From Farm Gate to Dinner Plate

TAINTED

FIFTY YEARS OF FOOD SAFETY FAILURES

Phyllis Entis, MSc

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eFoodAlert
Victoria, BC, Canada

Smashwords Edition

Dedicated to the millions of individuals around the world
who have suffered the effects of foodborne illness

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Abbreviations & Acronyms

Agencies and Countries

ADA:- American Dietetic Association

CDC:- U.S. Centers for Disease Control and Prevention (formerly, Center for Disease Control)

CFIA:- Canadian Food Inspection Agency

EPA:- U.S. Environmental Protection Agency

EU:- European Union

FAO:- Food and Agriculture Organization of the United Nations

FDA:- U.S. Food and Drug Administration

FSIS:- Food Safety and Inspection Service, U.S. Department of Agriculture

GAO:- U.S. Government Accountability Office (formerly, General Accounting Office)

HPB:- Health Protection Branch, Health and Welfare Canada

MOE:- Ontario Ministry of the Environment

MOSPL:- Microbial Outbreaks and Special Projects Laboratory, USDA

NACMCF:- National Advisory Committee on Microbiological Criteria for Foods, USDA

NASA:- U.S. National Aeronautics and Space Administration

NFPA:- National Food Processors Association

NIH:- U.S. National Institutes of Health

NRC:- U.S. National Research Council

OIG:- Office of Inspector General

PUC:- Public Utilities Commission (Walkerton, Ontario, Canada)

UK:- United Kingdom

US:- United States of America

USDA:- U.S. Department of Agriculture

WHO:- World Health Organization

Miscellaneous Abbreviations

BSE:- Bovine Spongiform Encephalopathy

CDAD:- *Clostridium difficile*-associated disease

CJD; vCJD:- Creutzfeldt-Jakob Disease; new variant Creutzfeldt-Jakob Disease

CUSTA:- Canada-US Free Trade Agreement

HACCP:- Hazard Analysis and Critical Control Points

HUS:- Hemolytic uremic syndrome

MBM:- Meat and bone meal

NAFTA:- North American Free Trade Agreement

NICU:- Neonatal intensive care unit

STEC:- Shiga-toxin producing E. coli

TSE:- Transmissible spongiform encephalopathy

TTP:- Thrombotic thrombocytopenic purpura

USMCA:- United States-Mexico-Canada Free Trade Agreement

Acknowledgments

TAINTED would never have seen the light of day if not for the willingness of ASM Press to release the worldwide copyright to *Food Safety: Old Habits, New Perspectives* to me. My thanks to the management of ASM Press for their generous acceptance of my request.

In my effort to ensure that *TAINTED* is easily digested by the non-technical reader, I have relied upon the advice and feedback of three stalwart beta-readers, who have helped me to avoid jargon and have kept me on the path I envisioned. My thanks to Barbara Bloomfield, Michael Entis and Iris Chacon for reading all or part of the original manuscript and offering their honest assessments of the content and the presentation.

One thing I have learned over the years, is that multiple pairs of eyes are essential in the copy-editing and proofreading phases of a book's production. I am deeply grateful to my friend and fellow-writer, Alison Henderson, for taking time away from her own writing to perform a detailed copy-edit of the manuscript.

I have learned over the years that, while you can't tell a book by its cover, potential readers are attracted by a good cover and repelled by a mediocre or bad one. I am beholden to my husband, Michael Entis, for pushing me to continue looking for the perfect cover concept rather than settling for and adequate cover. As always, I could not have developed and perfected the cover without the assistance and creative input of Hilary Quint. Thank you, Hilary, for your patience, your persistence, and your generous sharing of time and talent.

Finally, my thanks to the unsung heroes in government agencies, academia, and private companies around the world for devoting their talents to researching ways to improve the safety of our food supply.

Preface to *TAINTED*

When *Food Safety: Old Habits, New Perspectives* hit the bookshelves in January 2007, I thought I had said everything I ever wanted to say on the subject.

How wrong I was.

It took me less than a year to realize that I wasn't done.

In November 2007, the CDC reported that an outbreak of *E. coli* O157:H7 likely was due to feral swine tracking the bacteria from cattle feces to field of spinach one mile away. That outbreak was responsible for 205 illnesses and three deaths.

