

Food Safety and Consumer Concerns

Key Terms

BSE	HACCP
BST	Hemolytic-uremic syndrome (HUS)
Delaney clause	Irradiated foods
Electronic pasteurization (e-beams)	Pathogen
Emerging pathogens	Residue avoidance
Epidemiology	Residue monitoring program
Fight BAC!	Septicemia
Foodborne illness	Withdrawal time
GRAS list	Zero tolerance
Guillain-Barré syndrome	

INTRODUCTION

It must be said at the outset that the U.S. food supply is among the safest in the world, if not the safest. It must also be acknowledged that, despite our safe food supply, millions of Americans are made ill each year by the food they eat. According to the Food and Consumer Economics Division of the USDA, microbial **pathogens** in foods cause from 6.5 to 33 million illnesses and 9,000 deaths in the United States each year, often among the very young and the elderly. Estimates indicate that the cost of human illness for just six specific foodborne pathogens range from \$2.9 billion to \$6.7 billion annually. Foodborne illnesses are caused either by direct infection or the presence of a toxin. Foodborne infections result from consuming a food product contaminated by bacteria or viruses that subsequently multiply in the human body and cause illness. According to the Center for Disease Control (CDC) the bacteria that most commonly causes foodborne infections are *Campylobacter*, *Escherichia coli* O157:H7 and Salmonella. Calicivirus, also known as the Norwalk and Norwalk-like viruses, are largely responsible for the majority of foodborne infections caused from viruses. Toxins are another source of foodborne illness. Disease caused by consuming a toxin is usually referred to as a foodborne intoxication. The toxin is usually produced by a microorganism, such as bacteria or fungi, growing in the food prior to consumption. *Staphylococcus aureus* is a bacterium that can grow in some foods and produce a toxin that causes severe vomiting. *Clostridium*

Learning Objectives

After you have studied this chapter, you should be able to:

- Describe the complexities of the food safety issues facing the food industry.
- Discuss the basics of the history of food safety during the 20th century.
- Describe the magnitude of the problem of food safety to consumers.
- Identify the most important of the foodborne pathogens.
- Differentiate between the roles of various government agencies in providing for a safe food supply.
- Describe the current and changing roles of FSIS in food safety.
- Describe HACCP and state its purpose and principles.
- Explain the level of safety associated with bovine somatotropin, growth-promoting hormones, and antibiotics in animal production.
- Describe the value of food irradiation.

Pathogen A bacterium or virus that causes disease.



botulinum is another bacterium that can grow in canned foods if they are not processed correctly. This bacterium produces a powerful paralytic toxin. *Aspergillus* fungus found in many cereals, oilseeds, spices, and tree nuts. It produces the mycotoxin Aflatoxin which are not only toxic, but carcinogenic as well. Foodborne illness can result from consuming contaminated fruits, vegetables, grains, water, or animal-based foods. Threats range from disease-causing microorganisms to contamination with toxins of chemical and microbiological origin.

HISTORY OF FOOD SAFETY AS A PUBLIC ISSUE

Food safety has not always been such a high-profile public issue, although it does not mean a new issue. Concerns about the processing of food began at the turn of the 20th century. *The Jungle*, a novel by Upton Sinclair, caused great public concern by describing deplorable conditions in the meat-processing industry (Figure 27-1). Public pressure consequently resulted in the passage of the Pure Food and Drug Act of 1906 and the Meat Inspection Act of 1906, beginning the government regulation of food processing. In 1958, the Federal Food Additives Amendment made it the responsibility of the food product's manufacturer and established that any new food additive must be demonstrated as safe before it can be added to food. A part of the 1958 Food Additive Amendment was the **Delaney clause**, which prohibited the addition of any substance shown to cause cancer in any animal at any dose. Almost from its adoption, the clause was under attack as being unrealistic. Extremely high doses of some substances may cause cancer, but many are perfectly safe at much lower doses. To remedy this problem, Congress passed the Food Quality Protection Act (FQPA) in August 1996. It repealed the Delaney clause, replacing **zero tolerance** with a more science-based standard of "reasonable certainty of no harm" for raw and processed food tolerances. The EPA was given five years to implement the law.

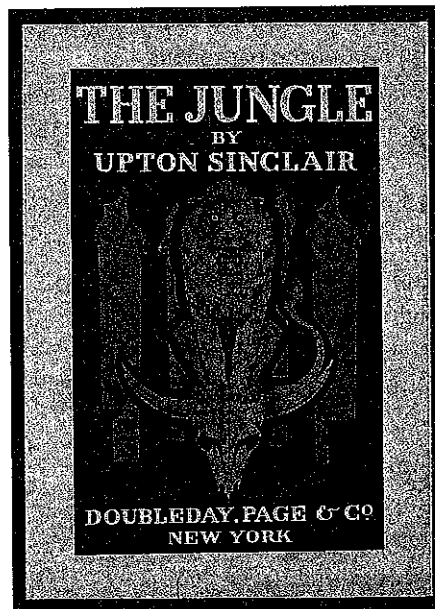
There was also another important outcome of the 1958 Food Additives Amendment. In effect, it created a grandfather clause for a group of compounds that were already in use when the legislation passed and were considered "generally recognized

Delaney clause Prohibited the addition of any substance to human food shown to cause cancer in any animal at any dose.

Zero tolerance Common term used to indicate restrictions imposed by the Delaney clause.

Figure 27-1

The Jungle, a novel by Upton Sinclair, described deplorable conditions in the meat-processing industry. Public outrage sparked by the novel led directly to the passage of the Pure Food and Drug Act of 1906 and the Meat Inspection Act of 1906. (Photo courtesy of Library of Congress.)



as safe (GRAS).” Compounds on this **GRAS list** were given special status and continued to be used. If they were removed from the list, it was because they had been proven to be a hazard. This list of compounds has been under constant review ever since its creation. By applying the strict provisions of the Delaney clause, several compounds have been removed from the GRAS list. The new provisions will result in some of those being returned to the GRAS list.

These measures have been highly effective and generally satisfied the concerns of the consuming public. For several decades, when food safety was discussed, the concerns focused on proper home-canning techniques to avoid botulism toxicity and the proper cooking of pork to avoid trichinosis. If there was an outbreak of food-related illness, it was usually associated with something like bad potato salad at a church social or Fourth of July picnic. Being very local, these outbreaks rarely created any media interest beyond the local paper (Figure 27–2). Perhaps the issues that most served to refocus the national attention on food safety were two incidents relating to fruits. The first was an incident with apples and the growth-regulator alar, which received sensationalized publicity because of the involvement of a well-known Hollywood actress, Meryl Streep, as spokesperson for the Natural Resources Defense Council and coverage in two *60 Minutes* programs. The second was an incident involving cyanide-tainted grapes.

The 1990s saw several episodes of food-related diseases. The most widely recognized and publicized incidents involved *Escherichia coli* (*E. coli*) O157:H7 in meat in 1993 and 1997, and in apple juice in 1996. Several incidents involved *Cryptosporidium* in drinking water. *Salmonella* caused outbreaks traced to cantaloupe in 1991, in ice cream in 1994, on alfalfa sprouts in 1995, and in homemade mayonnaise (traced to eggs) in 1996. In 1996, *Cyclospora* on raspberries from Guatemala caused an outbreak of that parasite; in 1997, oysters infected several hundred people with Norwalk virus; and in 1997, Hepatitis A—contaminated strawberries from Mexico caused an outbreak. However, the galvanizing event that brought public attention to the issue of food safety was probably in 1993 when *E. coli* O157:H7 contamination occurred in hamburgers from a well-known fast-food restaurant. The hamburger was unknowingly contaminated with the bacteria. Had it been cooked to the proper temperature, tragedy would have been averted. However, it was not properly cooked before it was served. The tragic deaths of children and the illnesses of several other individuals served to make *E. coli* a household word. From the time of that tragedy, food safety has been a national issue.



Figure 27–2

Prior to the 1990s, most outbreaks of food-related illnesses were usually associated with small groups of people at a picnic or a potluck social gathering. (Source: Stockbyte/Thinkstock.)

GRAS list A list of common food additives given special safe status under the 1958 food additive amendment because of their previous records as safe food additives.



IMPORTANCE OF FOOD SAFETY TO CONSUMERS

Irradiated foods Foods treated with ionizing pasteurization, which kills insects, bacteria, and parasites.

There is no doubt that the food safety issue is important to consumers. In a land of plenty, our consumers want the plenty to also be safe. The predominant food safety concerns of consumers are chemical residues such as pesticides and herbicides, food additives, antibiotics and hormones used on animals, **irradiated foods**, foodborne pathogens, and naturally occurring toxicants. Some are real threats, and some are exaggerated consumer perceptions of threats that are minimal. In actuality, the most significant threat to the average consumer is foodborne pathogens. Table 27-1 shows the sources, symptoms, onset, and duration of illnesses associated with common foodborne, disease-causing organisms.

Consumers generally do not understand that it is impossible to choose a diet free from all risk. This has always been true and will always be true. In addition, the potential for new risks comes with each change in food, agricultural, or processing technology, with each new trade agreement; and with each shift in eating habits. Such changes are responsible for some of the risks our food supply currently faces and have made today's food supply different than that from any time in history. We import over 46 million tons of food, much of it from developing countries (Figure 27-3).

Another issue is that the food supply is highly centralized. This is both a "curse and a blessing." It is a blessing because it makes monitoring easier and a curse because when there is a problem, it has greater potential to be a big problem. A hamburger from one plant can be processed and distributed to a dozen states in scores of food outlets per state in a matter of hours. Contaminated food can be processed and distributed in many different forms and can cause illnesses before it can be isolated (Figure 27-4). Changes in the demographics of our population also change the number of people susceptible to risk from foodborne microorganisms. The very young, the elderly, and those with compromised immune systems are at greater risk. All of these factors make foodborne illness a different issue today than it ever was in the past.

Survey after survey has shown the level of concern consumers have for this problem. There is also a good deal of confusion on the part of the consumer as to what is a threat, how large the threats may be, and what to do to protect themselves. Much of the focus of consumer demands for solutions have centered on the government. This concern has sparked several actions at local, state, and national levels. It is outside the scope of this chapter to give a complete accounting of the actions taken and planned. Significant changes in the food system are being addressed and will continue to unfold. If properly implemented, many of the changes will lead to a safer food supply. Many already have. The much-publicized recalls of hamburgers that occurred in the late 1990s are evidence of a system that is doing a better job of detecting contamination. One of the interesting ironies associated with the recalls is that segments of the consuming public and some consumer advocate groups have reacted negatively to the recalls. They have cited the recalls as evidence of an unsatisfactory food supply. Logically, the recalls should be comforting because the product did not get into the consumers' hands. The system worked to detect the problem before anyone became ill as a result. Unfortunately, this has not been the general response. Of course, recalls are not desirable. In 1997, Hudson Foods had to recall 25 million lbs of ground beef that was potentially contaminated with *E. coli* O157:H7. The publicity from the event was quite widespread. One of Hudson's major customers announced that it would no longer purchase from the company. A short time later the company was sold.

One of the difficult parts of the issue from a consumer-industry perspective is that many of the problems with food and its safety are the responsibility of

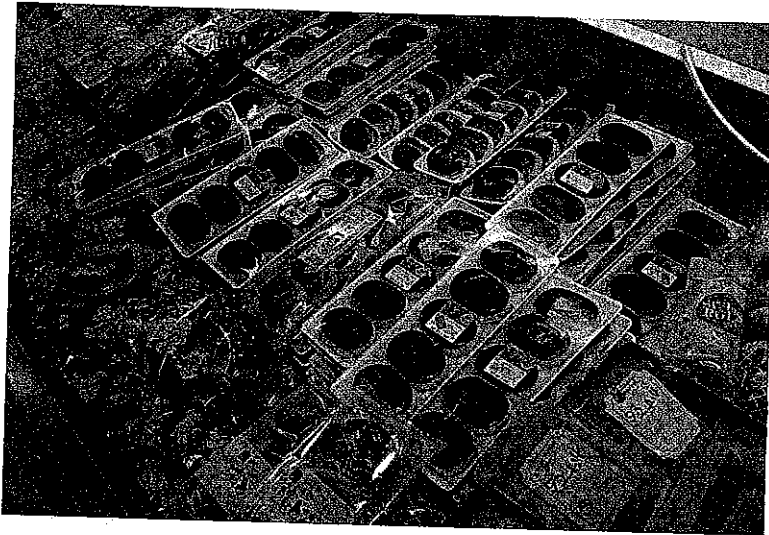
Table 27-1
FOODBORNE ILLNESS-CAUSING ORGANISMS IN THE U.S.

Organism	Common Name of Illness	Onset Time After Ingesting	Signs & Symptoms	Duration	Food Sources
<i>Bacillus cereus</i>	<i>B. cereus</i> food poisoning	10-6 hrs	Abdominal cramps, watery diarrhea, nausea	24-48 hours	Meats, stews, gravies, vanilla sauce
<i>Campylobacter jejuni</i>	Campylobacteriosis	2-5 days	Diarrhea, cramps, fever, and vomiting; diarrhea may be bloody	2-10 days	Raw and undercooked poultry, unpasteurized milk, contaminated water
<i>Clostridium botulinum</i>	Botulism	12-72 hours	Vomiting, diarrhea, blurred vision, double vision, difficulty in swallowing, muscle weakness. Can result in respiratory failure and death	Variable	Improperly canned foods, especially home-canned vegetables, fermented fish, baked potatoes in aluminum foil
<i>Clostridium perfringens</i>	Perfringens food poisoning	8-16 hours	Intense abdominal cramps, watery diarrhea	Usually 24 hours	Meats, poultry, gravy, dried or precooked foods, time and/or temperature-abused foods
<i>Cryptosporidium</i>	Intestinal cryptosporidiosis	2-10 days	Diarrhea (usually watery), stomach cramps, upset stomach, slight fever	May be remitting and relapsing over weeks to months	Uncooked food or food contaminated by an ill food handler after cooking, contaminated drinking water
<i>Cyclospora cayentanensis</i>	Cyclosporiasis	1-14 days, usually at least 1 week	Diarrhea (usually watery), loss of appetite, substantial loss of weight, stomach cramps, nausea, vomiting, fatigue	May be remitting and relapsing over weeks to months	Various types of fresh produce (imported berries, lettuce, basil)
<i>E. coli</i> (<i>Escherichia coli</i>) producing toxin	<i>E. coli</i> infection (common cause of "travelers' diarrhea")	1-3 days	Watery diarrhea, abdominal cramps, some vomiting	3-7 or more days	Water or food contaminated with human feces
<i>E. coli</i> O157:H7	Hemorrhagic colitis or <i>E. coli</i> O157:H7 infection	1-8 days	Severe (often bloody) diarrhea, abdominal pain and vomiting. Usually, little or no fever is present. More common in children 4 years or younger. Can lead to kidney failure	5-10 days	Undercooked beef (especially hamburger), unpasteurized milk and juice, raw fruits and vegetables (e.g., sprouts), and contaminated water
Hepatitis A	Hepatitis	28 days average (15-50 days)	Diarrhea, dark urine, jaundice, and flu-like symptoms, i.e., fever, headache, nausea, and abdominal pain	Variable, 2 weeks-3 months	Raw produce, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with an infected food handler; shellfish from contaminated waters

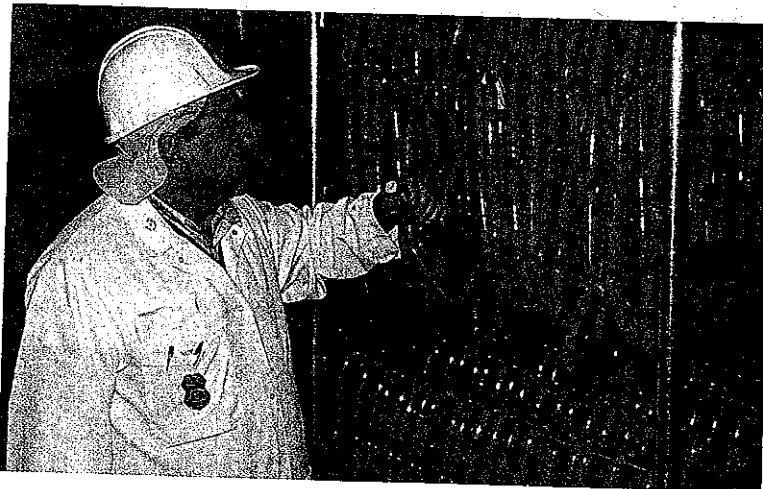
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Table 27-1 (continued)

