Hazard analysis and critical control point systems in the United States Department of Agriculture regulatory policy

T.J. Billy (1) & I.K. Wachsmuth (2)

(1) Administrator, Food Safety and Inspection Service, United States Department of Agriculture, 14th and Independence Avenue, SW, Washington, DC 20250, United States of America
(2) Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture, 14th and Independence Avenue, SW, Washington, DC 20250, United States of America

Summary
Recent outbreaks of foodborne illness and studies by expert groups have established the need for fundamental change in the United States meat and poultry inspection programme to reduce the risk of foodborne illness. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) has embarked on a broad effort to bring about such change, with particular emphasis on the reduction of pathogenic micro-organisms in raw meat and poultry products.

The publication on 25 July 1996 of the Final Rule on pathogen reduction and hazard analysis and critical control point (HACCP) systems was a major milestone in the FSIS strategy for change. The Final Rule provides a framework for change and clarifies the respective roles of industry and government in ensuring the safety of meat and poultry products.

With the implementation of this Final Rule underway, the FSIS has been exploring ways in which slaughter inspection carried out under an HACCP-based system can be changed so that food safety risks are addressed more adequately and the allocation of inspection resources is improved further.

In addition, the FSIS is broadening the focus of food safety activities to extend beyond slaughter and processing plants by working with industry, academia and other government agencies. Such co-operation should lead to the development of measures to improve food safety before animals reach the slaughter plant and after products leave the inspected establishment for distribution to the retail level.

For the future, the FSIS believes that quantitative risk assessments will be at the core of food safety activities. Risk assessments provide the most effective means of identifying how specific pathogens and other hazards may be encountered throughout the farm-to-table chain and of measuring the potential impact of various interventions. In addition, these assessments will be used in the development and evaluation of HACCP systems. The FSIS is currently conducting a quantitative risk assessment for eggs, and several surveys and studies are being performed to supply data needed to conduct other risk assessments. The FSIS has established a food safety research agenda which will fill data gaps.

Keywords
Introduction

The mission of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) is to ensure that meat, poultry and egg products are safe, wholesome and properly marked, labelled and packaged. In the past, the FSIS ensured meat and poultry food safety primarily by managing an inspection programme within meat and poultry slaughter and processing establishments. This programme relied heavily on detection and correction of establishment sanitation and food safety problems by FSIS inspectors.

Public concern about recent outbreaks of foodborne illness, together with studies conducted over the past decade by the National Academy of Sciences, the United States General Accounting Office and the FSIS, have identified the need for fundamental change in the FSIS meat and poultry inspection programme to improve food safety, to reduce the risk of foodborne illness in the United States of America (USA) and to make better use of resources.

Of particular concern was the acute need to address more effectively the documented problem of pathogenic micro-organisms in raw meat and poultry products. Such bacteria, including Salmonella, Escherichia coli O157:H7, Campylobacter and Listeria monocytogenes, are significant food safety hazards associated with meat and poultry products. The FSIS estimates that the contamination of meat and poultry products by these bacteria causes up to 4,000 deaths and 5,000,000 illnesses annually in the USA. In addition to inadequately targeting and controlling pathogenic micro-organisms, the traditional regulatory approach did not require the industry to integrate systematic, preventive process control into the production process.

Finally, the FSIS inspection programme has historically focused on the manufacturing of meat and poultry products. This focus will now become wider as the FSIS has embarked on a programme to ensure 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 that the hazard will occur. Those in control of each stage of the farm-to-table continuum bear responsibility for identifying and preventing or reducing food safety hazards which are under their operational control.

Pathogen reduction and hazard analysis and critical control point Final Rule

The publication on 25 July 1996 of a Final Rule on pathogen reduction and hazard analysis and critical control point (HACCP) systems was a major achievement in the FSIS strategy for change (3). The Rule has four key provisions:

a) sanitation standard operating procedures (SOPs)
b) HACCPs
c) testing for generic E. coli
d) pathogen reduction performance standards for Salmonella.

The pathogen reduction and HACCP Rule provides a framework for carrying out a comprehensive strategy of food safety improvements. The Rule will improve substantially the ability of both meat and poultry establishments and the FSIS to target and systematically prevent and reduce food safety hazards, and to upgrade food safety measures continuously as scientific and technological advances are made.

