disease, and the Agency also intends to undertake additional risk assessments to generate dose/response curves for specific pathogens. The Agency will use the new information from this research to adjust targets, if necessary, to meet its goal of risk minimization.

The Agency believes that it is reasonable to set a goal of risk minimization assuming the implementation of the requirements in this proposal. Current technologies can and frequently do produce product of minimal risk. Contamination occurs from poor practices (errors) and lack of systematic preventive controls throughout the production process. For the first time, in this proposal the Agency is focusing on reducing pathogens. It is mandating interventions that a large part of the industry already uses to correct errors that cause pathogen contamination, and it is proposing the use of a system of controls that prevents pathogens which is the most effective way of reducing them. Empirical evidence of how effective these interventions and HACCP process controls are where they are currently used and the Agency's knowledge that many establishments do not currently use them leads the Agency to believe that the risk of pathogens in the manufacturing sector can be minimized by the implementation and enforcement of these requirements for all inspected establishments.

Further, the Agency is mandating product testing for pathogens which will enable it to set targets that can establish a standard of pathogen control throughout the industry that will minimize the risk of foodborne illness.

II. Market Failure Justifies Regulation of Pathogens to Protect Public Health

Consumers make choices about the food they purchase based upon factors such as price, appearance, convenience, texture, smell, and perceived quality. In an ideal world, people would be able to make these decisions with full information about product attributes and choose those foods which maximize their satisfaction. In the real world, however, information deficits about food safety complicate consumer buying decisions.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food unavoidably entails some risk of pathogen exposure and foodborne illness to consumers. However, the presence and level of this risk cannot be determined by a consumer, since pathogens are not visible to the naked eye. Although they may detect unwholesomeness from obvious indications such as unpleasant odor or discoloration caused by spoilage microorganisms, consumers cannot assume products are safe in the absence of spoilage. They simply have no clear-cut way to determine whether the food they buy is safe to handle and eat.

When foodborne illness does occur, consumers often cannot correlate the symptoms they experience with a specific food because some pathogens do not cause illness until several days after exposure. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable 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.

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 and other hazard 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. An additional complication is that raw product is often fungible at early stages of the marketing chain. For example, beef from several slaughterhouses may be combined in a batch of hamburger delivered to a fast food chain. Painstaking investigation by public health officials in cases of widespread disease often fails to identify foodborne illness causes; in half the outbreaks the etiology is unknown.

Most markets in industrialized economies operate without close regulation of production processes in spite of consumers having limited technical or scientific knowledge about goods in commerce. Branded products and producer reputations often substitute for technical or scientific information and result in repeat purchases. Thus brand names and product reputations become valuable capital for producers.

In the U.S. food industry, nationally recognized brand names have historically provided significant motivation for manufacturers to ensure safe products. In recent years, more and more meat and poultry have come to be marketed under brand names.

Yet in the case of meat and poultry contaminated with pathogenic microorganisms, even brand name protection has not provided enough motivation for processors to produce the safest product they can make.

The failure of meat and poultry industry manufacturers to produce products with the lowest risk of pathogens and other hazards cannot be attributed to a lack of knowledge or appropriate technologies. The science and technology required to significantly reduce meat and poultry pathogens and other hazards is well established, readily available and commercially practical.

There are three main explanations for why a large portion of the meat and poultry industry has not taken full advantage of available science and technology to effectively control manufacturing processes.

1. Meat and poultry processing businesses are relatively easy to enter; there are no training or certification requirements for plant operators. Consequently, the level of scientific and technical knowledge of management in many plants is minimal.

2. The industry is very competitive and largely composed of small and medium-sized firms that have limited capital and small profits.

3. Management in many of these plants has little incentive to make capital improvements for product safety because they are not distinguishable by customers and therefore yield no income.

In spite of these barriers, many industry establishments do produce meat or poultry products using process controls that assure the lowest practical risk of pathogens and other hazards. But a significant part, particularly those producing raw products for consumers for further processing, do not.

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 to protect public health.

Regulating Pathogens

The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry