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## **HACCP in the United States: regulation and implementation**

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### **3.1 Introduction: the regulatory background**

All three branches of the US government (legislative, executive and judicial) have a role in the development of legislation governing the food industry. Congress (the legislative branch) passes laws that establish general requirements and provide authority to regulating agencies to implement and enforce them. Once the President (the executive branch) signs the legislation, it becomes an official statute and is published in the United States Code (USC). The principal legislation governing safety in the meat industry is the Federal Meat Inspection Act and the Poultry Products Inspection Act which cover all products derived from domesticated animals, and the Processed Products Inspection Act. The first two Acts are administered by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). By agreement the Food and Drug Administration (FDA) has responsibility for foods containing less than 3% meat and 2% poultry and all closed meat-containing sandwiches. The language of these acts does not delineate the actual method of inspection, but requires that the foods covered be safe and unadulterated within the meaning of the legislation.

Because laws are broad and non-specific, the President is given the responsibility of implementing them through the various regulatory agencies by establishing regulations which provide detailed requirements and procedures. All such regulations must go through a public rule-making process which is mandated by the Administrative Procedure Act of 1946. This procedure is initiated by publishing an advance notice of proposed rule making (ANPR) in the Federal Register (FR), designed to alert interested parties that a new regulation is being considered and to solicit their views. The

FR is published by the government every working day of the year and allows all interested parties to comment on the provisions of the proposed regulation, and gives the appropriate agency the chance to respond. The second step is the publication of the proposed rule where, once again, interested parties may comment. Under US law all comments, however trivial, must be addressed and answered in written form in the FR as part of the Final Rule. If, as a result of comments or changing circumstances, the Proposed Rule must be substantially modified, a second Proposed Rule must be published. Once finalised, the regulation has the force and effect of law, unless reinterpreted by the courts (the judicial branch). Final regulations are published in the FR and, once a year, compiled into the Code of Federal Regulations (CFR). Final regulations in the FR include a preamble which discusses why the regulation is being proposed and the science base underpinning it. It also contains responses to comments received, a cost/benefit analysis (especially for the impact on small businesses), any potential environmental impacts, and an analysis of the paperwork required of those organisations affected by the regulation in question.

### **3.2 Development of HACCP in the United States**

In the early 1970s it became generally accepted that the Hazard Analysis Critical Control Point (HACCP) system constituted an advanced and comprehensive system for producing safe food. A number of initiatives at this time anticipated or incorporated HACCP principles, notably the 1974 regulations governing low acid canned foods which applied to canned meats as well as other canned products. These prescribed a system designed to eliminate the threat of botulism and other microbiological hazards in the production of canned foods. Later partial and total quality control programs were developed as regulatory options by the USDA for use within food processing. The USDA also developed so-called streamlined inspection systems for meat plants as an alternative to traditional inspection regimes. These initiatives incorporated elements of HACCP philosophy.

1985 marked a turning point for HACCP. Two seminal reports by the National Academy of Sciences paved the way. The first of these was *Meat and Poultry Inspection, The Nation's Program*. This report firmly endorsed implementing HACCP systems as the key to safer meat and poultry products. The second report had a broader focus: *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. However, it also championed HACCP systems, especially for high-risk foods. As a result, the National Marine Fisheries Service (NMFS) began a pilot program designed to incorporate HACCP principles into the harvesting, production and processing of fish and fish products, and to explore how HACCP could be integrated into the regulatory and inspection process. The FSIS also produced a comprehensive response to the two National Academy of Science reports designed to adapt the

agency to a new role of incorporating HACCP principles into meat and poultry processing and the way the industry was regulated.

Progress in incorporating HACCP principles into the regulatory framework, however, proved slow. Despite support from the two main trade organisations, the American Meat Institute and the National Fisheries Institute, consumer organisations were initially slow to champion HACCP as a concept, and the FSIS faced opposition from its inspectors' union. However, in January 1993 the new Clinton administration faced a major outbreak of food poisoning. A large number of cases of enterohemorrhagic *Escherichia coli* occurred in the Pacific Northwest, causing the deaths of some children who had consumed undercooked hamburgers. Renewed effort was put into developing a new HACCP-based regulatory system. Such a system was finally mandated for seafood plants in 1994 and for meat and poultry plants in 1996.