Organism	Common Name of Illness	Onset Time After Ingesting	Signs & Symptoms	Duration	Food Sources
<i>Listeria monocytogenes</i>	Listeriosis	9-48 hrs for gastro-intestinal symptoms, 2-6 weeks for invasive disease	Fever, muscle aches, and nausea or diarrhea. Pregnant women may have mild flu-like illness, and infection can lead to premature delivery or stillbirth. The elderly or immunocompromised patients may develop bacteremia or meningitis	Variable	Unpasteurized milk, soft cheeses made with unpasteurized milk, ready-to-eat deli meats, produce
Norovirus	Variously called viral gastroenteritis, winter diarrhea, acute non-bacterial gastroenteritis, food poisoning, and food infection	12-48 hrs	Nausea, vomiting, abdominal cramping, diarrhea, fever, headache. Diarrhea is more prevalent in adults; vomiting more common in children	12-60 hrs	Raw produce, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with an infected food handler; shellfish from contaminated waters
<i>Salmonella</i>	Salmonellosis	6-48 hours	Diarrhea, fever, abdominal cramps, vomiting	4-7 days	Eggs, poultry, meat, unpasteurized milk or juice, cheese, contaminated raw fruits and vegetables
<i>Shigella</i>	Shigellosis or Bacillary dysentery	4-7 days	Abdominal cramps, fever, and diarrhea. Stools may contain blood and mucus	24-48 hrs	Raw produce, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with an infected food handler
<i>Staphylococcus aureus</i>	Staphylococcal food poisoning	1-6 hours	Sudden onset of severe nausea and vomiting. Abdominal cramps. Diarrhea and fever may be present	24-48 hours	Unrefrigerated or improperly refrigerated meats, potato and egg salads, cream pastries
<i>Vibrio parahaemolyticus</i>	<i>V. parahaemolyticus</i> infection	4-96 hours	Watery (occasionally bloody) diarrhea, abdominal cramps, nausea, vomiting, fever	2-5 days	Undercooked or raw seafood, such as shellfish
<i>Vibrio vulnificus</i>	<i>V. vulnificus</i> infection	1-7 days	Vomiting, diarrhea, abdominal pain, bloodborne infection. Fever, bleeding within the skin, ulcers requiring surgical removal. Can be fatal to persons with liver disease or weakened immune systems	2-8 days	Undercooked or raw seafood, such as shellfish (especially oysters)

**Figure 27-3**

There are many obstacles to providing a safer food supply including control over the millions of tons of food we import, much of it from developing nations. (Photographer Ken Hammond. Courtesy of USDA.)

**Figure 27-4**

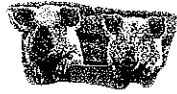
The food-processing system is centralized in a way that brings lower prices and other consumer benefits but creates problems as well. Meat processed in a given batch can be packaged and distributed to many states and distributed in many consumer outlets in a matter of hours. Should contamination exist in a batch, thousands of people could potentially be affected. (Courtesy of USDA. Used with permission.)

consumer or the food handlers. Yet there seems to be an abdication of that responsibility. Whether that is from a lack of knowledge on the part of the consumer, or a general feeling that it's simply someone else's job, is unclear. The following remarks by Michael T. Osterholm, then state epidemiologist and chief of the Minnesota Department of Health's Acute Disease Epidemiology Section, were made in the wake of the massive 1997 recall of ground beef by Hudson Foods:

Most people desperately want to believe that someone else will look out for them. We'd like to believe that just as we can drive over a bridge and not have to get out of the car and check it for safety, we can be equally confident that the government has declared our food safe. But it's not that easy. Despite our improvements . . . the problem is still present. This is not meant as a criticism either of those who raise or produce beef or of the public-health community. It is simply very difficult to eliminate the organism. . . .

Newsweek, Sept. 1, 1997, p. 33

The livestock producer is responsible for only a very small percentage of the problem. Food safety experts estimate that 77% of all illnesses can be prevented if the food handler and preparer take proper measures. Most foodborne illnesses are caused by foods prepared in the home.



PREVENTING FOODBORNE ILLNESSES

To prevent foodborne illnesses, food preparers should be aware of a few simple, but highly effective, measures:

- Cook foods thoroughly. Cooking kills most bacteria, parasites, and viruses that are found on foods. Meat, dairy, and egg products should be cooked before being eaten. Ground beef, veal, lamb, and pork should be cooked to a temperature of 160°F. Whole cuts of beef, veal, lamb, and pork should be cooked to a minimum temperature of 145°F followed by a three-minute rest time before carving or consuming. The safe cooking temperature for all poultry products is 165°F. Reheated foods should be heated to at least 165°F (Figure 27-5).
- Prevent cross-contamination. The juices and drippings of raw meat products should not come into contact with other foods, especially those that will receive no further cooking. Be careful of refrigeration practices. Wash hands, cutting boards, spills on countertops, and other items with warm, soapy water to prevent meat juices from coming into contact with other foods.
- Refrigerate foods, including leftovers, properly. Bacteria have a hard time growing in properly refrigerated conditions. Refrigerator temperature should be set at 40°F or lower. Don't overpack the refrigerator. Keep the refrigerator clean (Figure 27-6).
- Select only the freshest meat, poultry, fish, and other food products. Do not purchase dented, bulging, or rusted cans of food. Observe the "purchase by" and "use by" dates on products.
- Freeze fresh meat, poultry, and fish that will not be used within a couple of days. Proper freezer temperature is 0°F. Thaw foods in the microwave, in the refrigerator, or under cold, drinkable running water.

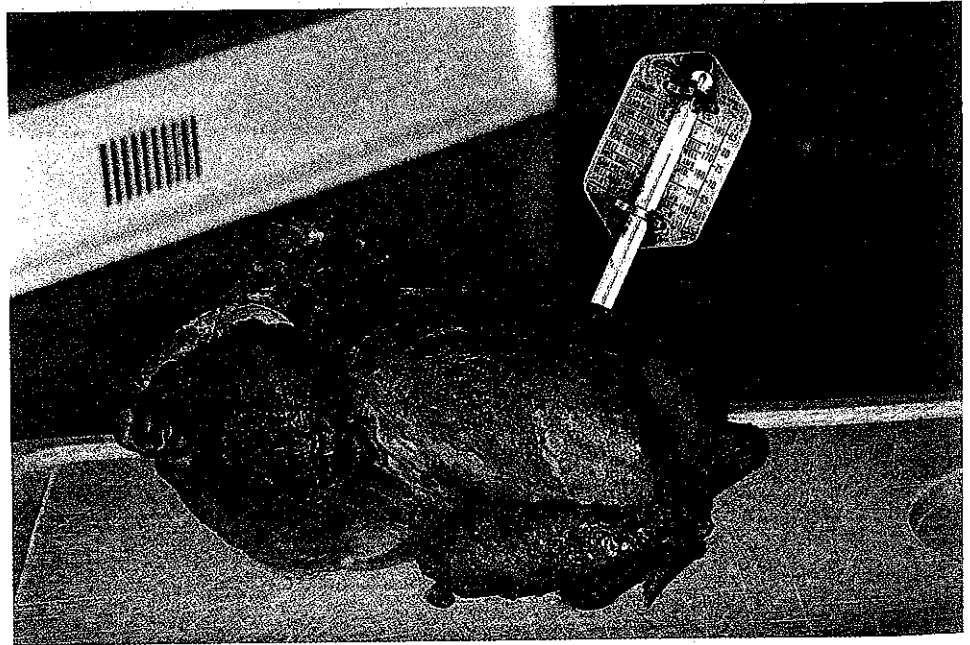


Figure 27-5

Cooking to the proper temperature is extremely important in preventing foodborne illness. Meat thermometers help ensure that safe internal temperatures are reached during cooking.

**Figure 27-6**

For food safety, don't overpack refrigerators. Segregate products, especially those that will not be further cooked. Keep the refrigerator clean and make sure the temperature is no warmer than 40°F. Can you spot the problems in this refrigerator?

SOME IMPORTANT MICROBIAL PATHOGENS ASSOCIATED WITH FOODBORNE ILLNESS

The surveillance and identification of new emerging foodborne diseases has always been a challenge for public health officials. Several agencies are all responsible for different aspects of food safety monitoring and testing. Historically, the communication between these agencies has been seriously lacking and as a result, made the tracking and identification of foodborne diseases very difficult. In an attempt to improve the surveillance of foodborne diseases in the United States, the CDC, in cooperation with the USDA and FDA, established in 1995 the Foodborne Disease Active Surveillance Network (FoodNet, <http://www.cdc.gov/foodnet>). The FoodNet surveillance started with five sites around the United States (West Coast—California; East Coast—Connecticut; South—Georgia; North—Minnesota; Pacific Northwest—Oregon). Officials felt that monitoring a site of population at different regions across the United States would prevent a data overload to the system and provide a better picture of the types of foodborne diseases occurring in the United States. Since 1995, the selected monitoring sites have expanded to 10 states with about 14% of the U.S. population being monitored. FoodNet is helping public officials better understand the **epidemiology** of foodborne disease in the United States. The following information was excerpted and edited from FDA (1997) and is found in Appendix B of that report. It is presented here to provide information about the specific pathogens and to demonstrate that the federal agencies involved do indeed have an understanding of the magnitude of the problem facing them.

