

BACKGROUND

A 1988 outbreak involving precooked patties led to a rapid FSIS policy change on December 27, 1988. This increased the cooking temperature from 140 to 160°F (60 to 71.1°C). Opposition to the ruling was expressed as the high temperature often resulted in a very dry unpalatable hamburger.

In mid-1992, the USDA published a study and policy that required cooking temperature for hamburgers to 155°F (68.3°C). Although this is a “requirement,” undercooked hamburgers can be ordered at food service establishments and restaurants if specifically requested. The FDA changed its policy in the Food Code during the 1993 outbreak to match the USDA recommended cooking temperature.

In 1993, Jack-In-The-Box, an American fast-food restaurant was the focal point of an *E. coli* O157:H7 epidemic in the Northwest of the United States. Hundreds of people were sickened in this outbreak, which resulted from the consumption of undercooked, contaminated ground beef, and four children died. It was the largest and deadliest *E. coli* O157:H7 outbreak in American history up to that time.

This epidemic sparked significant structural changes to how USDA/FSIS conducts inspection activities. FSIS developed the regulatory proposal that became the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP) Rule (published as a final rule in 1996). In this rule, FSIS established that its food safety goal was 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. With respect to major enteric pathogens that contaminate meat and poultry products during the slaughter process, FSIS stated in this rulemaking that it believed that the risk of foodborne illness associated with these pathogens is largely avoidable and can be minimized by proper implementation of HACCP. The agency was clear that implementation of HACCP did not mean the absolute elimination of pathogens, but that it did mean preventing and reducing contamination with pathogenic microorganisms to a degree that very substantially reduces and minimizes the risk of foodborne illness.

HACCP is a system that enables the production of safe meat and poultry products through the thorough analysis of production processes, identification of all hazards that are likely to occur in the production establishment, the identification of critical points in the process at which these hazards may be introduced into product and therefore should be controlled, the establishment of critical limits for control at those points, the verification of these prescribed steps, and the methods by which the processing establishment and the regulatory authority can monitor how well process control through the HACCP plan is working.

Before the January 1993 Jack-In-The-Box outbreak in the Pacific Northwest, *E. coli* O157:H7 and related strains were considered by many to be relatively rare. During the outbreak the FDA increased its recommended cook temperature from 140°F to 155°F. Through the years, the federal government has recognized the danger of *E. coli* O157:H7, and has accordingly instituted specific policies regarding this pathogen. In 1993, USDA/FSIS implemented a “zero tolerance” policy for fecal contamination on beef carcass and it was strictly enforced. The USDA/FSIS declared *E. coli* O157:H7 an adulterant in ground beef under federal law in 1994. According to the International Commission on Microbiological Specification for Foods (Book 7 - 2002), no feasible sampling plan can ensure complete absence of a pathogen. It cannot be guaranteed that the lot is completely free of the organism, no matter how large the number of sample units.

The decision was then made in January, 1999 that the presence of *E. coli* O157:H7 would adulterate not just ground beef, but any non-intact product or intact product intended for use as a non-intact product. In February 1999, the USDA approved irradiation in red meats as a means of controlling *E. coli* O157:H7 and other pathogens. Currently, consumers are recommended to cook hamburgers to 160°F as measured by a thermometer.

Escherichia coli O157:H7 commonly referred to as *E. coli* O157:H7 has been a major concern in the meat industry for decades and has increasing concerns with the development of new processing techniques. *E. coli* O157:H7 has been associated with food since 1982, but *E. coli* O157 is naturally found in the intestinal tract of cattle and in cattle feces. A cascade effect of *E. coli* O157:H7 can be seen during the slaughter and production process. *E. coli* O157:H7 in the feces of cattle can be transferred to the hide. The feces on the hide are transferred to the carcasses during the de-hiding process and from the carcass the knives and saws become a vector to transfer *E. coli* O157:H7 onto other cuts of meat. The contaminated cuts of meat are then ground and added to other animal's cuts of meat. This is a possible cascade of events that can lead to massive amounts of ground products contaminated with *E. coli* O157:H7.

E. coli is a common kind of bacteria that lives in the intestines of animals and people, and there are many strains of the pathogen. Most are relatively harmless, but *E. coli* O157:H7 is a strain that produces a powerful toxin that makes those affected very ill. *E. coli* can be found in meat, unpasteurized milk, raw fruits and vegetables, and contaminated water sources. Bloody diarrhea and stomach pain are the most common signs of *E. coli* O157:H7 sickness. Some of the population, especially children under 5 and the elderly, can become very sick from *E. coli* O157:H7. The infection damages the body's red blood cells and kidneys, and can cause hemolytic uremic syndrome. The Centers for Disease Control and Prevention (CDC) estimates that every year at least 2000 Americans are hospitalized, and about 60 die as a direct result of *E. coli* O157:H7 infections and its complications. A study conducted in 2005 estimated the annual cost of *E. coli* O157:H7 illnesses to be \$405 million (in 2003 dollars), which included \$370 million for premature deaths, \$30 million for medical care, and \$5 million for lost productivity.

According to FSIS data, in 2007 there were 20 *E. coli* recalls, 10 of which were related to human illnesses. In 2008, however, there were 15 *E. coli* O157:H7 recalls, with five human illness related. Indeed, according to Centers for Disease Control's (CDC) FoodNet data, the illness rate associated with *E. coli* O157:H7 went from 1.2 in 2007 to 1.12 in 2008.

USDA/FSIS and the meat industry instituted a testing program for the pathogen that focused on components used in the production of ground beef products as well as end-product sampling programs for ground beef. The goal is to keep contaminated product from reaching consumers and to spur industry focus towards pathogen reduction and HACCP-associated verification programs to reduce the risk of this pathogen in beef products. The USDA/FSIS policy is currently reflected in FSIS Directive 10,010.1. This testing is random and sporadic and still allows the potential for contaminated product to reach the consumer.

On September 13, 2011, USDA's Under Secretary for Food Safety, Dr. Elisabeth Hagen, announced that six additional serogroups of pathogenic *E. coli* were declared as adulterants in non-intact raw beef. As a result of this action, if the *E. coli* serogroups O26, O103, O45, O111, O121, and O145 (commonly referred to as non-O157 STECs) are found in raw ground beef or its precursors, those products will be prohibited from entering commerce. FSIS will begin testing for these six serogroups of STEC and enforcing the new policy on March 5, 2012.

Ground beef makes up the largest market share of beef consumption in the U.S. Billions of hamburgers are consumed annually. Approximately 28.1 billion pounds of beef was consumed in 2007, and approximately 50% of this amount was in the form of ground beef. Most Americans buy the product at least two times a week, and ground beef accounts for more than half of all beef sales, as well as a quarter of all the meat sold in North America. Consumers eat about 28 pounds of ground beef annually. Because of the amount of ground beef consumed, the concern over *E. coli* O157:H7 is taken very seriously by the beef industry, USDA/FSIS, and other stakeholders.