The Rule also clarifies the respective roles of industry and FSIS in ensuring the safety of meat and poultry products, and underlines the responsibility of the industry in the production and marketing of products which are safe, unadulterated and properly packaged and labelled. The FSIS is responsible for inspecting products and facilities to verify that the statutory requirements are being met (and also take appropriate compliance and enforcement actions when requirements are not being met).

Sanitation standard operating procedures

Inspected establishments must develop, implement and maintain written sanitation SOPs. The sanitation SOPs must describe all procedures which the establishment conducts daily to prevent direct contamination or adulteration of products. The requirements for sanitation SOPs stress that sanitation is the responsibility of the establishment: such requirements also assist the FSIS inspectors in verifying that plant management is assuming sanitation responsibilities, and in documenting deficiencies (when necessary) for regulatory enforcement purposes.

Hazard analysis and critical control points

Establishments must develop and adopt an HACCP programme to ensure that science-based controls for the prevention and reduction of food safety hazards are in place. Conceptually, an HACCP system is one whereby meat and poultry production establishments can identify and evaluate the food safety hazards which may affect product safety. An HACCP system also helps management to implement the controls necessary to prevent -- or to keep within acceptable limits -- those hazards, to monitor the performance of controls and to maintain routine records.

Establishments will be required to develop HACCP plans based on the seven principles established by the United States National Advisory Committee on Microbiological Criteria for Foods, namely:

a) hazard analysis
b) critical control point identification
c) establishment of critical limits
d) monitoring procedures
e) corrective actions
f) record-keeping
g) verification procedures.

HACCP systems will be required to have critical control points which address product safety hazards only, as opposed to control measures related to economic adulteration and quality. The FSIS will not approve HACCP plans in advance, but will review each plan for compliance with the requirements of the Final Rule and will continually verify the effectiveness of the plans.

**Testing for generic *Escherichia coli***

Slaughter establishments will also have to begin testing for generic *E. coli* to verify process control for faecal contamination. The FSIS has set performance criteria for generic *E. coli* for some product classes based on the results of nation-wide baseline surveys. The FSIS is collecting additional data in order to set performance criteria for all major production classes in the future. Until these performance criteria have been set, establishments will use statistical process control techniques to evaluate *E. coli* test results (4). Test results will not be used to take regulatory action, but will inform the industry of continuing process control effectiveness, and will guide the FSIS on when to look for other information to evaluate whether a process control problem exists which requires regulatory action. The cumulative plant data also will assist industry in the development of HACCP programmes.

**Pathogen reduction performance standards for *Salmonella***

The pathogen reduction performance standards for *Salmonella* apply to chilled carcasses and raw ground products. The standards are designed to verify that slaughter and grinding HACCP systems are effective in reducing and controlling enteric pathogen contamination. *Salmonella* was selected as the target pathogen because this is the leading cause of foodborne illness in meat and poultry products, is present at varying frequencies in all types of raw meat and poultry products, and can easily be tested for in a variety of products. Plants will be required to achieve a prevalence of *Salmonella* contamination through their HACCP programmes which is below national baseline prevalence (as reflected in the FSIS baseline surveys) for each raw product. These are regulatory standards which the FSIS will require the plant to meet consistently over time as a condition to obtaining inspection, which is in turn a requisite for operation.

**Implementation dates**

The provisions of the Final Rule on pathogen reduction and HACCP are being implemented in phases. The provisions for sanitation SOPs and testing for generic *E. coli* became effective on 27 January 1997. The HACCP requirement and performance standards for *Salmonella* are being phased in according to the size of the establishment. Implementation will be enforced in large plants on 26 January 1998, and will be completed in the smallest plants by 25 January 2000.

**Future directions in inspection**

With the provisions of the Final Rule scheduled to be implemented, the FSIS is beginning to explore ways in which changes can be made to slaughter inspection procedures in accordance with an HACCP-based system. The current slaughter inspection personnel perform carcass-by-carcass inspection to detect disease and contamination, has remained largely unchanged for decades and does not adequately apportion work according to public health risk. The implementation of HACCP systems provides the FSIS with an opportunity to test new inspection models, as establishments will have greater control of their operations. The FSIS believes there is substantial consumer protection regulatory work which can be performed at other points of the farm-to-table chain, and the FSIS intends to redesign slaughter inspection procedures in order to redeploy resources to other points both inside and outside slaughter plants.