Bacteria

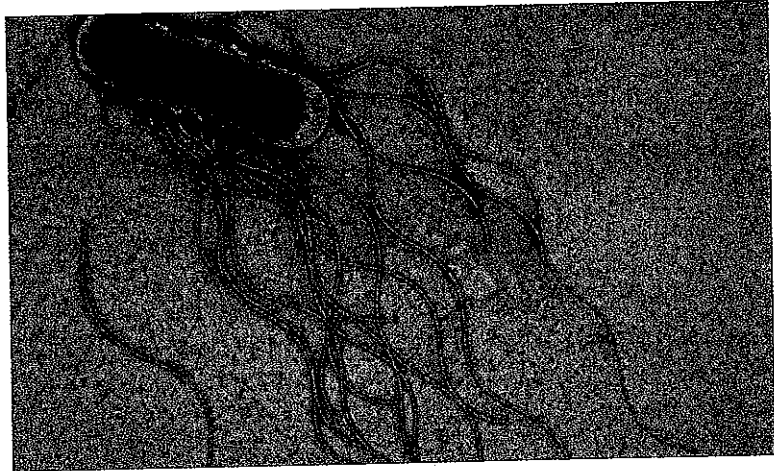
Salmonella *Salmonella* species cause diarrhea and **septicemia**, which can be fatal in particularly susceptible persons such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of *Salmonella*, which can subsequently contaminate foods such as meat, dairy products, and eggs.

Epidemiology Medical service that involves the study of the incident distribution of diseases in large populations and conditions influencing the spread and severity of diseases.

Septicemia Invasion of the bloodstream by virulent microorganisms from a focus of infection.

**Figure 27-7**

Salmonella enteritidis is often the cause of foodborne illness. It is a difficult organism from which to protect consumers because animals used for food production are common carriers of the disease. (Courtesy of USDA).



Foods often implicated in outbreaks include raw meats, poultry, eggs, milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressings, cake mixes, cream-filled desserts, dried gelatin, peanut butter, cocoa, and chocolate. An estimated 2 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Between 128,000 and 640,000 of those infections are associated with *Salmonella enteritidis* (Figure 27-7) in eggs. During the 1990s, more than 500 outbreaks were attributed to *S. enteritidis*, with more than 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter The bacterium *Campylobacter* (Figure 27-8) is the most frequently identified cause of acute infectious diarrhea in developed countries and the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120–360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and they are the infectious agents most frequently described in association with **Guillain-Barré syndrome**, a frequently as 1 in 1,000 cases. Approximately 50% of infections are associated with eating inadequately cooked or recontaminated chicken meat or from handling chickens. It is the leading cause of sporadic (nonclustered cases) diarrheal disease in the United States. Unpasteurized milk and untreated water have also caused outbreaks.

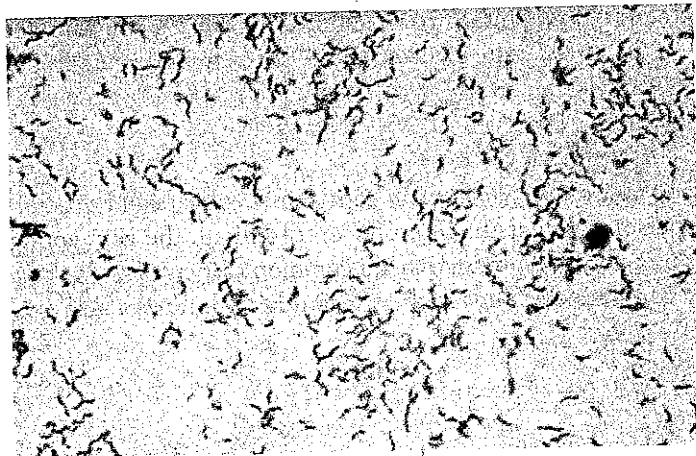
Listeria Infection with *Listeria monocytogene* (listeriosis) was added to the list of nationally notifiable diseases in 2001. Listeriosis primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems and only infrequently affects people without these risk factors. The Center for Disease Control

Guillain-Barré syndrome

An inflammatory disease of the peripheral nerves characterized by weakness and often paralysis of the arms, legs, breathing muscles, and face.

Figure 27-8

Campylobacter is considered the most frequently identified cause of acute infectious diarrhea in developed countries. *C. jejuni* and *C. coli* are the infectious agents most frequently associated with Guillain-Barré syndrome. (Source: USDA (U.S. Department of Agriculture)).



estimates there are approximately 1,600 cases of listeriosis in the U.S. annually. *Listeria* has been found in uncooked meats and vegetables, soft cheeses, processed meats such as hot dogs and deli meat, and smoked seafood. Unpasteurized milk and foods made from unpasteurized milk are particularly likely to contain the bacterium. *Listeria* is killed by pasteurization and cooking. Some contaminations have been traced to ready-to-eat foods, such as hot dogs and deli meats, contaminated after factory cooking but before packaging. Unlike most bacteria, *Listeria* can grow and multiply in some foods in the refrigerator. Generally, those diagnosed with listeriosis have an invasive infection: the bacteria has spread beyond the gastrointestinal tract. Symptoms include fever, muscle aches, diarrhea and other gastrointestinal symptoms, headache, stiff neck, confusion, loss of balance, and convulsions. Pregnant women generally have only a mild, flu-like illness, but infections during pregnancy can lead to miscarriage, stillbirth, premature delivery, and/or life-threatening infection of the newborn. Before 2011, the largest outbreak occurred in 2002 and was associated with turkey deli meat. Other recent outbreaks have been associated with hotdogs, sprouts and celery. In 2011, an outbreak linked to cantaloupes affected more than 120 people in at least 26 states and caused over two dozen deaths.

Shiga-Like Toxin-Producing *Escherichia coli* Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* that cause illness produce a toxin called Shiga toxin. Shiga toxin-producing *E. coli* are also referred to as STEC. *E. coli* O157:H7 (Figure 27-9) is the most commonly identified STEC in North America. However, recently there has been growing concern about the other types of STEC aside from *E. coli* O157:H7 that are being found in food, particularly meat. Some important "non-O157" STEC *E. coli* serogroups are O26, O111, and O103. STEC cause hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools. It has been associated with **hemolytic-uremic syndrome (HUS)**, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 73,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year, with as many as 60 deaths resulting. However, it is estimated that non-O157 STEC may cause 36,700 illnesses each year. *E. coli* O157:H7 outbreaks have been associated with ground beef, raw milk, and minimally processed nuts, vegetables, and fresh fruit juices.

Vibrio *Vibrio* species are gram-negative bacteria most commonly associated with seafood dishes. *Vibrio parahemolyticus* is the species most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold

Hemolytic-uremic syndrome (HUS) A rare condition that mostly affects children under the age of 10; characterized by damage to the lining of blood vessel walls, destruction of red blood cells, and kidney failure.

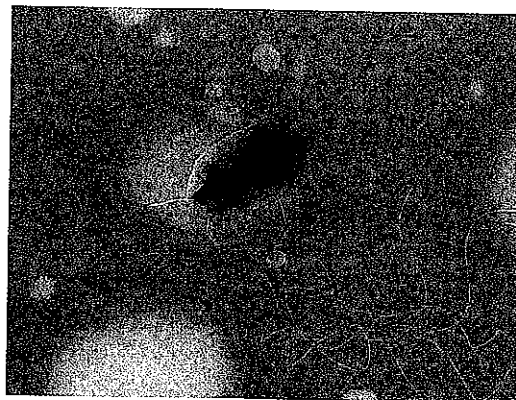
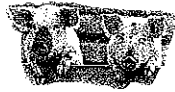


Figure 27-9

Only recognized as a pathogen in 1982, *Escherichia coli* O157:H7 is a gram-negative bacteria that has been associated with HUS, which is a life-threatening condition. Pictured here is a transmission electron micrograph of *E. coli* O157:H7 showing flagella. (Micrograph by Elizabeth H. White. Courtesy of Centers for Disease Control and Prevention.)



seafood salads. *V. vulnificus* is one of the more serious foodborne pathogens, with case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw mollusks and shellfish. Since the late 1980s, the FDA, the CD and the Gulf Coast states have intensified efforts to collect information on *Vib* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Parasitic Protozoa

Toxoplasma Gondii *T. gondii* is a parasitic protozoan responsible for some 1.4 million cases of toxoplasmosis and 310 deaths annually. Otherwise, healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life threatening in persons with weaker immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. A single cat can shed millions of oocysts after eating rodents, birds, or other animals infected with *T. gondii*. Under some conditions, the consumption of unwashed fruits and vegetables can contribute to infection.

Cryptosporidium Parvum *C. parvum* is a parasitic protozoan. The most common sequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life threatening among people with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manure. Farm workers have been infected from this source.