Thus began the eFoodAlert blog.

I have been reporting on food safety issues, on eFoodAlert and elsewhere, for almost thirteen years now (with time off to jump-start my fiction writing in 2013 and 2014). When ASM Press returned to me the worldwide copyright to *Old Habits* early in 2020, I took my copy of the book down from the shelf and read it again with fresh eyes. I realized that, with some revision and updating, this book had a story to tell to the general public.

TAINTED was born.

Readers familiar with *Old Habits* will recognize much of the information presented in *TAINTED*. But this is not a simple reprinting of the old book.

Some of the older stories of foodborne disease outbreaks have been abbreviated or scrapped and have been replaced with more current material. I have deleted two of the original chapters, have added two new ones that deal largely with foodborne outbreaks that

took place since 2007, and have simplified the technical explanations and removed the accompanying charts, tables and graphs.

I have drawn upon scientific literature reports, news stories, material obtained from government agencies (notably the FDA) in response to Freedom of Information Act requests, and my own personal experiences for the contents of this book. Readers who are interested in the sources of my information can consult the detailed list of references contained in Appendix B.

I am a passionate advocate for food safety, and have been so for almost five decades. I hope that *TAINTED* will help to raise public awareness of why and how food becomes contaminated, and how you, the consumer, can take steps to ensure the safety of the food you eat.

Preface to *Food Safety: Old Habits, New Perspectives*

When I was in my teens, one of my favorite writers was Frances Parkinson Keyes. A "romance novelist" who began her writing career as a journalist, Ms. Keyes imbued her stories with a strong sense of place and a believable set of characters, and swept her readers along with a strong and smooth narrative style. Unlike many other authors in the genre, she also prefaced each book with a detailed explanation of its evolution, deftly setting the scene for her "Gentle Readers". Often, her prefaces were almost as interesting as the novels they introduced. While I can't hope to match Ms. Keyes' powers of observation and storytelling, I beg the indulgence of my own Gentle Readers as I sketch in some background to this book.

My involvement in food safety began in mid-1972, when I joined Canada's Health Protection Branch (HPB). I began my career with HPB in the Winnipeg, Manitoba regional laboratory and, in mid-1974, moved to the agency's Quebec regional lab, based in the Montreal area. In 1975, I took over responsibility for managing HPB's Montreal area microbiology group. The Regent Chocolate *Salmonella* outbreak described in Chapter 4 took place while I was working in Winnipeg, and the investigation into the source of repeated contamination of milk powder production plants with *Salmonella* (Chapter 2) was carried out while I was in Montreal. Many of the details included in the description of both of those events (those not supported by specific literature reference citations) are based on first-hand information.

In 1979 I left HPB and, with my husband, co-founded QA Laboratories (later QA Life Sciences). The description of the wiener processing facility in Chapter 2 is based on first-hand information. I was the consultant hired by the company to determine the source of their on-going post-process contamination program.

In 2003, I wrote a series of articles on food safety for the Del Mar Times, a Del Mar, CA weekly newspaper. Some of the information and anecdotes that appeared in those articles are scattered through this book. Notably, the story of Kevin Kowalcyk (Chapter 6), and portions of the discussion of the BARF (raw food) diet for companion animals (Chapter 15) first appeared in those Del Mar Times articles.

Gentle Readers should keep in mind that science doesn't stand still. All cumulative totals of outbreaks, cases, etc. are valid as of June 2006. Likewise, statements in the text that relate to on-going investigations or situations also are effective as of that same date. The continuing saga of US-Japan trade talks aimed at reopening the Japanese market to US beef is an example of a situation that can change from day to day. Also, URLs (web page addresses) cited in the References at the end of each chapter were verified on the dates shown. Given the ephemeral nature of the Internet, these are also subject to change.

What is not – and never should become – subject to change is the responsibility of food producers and processors to put food safety concerns ahead of expediency when making decisions. Choosing to ignore unfavorable or inconvenient test results, opting for the least expensive, most "cost-effective" processing method, and establishing token food safety programs that look good on paper but are ineffective, are not the actions one would wish to associate with major food companies. Yet these choices are made again and again – not just by small food processors, but also by major, multinational food companies. As I write this Preface, Cadbury-Schweppes is facing possible prosecution for its involvement in a UK *Salmonella*

outbreak traced to chocolate produced in the company's Herefordshire production facility. Cadbury's management waited five months before alerting British health authorities to a leaking pipe that had contaminated some of its chocolate crumb.