**Food safety from farm to table**

This strategy for redeploying resources to points beyond slaughter and processing plants is consistent with the FSIS belief that measures taken to improve food safety within inspected establishments must be part of a comprehensive food safety strategy which addresses hazards at other points in the farm-to-table chain. The scope of FSIS food safety activities is broadening beyond slaughter and processing plants, with particular new emphasis on hazards which arise during transportation, distribution and retail sale.

**Animal production**

The FSIS is working with industry, academia and other Government agencies to develop and encourage measures which can be taken both on the farm and during distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. The FSIS has no regulatory authority at this stage, and does not intend to mandate production practices. However, the FSIS believes that the voluntary application of food safety assurance programmes, based on HACCP principles, can be useful in establishing risk-reduction practices on the farm and during intermediate marketing stages. The FSIS believes that continued public concern about foodborne pathogens, and the need for slaughter establishments to address these and
other hazards effectively, will increase incentives for producers to adopt food safety practices at the animal production level.

Transportation and storage

Food safety during transportation and storage also are important links in the food safety chain. In the USA, the FSIS, the Food and Drug Administration (FDA), and State and local governments share authority for the inspection of food products. The FSIS and the FDA are working together to develop standards which will govern the safety of foods during transportation and storage, with particular emphasis on the importance of time/temperature control in minimising the growth of pathogenic micro-organisms.

Retail

In the retail area, the FSIS and FDA are working with State officials to ensure the adoption of uniform, science-based standards and to foster the adoption of HACCP-type preventive approaches. State and local authorities have primary responsibility for the food safety inspection of retail stores and restaurants, but the FSIS and FDA can provide guidance through the Food Code to encourage the development and adoption of sound food safety standards and practices nation-wide. Technical support and training can also be of assistance (2).

Consumer education

Even as progress is achieved in reducing contamination during these stages, food-handling practices of retailers and consumers continue to be of critical importance. Proper storage, preparation and cooking of meat and poultry products are essential if the national goal of reducing foodborne illness to the maximum extent possible is to be achieved. The FSIS is augmenting food safety education and information efforts through expanded co-operation with industry, other Government agencies, consumers and public interest groups, educators and the media.

Risk assessment

For the future, the FSIS believes that quantitative risk assessments are the most effective means of identifying how specific pathogens and other hazards may be encountered throughout the farm-to-table chain and of measuring the potential impact of various interventions. These assessments could then be used to make risk management decisions, including the development and evaluation of HACCP systems.

While the science of microbial risk assessment is still at an early stage, recent advances in predictive microbiology and the systematic collection of baseline data on the presence of pathogenic bacteria in foods, coupled with limited human health data, have allowed the first rough quantitative microbial risk assessments to be made. These efforts are particularly difficult since levels of bacteria in food can both increase and decrease, the infectious dose of most foodborne pathogens is not known and there are sub-populations which are more vulnerable to infection. USDA scientists have taken those limitations into account and have designed a risk assessment conceptual model – a dynamic fault tree – which is being used to assess the risk or probability of adverse health effects from the consumption of hamburgers contaminated with E. coli O157:H7 (1). This model should be suitable for application to other pathogens and foods.

At the same time, the FSIS and others are conducting a quantitative risk assessment for shell eggs and egg products. The project will yield information which is critical to the understanding of the safe handling of eggs to prevent the growth of harmful bacteria, particularly Salmonella Enteritidis. After initial risks have been estimated, potential interventions can be modelled to evaluate the impact on the risk. In this way, the most sensitive, or critical, controls can be identified.

A number of surveys and studies are being conducted by the FSIS to provide new data which can be used to conduct risk assessments. For instance, the FSIS is conducting microbiological baseline studies which measure the presence and numbers of Staphylococcus aureus, Clostridium perfringens, Listeria monocytogenes, Campylobacter jejuni and C. coli, E. coli O157:H7 and Salmonella present in various animal species. As previously indicated, baseline studies have provided data which the FSIS has used to set pathogen reduction performance standards for Salmonella in beef and poultry plants in the Final Rule on pathogen reduction and HACCP.

To provide more accurate information on the human health effects of pathogens, the United States Centers for Disease Control and Prevention, the FSIS and the FDA, working with local health departments in five States, have established sentinel sites for the collection of data which can be used to establish the incidence and aetiology of foodborne disease. Plans are under way to expand the number of sites and the number of foodborne pathogens associated with both acute and chronic diseases for which tests are performed.