Viruses

Norwalk Virus Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multistate outbreak of viral gastroenteritis related to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of oysters. In 1992, another outbreak resulted in 250 cases. Outbreaks of Norwalk virus gastrointestinal disease have been linked to contaminated water and ice, salads, frozen shellfish, and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

Hepatitis A Hepatitis A (HAV) is a virus that infects the liver and causes hepatitis, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period (e.g., more than 2 months). In children less than 6 years old, most (70%) infections are asymptomatic but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last less than 2 months, and there are no chronic consequences. About 130,000 infections



HAV and 100 deaths occur each year in the United States. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2–5% of hepatitis A cases reported in the United States each year, most of which are caused by an infected food handler. Outbreaks owing to foods contaminated before preparation, although uncommon, are associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented by good personal hygiene and safe food-handling practices. It can also be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.

GOVERNMENTAL AGENCIES AND FOOD SAFETY

Six different federal agencies bear the responsibility for the government's role in food safety. These include two agencies under the Department of Health and Human Services (HHS)—the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)—the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). This system has long been criticized as being unnecessarily cumbersome and wasteful as well as inefficient in the way it conducts the business of providing a safer food supply. To address these issues, Congress passed in November 2010 the Food Modernization Act. All food processors will now be required to evaluate the hazards in their facilities. In addition, the act gives FDA mandatory recall authority to swiftly remove contaminated food from the market. FDA must also conduct risk-based inspections of food processing facilities. All high-risk domestic facilities must be inspected within five years of enactment of the Food Modernization Act and no less than every three years thereafter. Finally, FDA has also been given the authority to require importers verify the safety of food from their suppliers and FDA has also been given the authority to block food from facilities/countries that refuse inspection.

The following sections explore the roles of some of these agencies in assuring a safe food supply with emphasis on animal products. Meat exported into the United States must come from countries with residue avoidance efforts equivalent to or more rigorous than the U.S. program. As a safeguard, imported meat is reinspected and tested for residues when it enters the country.

The Role of the FDA

The concerns that consumers express over food additives and the hormones and antibiotics used in animal production are largely without foundation. The government requires a rigorous approval procedure before these products can be offered for sale. This system assures the safety of the products used. The FDA is in charge of the approval process. Animal health companies are required to show that any new product they wish to offer for sale is both safe and effective. In addition, the company must provide a reliable method for detecting the drug in slaughtered animals. A new drug is approved for use only after the company has done these things. In addition to its product supervision/approval role, the FDA also limits the amounts of drug residues that can be found in animal tissue. The tolerance level for a given drug is intentionally set at 100 to 1,000 times less than a potentially harmful amount to provide a margin of safety for the consumer. Thus withdrawal times are calculated for additives and antibiotics that ensure the compound is cleared from the animal's body before it goes to slaughter. It then becomes the job of the USDA to monitor tissue samples from slaughtered animals for the compound. The agency currently monitors for over 100 compounds.



The specific FDA requirements for approval of agricultural chemicals and drugs are as follows:

1. The product must be effective at the proposed dosage level for the proposed use.
2. The drug must not create a residue in the edible tissue of the animal or bird that is at a level judged to be harmful to the consumer.
3. The drug or agricultural compound must serve a useful purpose in the production of a feed crop, animal, or bird.
4. An analytical detection method must be available that is capable of detecting the substance at or below the tolerance level.
5. The drug must be used in a manner that will not contaminate the environment or food supply.

The FDA also provides the guidelines to states for regulating the safety of dairy foods, and foods served in restaurants. However, FDA delegates the responsibilities of inspecting restaurants, groceries, and other food-related operations to the states.

The Role of FSIS

The USDA, through the FSIS, has a comprehensive program in place to protect consumers from drug and other chemical residues. The FSIS inspection of carcasses at slaughter plants, as one means of protecting consumers from contaminated meat and poultry, is central to the success of the program. The sampling is done in different phases, each with slightly different goals. The comprehensive inspection is designed to ensure the safety of the consumer from drug residues and other substances.

Residue Monitoring Program Carcasses are monitored to provide information on the occurrence of residues. Compounds tested include drugs, pesticides, and environmental and agricultural chemicals. In the monitoring program, carcasses are sampled at random in a way that produces a statistically valid sample. This requires the sampling of approximately 22,000 animals. Multiple samples are taken from each animal (muscle, liver, kidney, and fat). The goal of the sample procedure is to detect a 1% incidence of illegal residues and have 95% statistical confidence in the results. Results from the monitoring program suggest an industry largely in compliance with withdrawal times and appropriate use of drugs and additives. The number of drug residues detected annually has been less than 1%.

If the residue data suggest an emerging problem, a special surveillance program may be implemented. One such program was initiated in 1977 because the number of sulfonamide residue violations in swine was unacceptably high. A special program of increased sampling that was specific for sulfonamides was implemented. In addition to protecting the consumer in the short run, such programs tend to focus attention of the industry on the problem. This greatly heightened awareness helped bring the problem under control. When the sulfa drug problem occurred, those in the industry, extension agents, university personnel, news reporters, and others were all working "overtime" on this issue.

The monitoring program is also used as a means of avoiding problems. Incidents are notified when a sample produces a level of a compound that is four times within 80–100% of the allowable residue tolerance level. Follow-up testing of samples from that producer helps the producer maintain residue levels below allowable levels.

When illegal substances are discovered, the FDA launches follow-up investigations to determine why the residues are present and who was responsible. Depending on the results of the investigation, the FDA and FSIS may initiate the surveillance program.

Surveillance Program The surveillance program is initiated if illegal residues are found or if there are other indications of a potential for illegal residues. The surveillance program may also be used to sample sick or diseased animals. Any time

illegal drug residue is found, FDA can initiate an investigation and FSIS will prevent future shipments from the producer until tissue samples are free of illegal residues. Then, and only then, will the producer's next shipments be approved.

Residue Avoidance Program This portion of the overall effort is educational and is designed to help producers avoid problems. It is designed to help producers understand how to prevent illegal levels of residues from occurring. The program seeks to prevent problems from birth through slaughter and processing by educating producers on the proper use of drugs and other chemicals. Producer groups and the extension service have been instrumental in working with FSIS in this portion of the overall effort.

In-Plant/On-Farm Testing Several tests are employed to determine if illegal residues are present. The Swab Test on Premises (STOP) is used by public health veterinarians or designated consumer supply inspectors to determine if antibiotics are present. It is fast and can detect problems with a carcass before the carcass leaves the slaughter facility. A recently developed test, Fast Antimicrobial Screen Test (FAST), reduces test time from 8 hours to 6 hours. Field tests have also been developed to screen for potential antibiotic residues. These tests are not USDA/FSIS approved, but they do allow the producer to test animals on the farm. The Live Animal Swab Test (LAST) tests the urine of live animals for illegal antibiotic levels. Live animals can thus be tested before they are marketed. The Sulfa-on-Site (SOS) test screens swine serum, urine, or feed for sulfamethazine. Other tests are used in specific circumstances, and more are under development.

Responsibilities of the Federal Agencies

The FDA, the USDA, and the EPA have specified responsibilities in the residue monitoring program and responsibilities for working with states to correct detected problems. FDA has the responsibility to investigate illegal residues in animals. In some instances, the responsibility may be delegated to the state agency if there is an agreement with the state. If pesticide residues are the problem, either from direct applications or environmental contamination, EPA joins FDA and FSIS in taking corrective measures because the EPA is responsible for the proper use of pesticides. FSIS has the primary responsibility for the carcass. FDA has the authority for enforcing the proper use of animal drugs and medicated feeds. Both FDA and FSIS can seize or condemn contaminated food. In addition, the FDA has the same power with regard to animal feed. Depending on the nature of the violations, those responsible for illegal residues may face criminal prosecution, resulting in fines or imprisonment.

Changes in FSIS

FSIS also has had the responsibility for checking carcasses for diseases that may affect the wholesomeness of food. This practice originated at the turn of the 20th century when diseased animals posed a real threat to the welfare of the consuming population. This is rarely the case anymore. By and large, the animals slaughtered for human consumption are young and healthy. In recognition of this fact and in response to the need to direct more effort to foodborne pathogens, the FSIS is in the process of changing the way it works to fulfill this portion of its mission. The agency describes this change as moving from plant-based inspections to a farm-to-table consumer safety system.

The greatest risks to the food supply currently come from microbial pathogens. The type of inspection system that has been in place cannot detect those problems. Recommendations springing from studies conducted by the National Academy of Sciences (NAS), the U.S. General Accounting Office (GAO), and FSIS itself have established the need for fundamental change in the FSIS inspection program. In response to this need, the FSIS is moving to reduce its reliance on the direct inspection of carcasses and shifting to prevention-oriented inspection systems. This change will

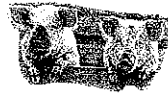


shift resources away from inspection to a broader approach intended to minimize hazards throughout the farm-to-table food chain and thus reduce foodborne illness.

