

This line between industry and FSIS responsibility has become blurred. This may be due in part to the continuous presence of FSIS inspectors in meat and poultry establishments and the statutorily mandated USDA inspection legend, which together may have encouraged some establishments to rely on FSIS to ensure the safety of the establishment's products rather than take full responsibility themselves for the safety of their products. Because the FSIS inspector is obligated to prevent adulterated product from leaving the establishment, some establishments may operate on the assumption that what is not specifically prohibited or detected by the FSIS inspector may continue. This is not acceptable.

Likewise, the FSIS inspection program has too often taken on the burden of expending significant inspectional resources to bring establishments into compliance—such as in cases of repeat violators of sanitation standards—rather than finding efficient means to hold establishments accountable for complying with applicable standards. As a result, the inspection resources needed to ensure that all establishments have appropriate production controls are frequently spent on intensified inspection of poor performers. For these reasons, the lines of responsibility for food safety must be clarified.

Finally, change is needed to move toward a more preventive approach to ensuring the safety of food. The current system relies too heavily on FSIS inspectors to detect and correct problems after they have occurred, whether in establishments or after the product has left the establishment. This is not the most efficient use of FSIS resources, and, especially in the case of pathogenic microorganisms, it is not effective in protecting public health. Many meat and poultry establishments, as well as other segments of the food industry, have found that safety can best be ensured by systems designed to prevent food safety problems. To protect public health and make the best use of its resources, FSIS needs to build the principle of prevention into its inspection system.

The changes FSIS plans in its inspection program—targeting pathogenic microorganisms, setting priorities on the basis of public health risk, clarifying roles and responsibilities, and building in the principle of prevention—constitute an institutional paradigm shift that can significantly enhance the effectiveness of the FSIS program and reduce the risk of foodborne illness.

To achieve such change, FSIS must articulate its food safety goal in broad terms and adopt a food safety strategy that will work to achieve both a real reduction of pathogens in the near term and, in the long term, the fundamental changes in the inspection program that are needed to better protect public health.

FSIS Food Safety Goal

It is tempting to think of food safety as an absolute. In an ideal world, there would be no cases of foodborne illness. The world we live in is, however, far from ideal. The production of the food that feeds 250 million Americans every day is an enormously complex task. It is undertaken in a natural environment where hazards, including pathogenic microorganisms, are common. It requires a level of technological intervention—in the form of machinery, chemicals, and processing—that itself can introduce hazards. And it is an enterprise that depends, in the end, on a vast array of human interventions and activities, which means that human error is a constant factor that can contribute to food safety hazards.

FSIS believes the public can understand that safety is not an absolute, and the laws FSIS administers do not speak in absolute terms. FSIS also believes, however, that public expectations are justifiably high when it comes to measures the food production system should take to reduce risk and ensure the safety of food. Furthermore, the laws FSIS administers set high standards—for example, meat and poultry products are deemed “adulterated” and thus unlawful if they are for any reason “unhealthful”—and they empower FSIS to take actions needed to meet those standards and meet the public's high expectations concerning the safety of the food supply.

FSIS believes its food safety goal should be to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur.

There is no single technological or procedural solution to the problem of foodborne illness, and the Agency's food safety goal will not be achieved overnight. Indeed, inherent in the nature of the Agency's goal is the concept that food safety requires continuous efforts to improve how

hazards are identified and prevented. It is based on the public health principle that, on a continuing basis, society should seek out and take preventive measures to reduce the risk of illness. It reflects the Agency's belief that steps that can be taken today to reduce the risk of foodborne illness should be taken today, but that steps judged adequate today may not be judged adequate tomorrow.

In the case of the major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS believes that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. This does not necessarily mean absolute elimination of such pathogens, but it does mean preventing and reducing contamination with these pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

Achieving this food safety goal requires long-term commitment and action by Government and industry. It also requires general agreement on a regulatory strategy that can achieve the goal.

FSIS Food Safety Regulatory Strategy

FSIS believes that to achieve its food safety goal, and bring about the change described above, a new regulatory strategy is needed. The major elements of the Agency's proposed strategy are outlined in this section, with a brief explanation of how the regulatory changes FSIS is proposing in this document will advance the strategy.

1. *FSIS must clearly define the minimum requirements all establishments must meet to produce safe meat and poultry products and make establishments readily accountable for meeting them.* Good sanitation and basic good manufacturing practices (GMP's) are generally regarded as essential prerequisites for the production of safe food. The current FSIS program includes sanitation regulations that set out certain standards of cleanliness establishments are required to meet; and the Agency has provided guidance, in the form of a Sanitation Handbook, on how sanitation requirements can be met. FSIS also has promulgated regulations that impose various specific requirements, especially regarding processing operations, that might be characterized as GMPs.

In the sanitation area, however, FSIS has not spelled out clearly the responsibility every establishment has to install procedures that ensure sanitation requirements are met every