process and plant risks. A regulatory program that imposes better manufacturing process control methods as a means to reduce pathogen contamination and control other hazards emphasizes the fact that industry is primarily responsible for product safety while the Government's role is oversight.

B. Factors Considered in Evaluating A Process Control Strategy

The process control regulatory strategy was evaluated using five factors for effectiveness. A processing control program is effective if it:

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.

The following sections discuss these five effectiveness factors that have been applied to evaluate process control alternatives.

Controls Production Safety Hazards

Process control is a system for identifying food hazards and reducing or eliminating the risks they present. In operation, control points are established in a food production line where potential health hazards exist; management of these points has proven to be effective in reducing the probability that unsafe product will be produced. Ongoing records of each process control will enable plant managers and quality control personnel to spot trends that could lead to problems and devise a strategy that prevents them before they occur.

Detection by end product testing is not a viable alternative to process control because it only sorts good product from bad and does not address the root cause of unacceptable foods.

Additionally, keeping ''bad'' foods out of commerce through sorting end product is possible only when tests and standards for sampling are well established and it is practical only where the ''test'' is not expensive because sorting requires a huge number of samples for reliability.

Reduces Foodborne Illness

As industry improves its control over the safety aspects of meat and poultry production, foodborne illness will begin to decline. This is the principal non-negotiable goal for both USDA and industry.

The precise occurrence of human health problems attributed to pathogenic microorganisms or other potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants is not known. Foodborne illness is nevertheless recognized by scientists around the world as a significant public health problem and there is wide agreement that pathogenic microorganisms are the major cause of food-related disease. The cost of foodborne illness related to meat and poultry products alone is between $4.5–7.5 billion annually.

Makes Inspection More Effective

Currently, FSIS inspectors in meat and poultry plants perform random inspection tasks that generate independent data about a plant's production processes and environment. This activity produces ''snapshots'' of plant operations at that moment. In contrast, process control generates records of plant performance over time. These records and periodic verification inspections will enable FSIS inspectors to see how a plant operates at all times, i.e., whether and where processing problems have occurred, and if so, how they were addressed.

The availability of more and better processing data will establish trends that set benchmarks from which deviations can be more quickly and accurately assessed. USDA inspectors will be trained to spot these deviations and take action when needed to ensure plants bring a faulty process back into control. This type of Federal oversight is substantially more effective than a regulatory program that merely detects and condemns faulty end products. In the words of the National Advisory Committee on Microbiological Criteria for Foods, ''Controlling, monitoring, and verifying processing systems are more effective than relying upon end-product testing to assure a safe product.''

Increases Consumer Confidence

The number of foodborne illness outbreaks and incidents attributable to pathogens in meat or poultry raise questions about whether federal inspection is as effective as it should be. Highly visible public controversies about meat and poultry inspection indicate an erosion of public confidence in the safety of meat and poultry products. There are growing demands that USDA improve its regulation of pathogens. The process control regulatory strategy described in this paper is USDA's response to those demands.

Many outbreaks of foodborne illness have been determined to be caused by mishandling of meat and poultry products after federally-inspected processing. USDA believes that additional efforts to reduce pathogens during manufacturing will reduce these risks as well. This, coupled with the improved retail regulatory controls from state adoption and enforcement of the Food and Drug Administration's Food Code should reduce this cause of illness.

A significant portion of the meat and poultry industry does not take advantage of readily available methods to control its manufacturing processes. This is due in large part to the fact that meat and poultry processing industries are relatively easy to enter and are composed largely of small and medium-sized firms. Managers in these firms are frequently not as knowledgeable about safe production practices as they should be.

The Department has concluded that further regulation will bring industry standards up to what can practically be achieved in the manufacture of meat and poultry products through current scientific knowledge and available process control techniques. Raising the safety floor through regulations that mandate better process controls will demonstrate to the public that USDA and industry are making a concerted effort to reduce the risk of foodborne illness from meat and poultry.

The economic benefits of increased consumer confidence can be conceptually realized in the amount consumers would be willing to pay for safer food. This overall 'willingness to pay' is made up of several components. It reflects consumer desires to avoid foodborne illness and the expected medical and other costs associated with pathogens. In theory the total benefit associated with processing control regulations could be decomposed into two parts: first, the reduction in medical and other costs associated with pathogen-related illnesses (as discussed in a previous section), and the additional benefits which accrue to consumers not made ill but who may place a value on reduced risk of exposure to pathogens. At this time, the data are not available to make quantitative estimates of the consumer's willingness to pay.

Provides the Opportunity for Increased Productivity

Better process control is a sound and rational investment in the future of our nation's meat and poultry industry. USDA's process control strategy will educate industry management about the need and methodology for development of a consistent, preventive, problem-solving approach to safety hazards, which can be expanded to other business objectives such as product