This change in focus and responsibility is tied to the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule, published in July 1996. The Pathogen Reduction and HACCP rule was designed to establish a system that ensures appropriate and feasible measures are taken at each step in the food-production process to prevent or reduce and, ideally, eliminate foodborne illness hazards. FSIS set as its initial goal a 25% reduction in foodborne illnesses attributed to meat and poultry and put a comprehensive program in place to achieve this goal. The program, as outlined, published, and widely distributed by the FSIS, includes:

- Requiring establishments to develop and implement written Sanitation Standard Operating Procedures (SSOPs) to prevent contamination.
- Requiring that all meat and poultry establishments develop and implement a HACCP system of preventive controls designed to improve the safety of their products.
- Establishing food safety performance standards and microbiological test requirements.
- Placing clear responsibility for safe products on the establishments producing the products, backed up by rigorous FSIS monitoring and verification, with regulatory action where warranted. FSIS enforcement authorities are used to the fullest extent to address operators who violate food safety regulations and put consumers at risk.
- Enhancing FSIS's present food safety activities beyond slaughter and process plants. This will include increased oversight of the activities and systems that affect food safety after products leave the plant, including transportation, distribution, and retail, and restaurant or food service sale of meat and poultry products. FSIS will work collaboratively with other federal, state, and local agencies to help ensure this coverage.
- Encouraging research, education, and voluntary adoption of preventive strategies on the farm.
- Reshaping its workforce and the way it deploys that workforce. The agency is deploying its resources and improving the skills and qualifications of its workforce to meet its goal of reducing foodborne illness and providing appropriate regulatory oversight within its statutory authorities along the farm-to-table continuum.
- Deploying the workforce in a manner that will enable it to protect the integrity of the mark of inspection on a product as the product moves from the control environment of the plant through distribution, transportation, and retail to the consumer.

These historic changes include changes to the in-plant inspection procedure. Under HACCP rules, plants assume full responsibility and are held accountable for the safety of their products. The focus of FSIS in-plant inspection changes to verify compliance with the standards and rules. Inspection schedules are being changed. They are becoming less prescribed and instead are being designed to enhance the flexibility and effectiveness of the inspectors and their abilities to make day-to-day decisions about what food safety and consumer protection activities should be carried out in individual plants. Another part of the planned change includes the shifting of some consumer protection activities that have nothing to do with food safety issues to other agencies or units within FSIS. This will allow inspectors to focus more on specific food safety tasks. Several other changes are being discussed and tested. All plants were required to be in compliance with HACCP by the year 2000.



FSIS intends to improve its service in a number of ways once HACCP rules and procedures are sufficiently tested. Several of these improvements involve changes in regulatory activities beyond the processing plant. FSIS intends to monitor retail food stores, restaurants, commercial kitchens, hotels, and other institutions. FSIS will work to establish standards for postprocessing transportation, storage, and distribution systems. Educational programs are planned. The objective is to create a seamless national food safety system.

Hazard Analysis and Critical Control Points (HACCP)

The following explanation of HACCP is excerpted from documents published by FSIS to explain the HACCP final rule.

Hazard Analysis and Critical Control Points (HACCP) is a process control system designed to identify and prevent microbial and other hazards in food production. It includes steps designed to prevent problems before they occur and to correct deviations as soon as they are detected. Such preventive control systems with documentation and verification are widely recognized by scientific authorities and international organizations as the most effective approach available for producing safe food. HACCP is endorsed by such scientific and food safety authorities as the National Academy of Sciences and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and by such international organizations as the Codex Alimentarius Commission and the International Commission on Microbiological Specifications for Foods.

Under the Pathogen Reduction and HACCP systems regulations, USDA is requiring that all meat and poultry plants design and implement HACCP systems. Plants will be required to develop HACCP plans to monitor and control production operations. HACCP was implemented first in the largest meat and poultry plants, with 75% of slaughter production under HACCP-based process control systems on January 26, 1998, with the remainder allowed to be phased in by January 25, 2000.

The Seven HACCP Principles

HACCP systems must be based on the seven principles articulated by the NACMCF. The seven principles are (1) hazard analysis, (2) critical control point identification, (3) establishment of critical limits, (4) monitoring procedures, (5) corrective actions, (6) recordkeeping, and (7) verification procedures.

Principle 1: Conduct a hazard analysis. Plants determine the food safety hazards that can occur as a result of the way food is processed in that establishment.

Principle 2: Identify critical control points. A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, reduced to an acceptable level, or eliminated. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Principle 3: Establish critical limits for each critical control point. A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce risk to an acceptable level.

Principle 4: Establish critical control point monitoring requirements. Monitoring activities are necessary to ensure that the process is under control at each critical control point. FSIS requires that each monitoring procedure and its frequency be listed in the HACCP plan.

Principle 5: Establish corrective actions. These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final

HACCP Process control system designed to identify and prevent health hazards in food.



rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that a product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Principle 6: Establish recordkeeping procedures. The HACCP regulation requires that all plants maintain certain documents, including hazard analysis and a written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Principle 7: Establish verification procedures. Validation ensures that the plans do what they were designed to do; that is, they are successful in ensuring the production of safe product. Verification ensures that the HACCP plan is adequate; that is, it is working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits, and microbial sampling and analysis. FSIS requires that the HACCP plan include verification tasks to be performed by plant personnel. Verification tasks are also performed by FSIS inspectors. For example, both FSIS and industry conduct microbial testing as one of several verification activities.

Additional Changes at FSIS and Other Food Safety Initiatives

Additional changes at FSIS are being heralded as a new era for food safety. One of the initiatives at FSIS is to emphasize that everyone has a responsibility for food safety. An important part of these initiatives is emphasizing that the consumer is the final critical link in preventing foodborne illness. To accomplish this, consumer education programs emphasizing "safety from farm to table" have been developed in cooperation with public and private groups to educate consumers on safe food handling. Information is provided by the USDA Meat and Poultry Hotline through direct consumer inquiries, e-mail, and the FSIS website. The cooperation of the media, extension and public health offices, and other public and private educators has also been sought to distribute food safety information. Various programs have been developed for different audiences and are delivered in different ways. Programs are based on scientifically substantiated information. One major information campaign includes the safe handling information label: *food handling reminders*. Other food safety educational initiatives have made additional information available. Many of these initiatives are in cooperation with the FDA, the CDC, and the EPA. One example is the national education campaign called Fight BAC!, which is sponsored and coordinated by the Partnership for Food Safety Education whose membership includes federal agencies, industry organizations, and consumer groups. The Fight BAC! campaign focuses consumer attention on four critical food safety messages:

- Clean: Wash hands and surfaces often.
- Separate: Don't cross-contaminate.
- Cook: Cook to proper temperatures.
- Chill: Refrigerate promptly.

The Bioterrorism Act of 2002

The events of September 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which



President Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into five titles:

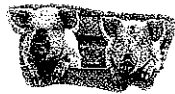
- Introduction
- Title I – National Preparedness for Bioterrorism and Other Public Health Emergencies
- Title II – Enhancing Controls on Dangerous Biological Agents and Toxins
- Title III – Protecting Safety and Security of Food and Drug Supply
- Title IV – Drinking Water Security and Safety
- Title V – Additional Provisions

FDA is responsible for carrying out certain provisions of the Bioterrorism Act, particularly Title III, Subtitle A (Protection of Food Supply) and Subtitle B (Protection of Drug Supply). In September 2004, the USDA, in partnership with the FDA and the Department of Homeland Security (DHS), signed a cooperative agreement with the National Association of State Departments of Agriculture (NASDA) to further develop integrated federal-state response plans for food and agricultural emergencies. USDA's Food Safety and Inspection Service (FSIS), FDA, and DHS's Information Analysis and Infrastructure Protection are funding the development of an integrated approach to prepare for and respond to emergencies affecting national agriculture and food infrastructure. The state departments of agriculture gain technical expertise from FSIS, FDA, and DHS officials. Best practices and guidelines for federal and state food regulatory officials will be developed to address lessons learned from case studies and threat assessments. A result of this coordinated effort was the development by NASDA of a Food Emergency Response Plan (FERP) template for states to coordinate their activities with the National Response Plan (NRP).

