period immediately before slaughter within its current authority. This is a period during which the health of the animal and its external cleanliness and degree of external microbial contamination can be affected in a way that may adversely affect food safety.

The FSIS in-plant inspectional role will certainly be affected by adoption and implementation of HACCP. As explained above in the portion of this preamble relating to the HACCP proposal, FSIS inspectors will be playing a verification role to ensure that appropriate HACCP plans are in place, are being implemented properly by the establishment, and are achieving the desired food safety results. This role will require increased activity by FSIS inspectors in the areas of records review, visual process verification, and product sampling. FSIS inspectors will, in some cases, have to develop new skills to carry out these activities within the HACCP framework. FSIS will be focusing on the specific additional tasks FSIS inspectors should be performing under HACCP and the training and skills that will be required.

FSIS is considering, in concert with FDA, the need for additional standards and Federal oversight to ensure that food is handled safely during transportation and distribution from processing establishments to the retail level. In the case of meat and poultry products, it is critical that products be shipped and stored in sanitary conditions and, in many cases, under refrigeration. If Federal standards are developed in this area, FSIS will have to consider what the role of Federal inspectors should be in ensuring such standards are met. No Federal agency would have the inspectional resources to inspect on a regular basis all of the hundreds of thousands of trucks, trains, vessels, planes, and storage/distribution facilities in the United States. FSIS will be considering whether there is an appropriate role for a targeted approach to inspection or random surveillance inspection, perhaps in collaboration with State and local food safety authorities, that would help ensure that safe practices are being observed at these critical stages of the food safety continuum. FSIS is interested in determining whether technologies, such as recording thermometers or temperature indicators on refrigerated trucks, could be adopted to enhance the roles of some relatively limited, periodic inspectional oversight and enable FSIS inspectors to work effectively in this area with inspectors from FDA and from counterpart agencies at the State and local levels.

At the retail level, FSIS intends to work closely with FDA and State and local officials and will continue to rely primarily on State and local authorities for inspectional coverage of restaurants, grocery stores and other conventional retail outlets. FSIS will be exploring how FSIS inspectors and field compliance officers can better collaborate with State and local food safety inspectors and other officials.

The FSIS inspection program for imported products relies on review of foreign inspection systems and exporting establishments to ensure that their approaches to food safety are equal to the U.S. approach, coupled with limited reinspection of incoming product at the U.S. border by FSIS inspectors. FSIS currently reinspects approximately 10 percent of import shipments, relying largely on organoleptic inspection techniques. Foreign establishments exporting to the United States will be required to adopt the pathogen reduction measures and HACCP requirements FSIS imposes on domestic establishments pursuant to this rulemaking. As HACCP develops, FSIS will be considering what effect adoption of HACCP should have on the nature and frequency of import inspection, including whether microbial testing should be incorporated, whether the periodic inspections FSIS currently conducts of foreign establishments should change, and how FSIS could best gain assurance on a continuing basis that establishments exporting to the United States are properly implementing appropriate HACCP plans.

Finally, some groups advocate amendment of the FMIA and PPIA to alter or repeal the current requirements for carcass-by-carcass and continuous inspection in meat and poultry establishments. This is necessarily an issue Congress would have to decide. As discussed in Part I of this document, carcass-by-carcass and continuous inspection play an important role in ensuring sanitation compliance is maintained, excluding diseased animals from the food supply, and detecting and removing other defects, such as fecal contamination, which are directly related to food safety. FSIS believes that, under any model of inspection, these objectives must continue to be met if food safety is to be ensured and the legitimate expectations of the public concerning the safety and quality of the food supply are to be satisfied.

Some propose that, with or without any statutory change in the carcass-bycarcass and continuous inspection mandates, establishments take more initiative in these areas. FSIS must consider how FSIS inspectors could verify with an acceptable degree of confidence that functions currently performed by a Federal inspector are being performed consistently, with the same rigor and effectiveness, by establishment employees. If establishment employees take on such functions currently performed by FSIS employees, consideration will have to be given as to whether "whistleblower" protection, which would shield them from retaliation of any kind for reporting problems, should be extended to them.

In general, under its proposed pathogen reduction and HACCP regulatory initiatives, FSIS will be considering what new inspectional tools and techniques FSIS should adopt to oversee the safety of meat and poultry products in a regulatory environment where greater responsibility for safety is being placed on establishments and their employees.

FSIS invites comment on these issues and on all aspects of how FSIS can best make use of its inspectional resources to improve the safety of meat and poultry products, both within currently inspected establishments and throughout the continuum from the farm to the consumer.

## IV. Economic Impact Analysis and Executive Orders

## A. Executive Order 12866

This proposed rule has been determined to be economically significant and was reviewed by OMB under Executive Order 12866.

Summary: Preliminary Regulatory Impact Assessment HACCP and Related Near-Term Initiatives Produce Net Benefit to Society

FSIS has prepared a Preliminary Regulatory Impact Assessment (PRIA) that evaluates the costs and benefits of a mandatory HACCP regulatory program and related near-term initiatives for all meat and poultry establishments under inspection. The PRIA concludes that mandating HACCP systems would result in net benefits that far exceed industry implementation and operation costs. **Mandatory HACCP Program** implementation at a cost of \$2 billion over 20 years is projected to produce a direct reduction in foodborne illness with public health benefits estimated at \$6-24 billion over 20 years.

The proposed near-term requirements, which would be incorporated into HACCP, would target pathogen reduction on carcasses and raw product, currently the products with the least systematically controlled hazards. The