

benefits are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli*, *E. coli* 0157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. The minimization of risk from these pathogens which can contaminate meat and poultry during slaughter and processing would produce a 90 percent reduction in the foodborne illness attributed to these pathogenic microorganisms. Ten percent of contamination occurs after the product leaves the manufacturing sector.

Industry costs to develop, implement, and operate HACCP processing control systems are estimated to total \$2 billion over 20 years. The proposed regulation would redistribute costs in a manner more acceptable to societal values which have always given priority to eliminating controllable diseases. Establishments that now have good processing controls would have relatively few implementation costs, while establishments that have little or no process control would need to spend more for compliance.

#### Market Failure Justifies Regulation of Pathogens

Since all raw meat and poultry products contain microorganisms which may be pathogens, raw food unavoidably entails some risk to consumers of pathogen exposure and foodborne illness. The presence and level of this risk cannot be determined by a consumer since pathogens are not visible to the naked eye. The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable either.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product.

The science and technology required to reduce meat and poultry pathogens is well established, readily available, and commercially practical. FSIS has concluded that the lack of consumer

information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention. The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS has determined to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry processing for commerce is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP regulatory program is the only means to attain this goal.

#### Alternatives

##### Process Control Regulatory Strategy

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination of food products and lower the risk of subsequent foodborne illness.

The process control regulatory strategy was evaluated using five factors for effectiveness:

1. Controls production safety hazards;
  2. Reduces foodborne illness;
  3. Makes inspection more effective;
  4. Increases consumer confidence;
- and
5. Provides the opportunity for increased productivity.

Using these factors, FSIS has determined that mandatory HACCP provides the greatest effectiveness.

FSIS examined six other process control approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

1. Status quo;
2. Intensify present inspection;
3. Voluntary HACCP regulatory program;
4. Mandatory HACCP regulation with exemption for very small establishments;
5. Mandatory HACCP regulation only for ready-to-eat products; and
6. Modified HACCP—negative records only.

Each of these alternatives was assessed using the five effectiveness factors for process control presented in the previous section. None was determined to meet all five criteria; each was found to be flawed in meeting one or more of the target factors.

The full text of the Preliminary Regulatory Impact Assessment is published as a supplement to this document.

#### B. Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the FMIA and PPIA from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different from, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the FMIA and the PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

#### C. Effect on Small Entities

The Administrator, Food Safety and Inspection Service, has determined that this proposed rule will have a significant economic impact on a substantial number of small entities. For purposes of this proposal, a small entity is defined as an establishment with a sales volume of meat and/or poultry products of no more than \$2.5 million per year. Based on this criterion, as of November 1994, there are 6,827 small slaughter and/or processing establishments that would be affected by this proposed rule. This analysis assumes that 5 percent of these small establishments or 341 establishments are currently operating under all the proposed requirements. Therefore, for these 341 establishments, this proposed rule would impose no additional costs.

For the remaining 6,486 small establishments, costs would be incurred as follows:

##### Near-Term Requirements

###### 1. Sanitation Standard Operating Procedures

Establishments would be required to develop a written plan addressing the required operating procedures, monitor