quality and production efficiency. There is much evidence of how process control has improved worldwide industrial productivity in the past 40 years. This proposal will extend process control principles to parts of the meat and poultry industry that have not formerly used them.

Some important non-safety benefits that will accrue from industry use of better process control methods are:

- First, better production controls will result in more efficient processing operations overall with fewer product defects. Fewer defects mean less reworking, waste and give-away, resulting in increased yields and more profit opportunities.
- Second, better controls will significantly reduce the risk to processors that product with food safety defects will slip into commerce.
 Expensive and embarrassing product recalls can be entirely avoided with proper process controls.
- Third, better control of pathogens will impact all microorganisms, including those responsible for decomposition, resulting in quality improvements and longer shelf life for products.
- Fourth, better production controls improve plant employee productivity which improves profit opportunities.

C. Evaluation of Mandatory HACCP to Provide Process Control

Considering the five effectiveness factors of process control, the most effective means for ensuring that all industry uses adequate process control systems is a mandatory HACCP regulatory program. This alternative clearly meets all five criteria described above. In fact, a mandatory HACCP program was judged to be the only option that will effect adequate processing improvements in all establishments throughout the industry. Only through mandatory HACCP can pathogen risks be minimized to the fullest extent possible; thereby reducing foodborne illness to the maximum, improving effectiveness of inspection, increasing consumer confidence, and ensuring a more viable industry. No other alternative accomplishes as much in these five areas as mandatory HACCP.

In summary, FSIS has determined that:

- HACCP is a processing control strategy that has been scientifically proven effective in food manufacturing plants; and, therefore
- Mandating HACCP systems in all plants under USDA jurisdiction will protect the public from unreasonable

risks due to meat and poultry consumption.

HACĈP is widely recognized by scientific authorities such as the National Academy of Sciences and international organizations such as the Codex Alimentarius. It is used today by a number of plants in the food industry to produce consistently safe products. This approach has been supported for years by numerous groups that have studied USDA meat and poultry regulatory activities.

In 1983 FSIS asked the National Academy of Sciences to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, issued in 1985, was the first comprehensive evaluation of a scientific basis for inspection. The 1985 NAS report provided a blueprint for change: it recommended that FSIS focus on pathogenic microorganisms and require that *all* official establishments operate under a HACCP system to control pathogens and other safety hazards.

After urging the intensification of "current efforts to control and eliminate contamination with micro-organisms that cause disease in humans," NAS encouraged USDA to "move as vigorously as possible in the application of the HACCP concept to each and every step in plant operations of all types of enterprises involved in the production, processing, and storage of meat and poultry products."

The General Accounting Office (GAO) has also identified needed improvements in USDA's present inspection system. In its reports and congressional testimony, and in numerous publications, GAO has endorsed HACCP as the most scientific system available to protect consumers from foodborne illness. This sentiment is most clearly expressed in a May 1994 report, "Food Safety: Risk-Based **Inspections and Microbial Monitoring** Needed for Meat and Poultry," in which GAO recommended development of a mandatory HACCP program that includes microbial testing guidelines. GAO urged USDA to assist meat and poultry plants in the development of their microbial testing programs by, among other things, disseminating information on the programs already in

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and of Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989 NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed "HACCP Principles for Food Production" in November 1989. In this report, the Committee endorsed HACCP as a rational approach to ensure food safety and set forth principles to standardize the technique. In 1992, the Committee issued an updated guide, "Hazard Analysis and Critical Control Point System."

In 1993 NACMCF defined the roles of regulatory agencies and industry in implementing HACCP. "The Role of Regulatory Agencies and Industry in HACCP" proposed responsibilities for FDA, USDA, and other agencies and industry during various phases of HACCP implementation. Similar suggestions for program change have been voiced by consumers, industry, state and local government representatives, as well as other constituent groups. For example, consumers at recent public hearings and the HACCP Round Table supported implementation of mandatory HACCP throughout the meat and poultry

The meat and poultry industry has itself provided broad support for HACCP as a means to control pathogens, emphasizing that HACCP-based food production, distribution, and preparation can do more to protect public health than any Federal inspection program. They have recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture have also endorsed the HACCP approach.

D. Evaluation of Other Alternatives

FSIS examined six other 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
- Modified HACCP—recording deviations and responses only.

These alternatives were assessed using the five effectiveness factors presented in the previous section. Since