ENSURING SAFETY OF THE MILK SUPPLY

The federal Food, Drug, and Cosmetic Act is the legislation that covers the safety procedures for milk and milk products as well as other foods shipped from state to state. FDA is responsible for enforcing the law. The Grade A Pasteurized Milk Ordinance (PMO) is the standard used in the Cooperative State Public Health Service (PHS)/FDA Program for certification of Interstate Milk Shippers (IMS). The PMO was recommended by PHS and FDA. State agencies assume the responsibility for routine inspection and sampling of milk. Each tank of milk from each producer must be tested before it is picked up for transport by the milk handler. In addition, FDA spot-checks hundreds of milk-processing plants annually. According to Anderson et al. (1991), over 99% of all samples test negative for contamination of any kind. If a milk sample is found to be contaminated, the sale of the milk is prevented. The producer is prevented from selling any subsequently produced milk until the milk tests clear of the contamination found in the earlier shipment.

As a part of the PMO, all dairy farms must be inspected at least twice a year. Some states require more frequent inspections. Part of the inspection includes examinations of animal drugs on the premises. Unapproved and/or improperly labeled drugs cannot be used or stored in the milk house, milking barn, stable, or parlor. This helps to ensure proper drug use and residue avoidance. This system has an extremely good record for ensuring the quality of dairy products. Very few incidents of food-borne diseases have ever been linked to dairy products. Most of the incidents that have been connected to dairy products were caused by mishandling during further processing or consumption of raw milk or milk products.



OTHER ISSUES OF CONCERN TO CONSUMERS

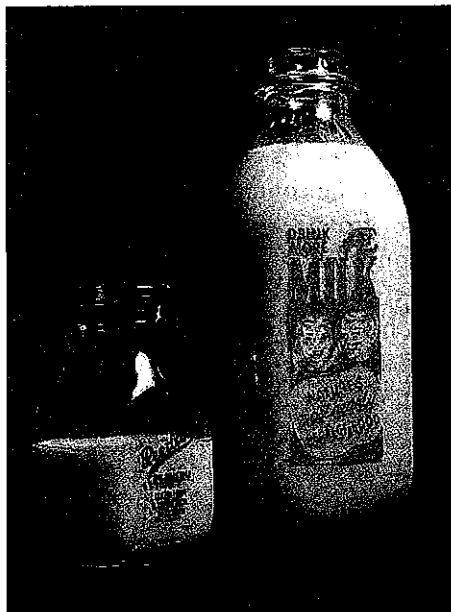
Science has brought a variety of tools to the modern livestock producer. Several of these are of concern to consumers because they are perceived to affect food quality and safety. These products are used because they produce meat and milk more efficiently or they keep animals healthier, benefitting the producer and the consumer. A brief discussion of each product follows, along with information to explain why each is considered safe. It is important to remember that each of these products has FDA approval.

Bovine Somatotropin

Bovine somatotropin (BST) is a protein hormone produced naturally by cattle from the pituitary gland. When BST is administered to dairy cows, their milk production generally increases. Some consumers have been concerned that milk from cows treated with BST will cause negative health effects when consumed by humans. Milk from BST-treated cows is safe for humans to consume and has no ill effects on human health (Figure 27-10). BST was approved by the FDA and has undergone rigorous follow-up study. There are three major reasons why BST use in cows is safe. First, BST is a species-specific protein that is active only in dairy cows. It is a protein that is structurally different from human somatotropin. The receptors for human somatotropin are sensitive to the structure (shape) of the protein. BST does not "fit" into the human structure. Second, over 90% of the BST found in milk is destroyed during the pasteurization process. Third, any BST found in milk is digested in the human digestive system as any other protein would be. (Remember, naturally occurring BST has always been found in milk. Slightly elevated levels of insulin-like growth factor (IGF-1) can be found in milk from cows treated with BST. This is not a cause for concern for three reasons. First, these levels are not above normal ranges for cows. Second, human milk has higher levels of IGF-1 and it has not caused any problem. Third, IGF-1 is not biologically active when ingested by humans and is digested by the human digestive system just as BST is. Multitudes of studies have demonstrated that BST has no effect on humans. In what should be the last word on the topic, the Institute of Food Science and Technology, through its Public Affairs and Technical and Legislative Committees, authorized a position statement on June 11, 1991.

Figure 27-10

Milk from BST-treated cows is processed along with all other milk for human consumption because BST-produced milk poses no threat to the consumer. (Photographer Charlie Rahm. Courtesy of USDA-Agricultural Research Service.)





In the summary, the institute states that objective scientific assessment of the use of bovine somatotropin (BST) to improve milk yield in cows indicates that it carries no harmful effects to humans, to the treated animals, or to the environment. The report goes on to state that the resulting milk and meat are not significantly different from milk and meat from untreated cows, in composition or quality; and in consequence there is no scientific or ethical basis for requiring distinctive labeling of milk or meat from BST-treated cows.

Hormones

Hormonal growth promotants (implants) are a tremendous tool for animal production, especially for beef production. Benefits include faster growth rate, improved feed conversion, increased amount of lean tissue gain, and decreased fat deposition. On an industry-wide basis, hormone implants improve beef production by an estimated 750,000 lbs and save 3 million tons of feed. They are a very cost-effective tool for beef production. Consumers' concerns about growth promotants are directed at whether or not the hormonal compounds can be found in the meat of implanted animals. The level of hormones that could be consumed from implanted cattle is less than 0.006% and 0.02% per 100 g consumed of estrogen and progesterone found in prepubescent boys who carry the lowest level of both hormones (CCABIC, 2006). In fact, many other foods have higher levels of hormones. According to the Council for Agricultural Science and Technology, "In a meal of mashed potatoes, whole wheat bread, green salad, green peas, and ground round steak from estrogen-treated cattle, the food that would contain by far the least estrogenic potency is the ground round steak."

Antibiotics

Antibiotics are used in animal production to treat animals suffering from infections. In addition, subtherapeutic antibiotic levels are used to maintain the health of pigs, veal calves, and poultry. This second use has been declining in recent years. Consumers are concerned with the potential for development of superbugs that are resistant to antibiotics that might threaten human health. It is important that consumers be aware that antibiotic use is tightly regulated. The length of time an antibiotic must be taken away from the animal before it goes to slaughter, or its milk can be used for feed, is called its **withdrawal time**. These withdrawal times are closely observed. Antibiotics are among the compounds that the FSIS Monitoring Program takes special interest in. Milk, meat, and poultry all have extremely good records of compliance with proper antibiotic use.

Withdrawal time The length of time an antibiotic must be taken away from an animal before the animal can be legally slaughtered.

Food Irradiation

Irradiation, or ionizing pasteurization or **electronic pasteurization (e-beams)** or cold pasteurization as it is also called, subjects the product to radiation from radioactive or machine sources. Three types of rays are used: gamma rays, electron beams, and X-rays. Gamma rays use a source of radioactive material (Cobalt 60 or Cesium 137). They emit high-energy protons that do not make the irradiated product "radioactive." This is an old technology that has been used for years to sterilize medical, dental, and household products. Electron beams, or e-beams, are produced by an electron gun. No radioactive material is used. This technology has been used in the medical field for at least 20 years. X-ray technology is the newest technology. Only commercial units have been built since 1996, and like e-beam, it does not use radioactive material (CDC, 2007). The radiation kills insects, pathogenic bacteria, and parasites. Irradiation does not make food radioactive. Its many uses include preservation of food by destroying organisms that cause spoilage and decomposition, thereby extending the shelf life of foods; sterilization

Electronic pasteurization (e-beams) Ionizing radiation from a focused beam of energy created by the acceleration of electrons using magnetic and electric fields.



so that foods may be stored without refrigeration; controlling sprouting, ripening, and insect damage in potatoes, tropical and citrus fruits, grains, spices, and seasonings; and controlling foodborne illness by destroying pathogens that cause foodborne illness. This latter use has tremendous implications for controlling *Escherichia coli* O157:H7 and *Salmonella* species. Irradiation, although a potentially useful tool for helping reduce the risks of foodborne disease, is a complement to, not a replacement for, proper food handling practices by producers, processors, and consumers.

The history of food irradiation dates to 1895 when the first paper was published on the idea of irradiating food. Over the course of the 20th century, the process was proven effective and approved for many foods such as spices, fruits, vegetables, and grains in both the United States and several other countries. The first approval of its use on animal products in the United States came about when the FDA, in July 1985, and FSIS, in January 1986, issued rules to allow pork to be irradiated to control *Trichinella*. Subsequent rules have declared irradiation safe for poultry, raw meat, and fresh eggs. Additional products are in the process of being approved, and more will be submitted for approval.

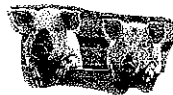
Mad Cow Disease

Bovine spongiform encephalopathy (BSE) is a disease in cattle. It is a degenerative, central nervous system disease that causes cattle to become nervous, lose coordination, lose weight, and have difficulty walking. Cattle die 2 weeks to 6 months after these symptoms appear. The incubation period is 5–8 years. In March 1996, it was announced that a new variant of Creutzfeldt-Jakob disease in humans might be linked to BSE. Evidence accumulated since that time strongly suggests this is the case.