To supplement the data from these surveys and studies, the FSIS has established a research agenda driven by both public health concerns and the need to fill data gaps which are preventing the Agency from conducting quantitative risk assessments. Primarily, the FSIS needs to establish the links between pathogens present on or in food animals and consequent human disease, so that interventions can be identified effectively. The FSIS also needs research to provide better tools to generate those data, for example, a much simpler and more rapid way to isolate and identify Campylobacter, which has been shown to cause the majority of sporadic outbreaks of foodborne illness associated with meat and poultry products in the USA.
To encourage further the use of risk assessment, the FSIS has established a Division of Epidemiology and Risk Assessment within the new Office of Public Health and Science. This new group will co-ordinate all future activities related to risk assessment with the broader goal of establishing performance standards for specific pathogens.

International trade

The steps currently being taken by the FSIS to improve food safety within the USA are consistent with international rules designed to facilitate fair trade. The pathogen reduction and HACCP rule and the increasing focus on risk assessment by the FSIS, for example, are both consistent with the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures, which requires countries to ensure that sanitary measures are based on science and risk assessment principles (5). In addition, the FSIS believes that the use of performance standards will simplify the process of determining equivalence by focusing on outcome rather than on the steps taken to achieve that outcome.

Conclusion

The FSIS believes that the food safety initiatives currently being undertaken will provide a framework for significant food safety improvements which will help achieve the goal of reducing foodborne illness. In the future, the FSIS will explore ways of changing the current slaughter inspection model to better address public health risks and to encourage the use of quantitative risk assessments when risk management decisions are made.
Sistemas de análisis de riesgos y control de puntos críticos en Estados Unidos de América: las normas del Departamento de Agricultura

T.J. Billy & I.K. Wachsmuth

Resumen
Una serie de brotes de intoxicaciones alimentarias y diversos estudios conducidos por grupos de expertos han puesto recientemente de manifiesto la necesidad de introducir cambios fundamentales en el programa estadounidense de inspección de carne y productos avícolas, con objeto de reducir el riesgo de estas enfermedades. El Servicio de Protección e Inspección de Alimentos (Food Safety and Inspection Service: FSIS) del Departamento de Agricultura de Estados Unidos de América ha iniciado un vasto proyecto para llevar a cabo tales cambios, haciendo especial hincapié en la reducción de microorganismos patógenos en la carne y los productos avícolas.

La publicación, el 25 de julio de 1996, de la Normativa Definitiva sobre la reducción de patógenos y los sistemas de análisis de riesgos y control de puntos críticos (hazard analysis and critical control point: HACCP) supuso un hito en la estrategia de cambio preparada por el FSIS. Esta reglamentación establece un marco para el cambio y define con claridad los papeles respectivos del sector privado y el gobierno en lo tocante a garantizar la inocuidad de la carne y los productos avícolas.

Con la aplicación de esta normativa ya en curso, el FSIS está explorando posibles reformas de la inspección en los mataderos, basadas en un sistema HACCP y que permitan tratar de manera más adecuada los riesgos ligados a la protección alimentaria y hacer un uso más eficaz de los recursos que se destinan a la inspección.

Por otro lado, en colaboración con el sector privado, la universidad y otros organismos públicos, el FSIS está ampliando el alcance de sus actividades de

Mots-clés
inspección de alimentos, cuya cobertura no deberá limitarse a las fases de sacrificio y de procesamiento industrial. La mencionada cooperación debería traducirse en la aplicación de medidas que incrementen el nivel de seguridad de los alimentos tanto antes de que los animales lleguen al matadero como una vez que los productos abandonan el matadero oficial para su distribución y venta al por menor.

El FSIS piensa que, en el futuro, la evaluación cuantitativa de riesgos constituirá la espina dorsal de la protección alimentaria. La evaluación de riesgos es el medio más eficaz para determinar cómo y en qué nivel de la cadena, desde la producción al consumo, pueden presentarse determinados patógenos u otro tipo de riesgos, y para medir el potencial impacto de varias intervenciones. También se utilizarán estas evaluaciones para crear y probar sistemas HACCP. El FSIS lleva a cabo en la actualidad una evaluación cuantitativa de riesgos centrada en los huevos, además de realizar varias encuestas y estudios que proporcionarán los datos necesarios para realizar otras evaluaciones de riesgos. El FSIS ha elaborado un programa de investigación en materia de protección alimentaria destinado a completar los datos existentes.

**Palabras clave**

**References**