The new regulatory regime for the meat and poultry industry introduced in July 1996 was implemented through the Pathogen Reduction Hazard Analysis Critical Control Points (HACCP) System Final Rule, popularly known as 'Mega-Reg' because of its scale in seeking to replace all existing regulations governing the inspection of meat and poultry products. These regulations, applying to all food processors inspected by the FSIS and similar state agencies, require meat and poultry product processors to take preventative and corrective measures at each stage of the food production process where food safety hazards occur, using a variant of the HACCP system as defined by Codex. Each plant has the responsibility and flexibility to base its food safety controls on an approved HACCP plan. This plan must identify the critical control points (CCPs) detailed in the regulations and use the controls set out in the regulations in managing them. Sanitation Standard Operating Procedures (SSOPs) are also required. These must describe daily procedures sufficient to prevent direct contamination or adulteration of products. Additional requirements include mandatory *E.coli* O157 testing by slaughter operations, and compliance with performance standards for *Salmonella*.

Regular auditing of HACCP plans by independent experts is a common practice. However, ultimate responsibility for the acceptability of the HACCP plan rests with the FSIS. When recalls of product or sampling problems occur, the FSIS will usually require a re-evaluation of the HACCP plan. Facilities failing to implement 'proper HACCP programs' will face enforcement action that could mean withdrawal of the USDA's inspectors and plant shutdown. In these cases responsible management may be permanently barred from operating a food plant in the United States. Civil and criminal penalties, including fines and imprisonment, might also follow. The more severe penalties are reserved for fraudulent activity such as destroying or falsifying documentation, serious cases of negligence or the wilful contamination of the food supply.

The endorsement of the HACCP system by the United States had significant international implications. Meat and poultry inspection laws in the United States require that countries wishing to export meat and poultry products into the United States maintain an inspection system that is equivalent to that required by

the FSIS for domestic production. This requirement meant effectively that the 40-odd countries approved to export meat and poultry products to the United States would have to produce and inspect products in accordance with HACCP principles. These countries discuss common food safety issues through the Codex Alimentarius, its committees, its staff and various meetings. Codex is a joint program of two United Nations agencies, the Food and Agriculture Organisation and the World Health Organisation, designed to set common standards that facilitate international trade in food. The early adoption of HACCP principles by the European Union as well as the United States has meant that they have also been adopted by Codex Alimentarius as the starting point for food safety systems around the world.

### **3.3 HACCP implementation in practice**

The nature of HACCP implementation in meat and poultry plants has been more traditional in the United States than in some other countries. As an example, 'Mega-Reg' requires continuous inspection of slaughter line operations and can thus be seen as layering HACCP onto existing inspection regimes rather than replacing the latter with the former. The key legislation lying behind the regulatory process predates HACCP as a concept and is based on a command and control approach requiring the constant presence of food inspectors. Short of this legislation being revised or replaced, there can be no full transfer of food safety from government inspectors to plant managers. Similarly, 'Mega-Reg' requires plant management to carry out microbiological sampling. This can be seen as antithetical to the concept of HACCP. Properly administered, HACCP obviates the need for routine microbiological sampling, replacing a reactive with a more proactive approach.

HACCP implementation under 'Mega-Reg' began initially in large meat and poultry operations, which had 18 months to comply, completing in early 1998. Small plants had 30 months to comply, completing in early 2000, and very small plants had 42 months. Preliminary results have been analysed by the Centers for Disease Control (CDC) and the USDA. Significant reductions in the levels of *Salmonella*, *Listeria* and *Campylobacter* contaminating raw meat have been documented. As an example, contamination rates for ground turkey fell by 45% from 1997–98, those for chicken by 45% and those for ground beef by 36%. Contamination rates for *Escherichia coli* O157:H7 have not been materially affected, but levels have not increased. However, overall contamination rates have remained high in some areas. In the case of *Salmonella*, 36% of ground turkey sampled was found to be contaminated, 11% of chicken and 4.8% of ground beef. In late 1998 there was a spate of product recalls caused by *Listeria monocytogenes* contamination and as many as 20 deaths caused by foodborne pathogens. The two largest recalls, at Bil Mar Foods in Michigan and at Thorn Apple Valley Foods in Arkansas, were reputed to involve 15 to 30 million pounds of product, making them some of the largest food product recalls in

American history. Most experts have attributed these two recalls to, in one case, contamination as a result of poor GMP in the handling and storage of rework material, and, in the other, a failure to maintain the Standard Sanitary Operating Procedures (SSOPs) set out under 'Mega-Reg'. In May 1999 the FSIS responded by announcing a requirement for reassessed HACCP plans for ready-to-eat livestock and poultry products to be submitted, including *Listeria monocytogenes* as a specific hazard. These developments show that, while HACCP provides a systematic approach to food safety control, it relies on an effective understanding of key hazards and a systematic approach to implementation, including implementation of the relevant prerequisite programs (such as Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP)), to succeed.

