pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS judges to be unacceptable. A Federal regulatory program that reaches every level of meat and poultry production, processing, distribution and marketing is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP program is the only means of achieving this goal. Alternatives cannot achieve the reduction in pathogens necessary to assure the maximum reduction in food illness. To the extent that reductions in pathogen levels in meat and poultry can be achieved with current technology

and without causing significant economic or social distortions, FSIS as a public health agency can support no alternative to HACCP.

The economic argument supporting HACCP is that its benefits to society outweigh the costs imposed by this proposal. Table 1 shows that in terms of the costs and benefits that can be quantified, HACCP implementation would generate considerable net benefits to society.

In addition, HÅCCP is supported by redistribution arguments that are based on widely accepted social values. Public health legislation itself clearly implies society's preference for having costs manifest themselves as regulatory or production costs rather than as costs associated with illness. Even with demonstrated net benefits to society, it is important to keep the HACCP costs to industry down as much as possible to avoid unintended economic effects of HACCP implementation such as higher food prices or putting firms out of business. The use of systematic process control as reflected in the HACCP system would not require any establishment to change its production process, and the costs of monitoring a HACCP system are relatively small.

Thus, costs should have a minimal effect on the industry as a whole. Table 2 shows the increased cost per pound of product based on the estimated HACCP costs.

TABLE 2.- EFFECTS ON THE COST PER POUND OF MEAT AND POULTRY

Inspection program	1993 poundage* (billion)	Four-year estimated poundage (billion)	Near-term and HACCP implementa- tion total costs (million)	Cost per pound
Total State and Federal	77.7	310.9	\$733.5	\$0.00236

*Poundage data is slaughter carcass weight for Federal and State establishments with 26 of 27 states reporting slaughter data.

A reduction in the incidence of foodborne illness is the principal performance goal for both USDA and industry. Mandatory HACCP implementation is projected to produce a direct reduction in foodborne illness with public health benefits estimated at \$6.4–24.0 billion for 20 years (see Table 1). The Agency believes that these benefits clearly outweigh industry discounted costs of \$2.3 billion associated with implementing and maintaining HACCP controls for 20 years.

III. Alternatives

A. 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 and control other hazards in food products and lower the risk of subsequent foodborne illness. Accordingly, a regulatory strategy has been formulated to mandate process control improvements to achieve immediate reductions and an eventual minimization of the risk of meat and poultry pathogens in the Nation's food supply. Chemical and physical hazards will also be prevented. This strategy is supported by consumers, scientists, and the majority of meat and poultry industry processors who already

recognize the benefits of good process control.

Process control is a proactive strategy that all segments of industry can undertake to anticipate manufacturing problems in advance and prevent unsafe foods from ever being produced. In practice, process control is a systematic means to:

• identify and control production hazards;

determine control points in the processing system;

• establish standard measures for each control point;

 set procedures for plant workers to monitor requirements;

• provide clear instructions for appropriate corrective actions when a control point goes out of control;

 establish record-keeping to document control point measurements; and

• provide procedures for product verification tests to ensure system continues to operate as planned.

The process control strategy summarized in this paper is founded on three principles:

1. USDA regulatory policy should be focused on providing a solution to meat and poultry biological, chemical and physical hazards that present the highest public health risks;

2. Pathogenic microorganisms—which present the greatest foodborne risk to

human health—are now present in significant percentages of raw meat and poultry products; and

3. These pathogens and resulting risks of foodborne illness can be largely avoided by uniform meat and poultry industry efforts to attain and maintain more effective methods of control during the manufacturing process.

The focus of this strategy is explicitly on prevention; it is designed to prevent the production of defective product as opposed to more costly and less effective detect-and-condemn methods.

Process control is not a substitute for inspection any more than inspection could be a substitute for process control. This distinction is important because Federal inspection was never intended to be—and cannot be—the front-line control for food safety in meat and poultry processing plants. Safety controls must be built into the manufacturing process and be administered continuously by industry. The objective of inspection in a process control environment is to assure that those controls are present, adequate and are being used properly.

The primary benefits of a process control regulatory strategy are that it will: (1) Provide industry the tools and incentive to reduce meat and poultry pathogens as a means to improve food safety and (2) help reorient Federal inspection to better address product,