A major outbreak of *E. coli* O157:H7 (183 cases and one death as of September 26, 2006) linked to spinach grown and packaged in the Salinas Valley area of California – unfolding as this book goes to press – is an example of what can happen when an industry chooses to stay with its old habits. Between 1995 and 2005, there were 19 outbreaks of *E. coli* O157:H7 tied by epidemiological evidence to spinach or lettuce; at least 8 of the outbreaks were traced to Salinas Valley produce. According to newspaper reports, in 2004 and 2005, the FDA advised farmers in California that their crops could become contaminated with *E. coli* O157:H7. Unfortunately, the growers closed their eyes and ears to the government's warnings, and are now suffering the consequences – as are the 183 (or more) outbreak victims and their families.

Legislators and regulators also bear a responsibility for improving and maintaining food safety. Notwithstanding industry's pleas for voluntary programs and self-regulation, government oversight is an essential part of the food safety mosaic. Just as drivers will push the speed limit when they know that they are not being monitored, so too will food processors push the limits of "voluntary compliance" – not maliciously or with intent to harm the consumer, but simply because it's human nature to do so. Self-regulation is an oxymoron.

The public, too, has an important role to play. All too often, food preparers and consumers engage in risky behavior – eating raw or undercooked meat, poultry, eggs or seafood, drinking unpasteurized milk or cider, neglecting proper kitchen sanitation practices, or storing food at an incorrect temperature. Lapses on the part of large food companies can result in massive foodborne disease outbreaks, but these occur only occasionally. Far more common are the sporadic cases and small outbreaks of foodborne disease caused by

mishandling of food on the part of food service workers and by individual food preparers in the home.

The need for a safe food supply is not debatable. But experts differ on the best ways to achieve and maintain that goal. Irradiation of raw meats and poultry, the role of microbiological testing, and the precise role that regulatory authorities should play are all areas of controversy. While I have received and considered the opinions of my reviewers, I alone am responsible for the accuracy and completeness of the contents of this book, and for any opinions expressed therein.

My Food Safety Credo

I believe that every individual is entitled to a reliable supply of safe food and safe drinking water.

I believe that food producers, processors, distributors, transporters and handlers are morally, ethically and legally responsible for ensuring the safety of the food that passes through their hands.

I believe that the responsibility for producing and selling safe food does not vary with the size of the company.

I believe that both imported and domestically produced foods must meet the same high standards of safety.

I believe that legislators are duty-bound to develop and promulgate unambiguous food safety laws, and to update those laws as the situation and the science dictate.

I believe that legislators are duty-bound to provide government agencies with the regulatory tools and financial resources needed to enforce food safety laws.

I believe that government agencies and their personnel are morally and ethically responsible for rigorously enforcing all food safety laws and regulations.

I believe that companies and individuals who **knowingly** sell or supply contaminated food should be subject to prosecution for reckless endangerment and, if convicted, should be severely punished.

I believe that consumers are entitled to full, factual and prompt information on all food safety recalls and food-borne disease

outbreaks.

I believe that consumers have a right to know where their food originated and what ingredients it contains.

I believe that consumers must accept responsibility for safely preparing, handling, and storing food at home.

Sadly, I also believe that we have a long way to go – both in the USA and elsewhere around the world – before my personal food safety credo becomes a reality.

Want to know more? Then please read on.

Chapter 1
Old Habits Die Hard

While ten-year-old Denise looked on, Martha washed the brisket, cut off a chunk of the triangle-shaped meat, seasoned both pieces, and placed them next to each other in a roasting pan. As she held open the oven door for Martha, Denise asked, "Mom, why did you cut off the end of the meat before putting it into the pan?"

"Because your Grandma always does it that way, and that's how I learned," replied Martha.

"But why does Grandma do it that way?" Denise asked.

Martha thought before responding. "I really don't know," she said, furrowing her brow, "but we'll her ask the next time we visit."