There have been a number of other initiatives designed to remedy such problems as these and to complement and support HACCP systems, for example in developing more expertise in understanding foodborne pathogens. In January 1997 President Clinton announced a Food Safety Initiative (FSI) designed to improve the system for detecting outbreaks of food illness, promote research on emerging pathogens such as *E.coli* O157:H7 and *Cyclospora*, and educate consumers and the industry on safe food handling practices. Part of the FSI introduced in the autumn of 1997 is the Product Safety Initiative (PSI) designed to address safety along the entire food chain from farm to table, including the adoption of HACCP principles in agricultural production and in catering.

### **3.4 Beyond HACCP**

Given continuing problems with outbreaks of foodborne disease, the food industry is continuing to look for new ways of managing risks. Two concepts under current discussion are kill steps and due diligence.

#### **3.4.1 Kill steps**

Kill steps are procedures that destroy residual bacteria in foods at the end of processing. It has been suggested that these can be used in conjunction with HACCP systems implemented within manufacturing operations. High temperature is the most frequently employed lethal agent, resulting in a straight-line inactivation curve. The level of inactivation is expressed in D values, which means decimal reductions at a given temperature. Two examples of kill steps are cooking of a product by the consumer and pasteurisation. Meat products are frequently subjected to post-processing pasteurisation, particularly ready-to-eat products that do not require further cooking prior to consumption. Post-processing pasteurisation is an established kill step for frankfurters (hot dogs), for example.

The effectiveness of kill steps depends on a number of factors, including the level of bacterial contamination of a product. Pasteurisation, for example, requires constant monitoring of bacterial loads in assessing product suitability

and type of treatment. In general, heat activation has the disadvantage that it cooks or further cooks a product, altering its sensory and nutritional quality. Perhaps the ideal kill step is ionising radiation which is at least as effective as high temperature but does not affect product quality. Other methods include electron beam acceleration, which concentrates a stream of electrically generated electrons on to the surface of foodstuffs.

The application of some of the newer non-thermal kill steps is currently limited by the need for more research and effective commercial application. Irradiation has, on the other hand, been extensively researched. At present 41 countries, including the United States, allow the irradiation of about 100 different classes of food, on either an unconditional or a restricted basis. In 1997 a joint FAO/IAEA/WHO Study Group examined current toxicological, nutritional, microbiological and radiation chemical data, and concluded that there was no need for an upper dose limit to be imposed for food irradiation. The Study Group recommended that technological guidelines incorporating these findings be prepared and incorporated into Codex Alimentarius standards. The main obstacle has been consumer distrust of the technology. However, there are signs that attitudes are changing in the United States. In 1999 a joint survey by the Grocery Manufacturers of America and the US Food Marketing Institute showed that 80% of consumers would be likely to purchase an irradiated food product for themselves or their children if it carried the label 'irradiated to kill harmful bacteria'. Further outbreaks of foodborne disease may accelerate the implementation of kill steps such as irradiation as a complement to HACCP systems.

### **3.4.2 Due diligence**

Due diligence is an ancient legal concept. It was developed as a way of establishing if an individual or organisation was guilty of negligence, by establishing a minimum standard of care against which a charge of negligence could be assessed. In the context of food production it addresses the question of whether the producer has done all that might reasonably be expected in the production of safe food. It assumes that, even if a product does cause illness, the producer is not at fault if he has exercised reasonable care in the way a product has been manufactured.

Due diligence can be seen as a radical concept in the area of food safety in that it implies that there can never be absolutely safe food, even with the implementation of HACCP systems. It focuses attention on producers accepting their special responsibilities in preparing food for others, and in meeting a commonly accepted industry standard for safe food production. The onus is then for stakeholders such as government and the food industry to establish common standards, such as GMP, quality or HACCP systems, and the framework for their implementation by individual producers. It also creates a responsibility for the appropriate agencies to monitor and improve those standards, the microbiological knowledge, technology and management structure which

underpin them, and for individual food producers to keep abreast of those changes, in the constant battle with foodborne disease.

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