It is believed that the disease is spread in cattle through the feeding of mammalian-derived protein by-product feeds. On June 5, 1997, the Food and Drug Administration Center for Veterinary Medicine published a rule banning mammalian-derived protein by-product feeds for all ruminants to protect the cattle population of the United States. Since 1989, the United States has restricted importation of ruminant ruminant products, and ruminant by-products from BSE-positive countries.

Despite all of these precautions, on December 23, 2003, the FDA was alerted to the first U.S. case of bovine spongiform in the state of Washington. A “downer” cow that suffered partial paralysis as a result of birthing difficulties had been slaughtered and, as required, a sample was sent to a USDA laboratory in Ames, Iowa, for BSE testing. Test results were positive. Unfortunately, because the results came about 2 weeks after slaughter, the carcass had already been processed. Edible meat had been converted to hamburger and steak and edible by-products were ground and rendered to make animal feed and produce fat for soap and other products. Once notified of the positive test, the FDA took immediate action and notified the public. During the next month, over 30 officials from the FDA and various state agencies would accomplish the diligent task of tracing down all the infectious material. Within 96 hours all potentially inedible by-products had been found. By the end of the month, over 2,000 tons of meat and by-product had been destroyed.

No other BSE-infected cows were found. Quick response and the cooperation and dedication of many professionals helped to minimize damage and protect the consumer. As a result of this incident, FSIS quickly worked to implement further protections against BSE. A surveillance program to test high-risk cattle was implemented. In addition, effective December 30, 2003, carcasses from cattle intended for human food that are sampled and submitted to APHIS for BSE testing are held from further processing until results are reported. In addition, the definition of meat clarified by FSIS not to include brain, trigeminal ganglia, spinal cord tissue, or dorsal root ganglia (all of which are central nervous system-type tissues).



Finally, slaughter and processing establishments are required to develop procedures that demonstrate specified risk materials (SRMs) are removed and not present in meat. SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, and vertebral column and dorsal root ganglia of cattle 30 months of age and older. SRMs also include the tonsils and distal ileum of all cattle (the removal of distal ileum requires removal of the entire small intestine). SRMs have been banned because science indicates this is where infectious material accumulates.

Genetically Engineered Products

Consumers abroad, and to a lesser degree in the United States, have expressed concern about consuming genetically engineered food products. Most of this controversy has centered on plant products. However, it is inevitable that those concerns will also be directed at animals fed those plant products and then ultimately at transgenic animals themselves.

Livestock have been fed products from plants whose genetics have been altered by recombinant DNA technology (biotech crops) since those crops were first introduced in 1996. Two important types of biotech crops are crops tolerant to pesticides and crops protected from insect pests. Expected in the future are more biotech crops, many with enhanced levels of nutrients or other beneficial substances in the plant.

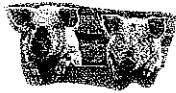
For those biotech crops currently available, both the levels of nutrients and anti-nutrients are the same as conventional crops. When fed to livestock, livestock digest and absorb the nutrients from biotech crops just as they do from conventional ones. Livestock grow and produce when fed biotech crops just as they do when fed conventional ones. The meat, milk, and eggs produced from animals fed biotech crops are the same as from conventional feeds. The proteins found in the biotech plants are broken down into smaller components during digestion and thus do not become part of the animal products. Thus, meat, milk, and eggs from animals fed biotech feeds are no different than those from animals fed conventional feeds, and they are safe for human consumption.

The use of animals with genetic alteration and of cloned animals as food is a consumer issue in the United States. In 2008, the FDA concluded that cattle, swine, and goat clones, and the offspring of any animal clones traditionally consumed as food, are safe for human and animal consumption." The issues have been debated for a number of years and will continue to be debated, at least for a time (Figure 27-11).



Figure 27-11

In 2008, the FDA concluded that "cattle, swine, and goat clones, and the offspring of any animal clones traditionally consumed as food, are safe for human and animal consumption." Meat from these clones and their offspring are considered "as safe as food we eat every day." (Photo courtesy of ViaGen, Inc.)



SOURCES OF INFORMATION

More information on the **Partnership for Food Safety Education** and the **Fight BAC!** campaign is available through the Internet at <http://www.fightbac.org/>.

The **National Food Safety Information Network** was part of the Food Safety Initiative of the Clinton administration. FSIS and FDA are working together to coordinate food safety information through the network. The network will coordinate and link work currently being done by both agencies' hotlines and enhance services provided by the USDA/FDA Foodborne Illness Education and Information Center, which develops and maintains a database of education materials. Food safety information from FSIS is available on its website at <http://www.fsis.usda.gov>. Interagency food safety information is available at <http://www.foodsafety.gov>.

EdNet is an electronic network allowing food safety educators around the country to keep abreast of new federal food safety education projects. It is a direct mail communication from the federal government. To subscribe, send the following message to listserv@foodsafety.gov: Subscribe EdNet-L firstname lastname (substitute your name for firstname and lastname).

The **Food Safety Educator** newsletter, produced by FSIS, provides a forum to communicate new initiatives and research information. The newsletter can be accessed through the FSIS website at http://www.fsis.usda.gov/News_&_Events/food_safety_educator/index.asp. To subscribe, send or fax your name and mailing address to USDA/FSIS, Food Safety Education Staff, Room 1180-South Building, Washington, DC 20250; fax (202)720-9063. Or e-mail your name and mailing address to fsis.outreach@usda.gov.

USDA Meat and Poultry Hotline. (202)720-3333; TTY: 1(800)256-7011(888) 674-6854.

Emerging pathogens

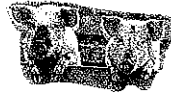
Pathogens that have mutated to become more virulent or have only recently been recognized as a safety issue.

SUMMARY AND CONCLUSION

The food supply in the United States is arguably the safest in the world. However, in spite of the safety of the U.S. food supply, people still become ill from their food. Most illnesses are traced to one of "seven bad bugs." Actually, around 14 organisms cause problems with enough frequency to be of concern. Several of these are referred to as "**emerging**" pathogens because the problem has just begun to be realized or because some mutation in the microorganism itself has made it more of a problem than it previously was. Understandably, food safety has become an important issue with consumers. However, consumers do not always do a good job of evaluating what is and what is not a real risk. Nor are consumers especially good at taking responsibility for the safety of their own food supply.

Even though the overwhelming majority of foodborne illnesses could be prevented if better

choices were made by the food preparer, the tendency of the average consumer is to look to the government to provide food safety. This task is not totally possible in a practical world. However, government agencies do have a role, and they are trying to expand their role. Various agencies in the federal government are responsible for segments of the food safety network. This is a system that has evolved since the passage of the Pure Food and Drug Act of 1906 and the Meat Inspection Act of 1906. Currently, these agencies are undergoing a transformation in the way they do business. The Food Safety and Inspection Service is dramatically changing its practices. This has been made possible by the adoption of the Pathogen Reduction Hazard Analysis and Critical Control Point Systems Final Rule, published in July 1996. Other changes are unfolding and many are still in the planning stage.



STUDY QUESTIONS

1. Describe the real versus perceived threats that the food supply poses to the average consumer. What are some events of the 1990s that focused the attention of the consumer on food safety?
2. What is the GRAS list? The Delaney clause? The Food Quality Protection Act of 1996? How do they relate to food safety?
3. What are the "bugs" that cause the majority of foodborne disease?
4. What role does the consumer have in protecting and preparing his or her own safe food supply?
5. Describe the FDA's role in ensuring a safer food supply.
6. What is the role of FSIS in ensuring a safer food supply? What are the purposes of the FSIS's monitoring program? Surveillance program? Residue avoidance program? In-plant/ on-farm testing?
7. FSIS is currently implementing and evaluating for implementation a myriad of changes in how it does business. Describe what the goals of the changes seem to be.
8. What is the Partnership for Food Safety Education and its Fight BAC! campaign? Where can you find more information about these programs?
9. Describe HACCP, its purpose, the seven HACCP principles, and when and where it was implemented.
10. Describe the safety/danger of using bovine somatotropin on cattle as it relates to the human food chain.
11. Is the use of growth-promoting hormones on food-producing animals a safe practice? Why or why not?
12. What are the benefits and risks of food irradiation? Would you eat irradiated food? Why or why not? Do you think you have already consumed any irradiated food? Why do you think consumers have been reluctant to consume foods they knew to be irradiated? If your job was to develop an advertising campaign to convince consumers to eat irradiated products, what would your slogan be?
13. What changes in animal products occur when producing animals are fed genetically engineered plant products?
14. What is FoodNet and what is its purpose?

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