A few days later, Martha took Denise to visit her grandmother. "Grandma," said Denise, as soon as she could wriggle free from her welcoming hug, "when you roast a brisket, why do you always cut off the end of the meat before putting it into the pan?"

"I've always done it that way," replied Denise's grandmother. "I learned by watching your Nana. Why don't we call and ask her? She should be at home."

Grandma reached for her phone, pressed the speed dial button for her mother's apartment in the nearby assisted living facility, and offered the handset to Denise.

"Nana, I have a question for you," said Denise. "Why did you used to cut the end off of the meat whenever you made a roast brisket? Mom and Grandma and I all want to know the secret to your recipe!"

Nana chuckled. "There's no secret, Sweetheart," was her reply. "The brisket was too large for my pan!"

Doubtless, Nana also cooled freshly cooked food on the kitchen counter or in front of an open window before putting it into the refrigerator. She would have learned this from her own mother in the days when kitchens had iceboxes instead of refrigerators. Putting a large portion of hot food directly into an icebox would have been a recipe for disaster. Heat from the food would melt the ice, causing the entire contents of the icebox to spoil. The first refrigerators were somewhat better, as they didn't rely on daily delivery of a block of ice to keep food cold. However, they were far less efficient at maintaining a consistently cold temperature than modern appliances.

Unfortunately, many food handlers have never realized that, just like the size of Nana's roasting pan, the cooling capacity of refrigerators has changed. Modern commercial and household refrigerators can easily handle a hot item without endangering the other foods. Allowing a hot dish to cool on the countertop is no longer advisable. In fact, it can be downright dangerous. A group of school kids, teachers and cafeteria workers found that out in the spring of 1986.

April Fools!

On March 31, 1986, the workers in an Oklahoma school district foodservice kitchen were preparing chicken to be served in four school cafeterias. They started by setting out the frozen chicken to thaw overnight at room temperature. On April 1st, a portion of the thawed chicken was placed into pans of water and baked in a 350°F [177°C] oven. The heat was turned off after 2 hours, and the chicken was left to sit overnight in the still-warm oven. The kitchen workers cooked the rest of the chicken in a steam cooker for 2 hours, then readjusted the temperature to the lowest setting and left the food in the warm cooker overnight. The chicken was delivered to the school cafeterias on April 2nd.

The outbreak erupted that same afternoon. Students, teachers and cafeteria workers reported experiencing nausea, vomiting, cramps or

fever, many of them suffering from a combination of two or more symptoms. Twenty-two ended up in the hospital. In all, more than 200 people were stricken with *Salmonella* food poisoning, courtesy of the chicken. Fortunately, everyone survived their ordeal.[1]

How could this have happened? Chicken cooked for 2 hours in a 350°F [177°C] oven should have been safe to eat. However, the foodservice workers had broken just about every rule for safe food preparation. Yet they had no idea they had committed three major errors, according to the investigation report.

Their first mistake was to thaw the chicken at room temperature overnight. Frozen meat does not thaw uniformly. The outer surface thaws first, followed by the interior. Once the surface of the chicken thawed, the bacteria on it began to multiply. Any *Salmonella* present on the chicken would have generated millions of offspring by morning.

Having succeeded in producing chicken laden with *Salmonella*, the food handlers made their second mistake. No one thought to verify the cooking procedure or bothered to check the temperature of the cooked chicken with a meat thermometer. The investigation report doesn't state how tightly the chicken was packed into water-filled pans for the 2-hour cooking period. Nor do we know how full the steam cooker was, or how evenly the heat was distributed through the chicken in either the oven or the steamer. One "cold spot" or undercooked area would have been enough to allow a few *Salmonella* to survive.

As for their third error, instead of refrigerating the cooked food immediately, the kitchen staff allowed it to remain in the warm oven and warm steamer overnight. *Salmonella* reproduces best at or near body temperature. Under these cozy conditions, it can double its population every 20-30 minutes. When conditions are right, a single *Salmonella* is able to generate more than 10 million offspring in 12 hours. Thus, even if only a few *Salmonella* managed to survive the

cooking process, the chicken would have been swarming with *Salmonella* by the next day. All told, a perfect recipe for a bacterial picnic.

Once they determined the likely source of the outbreak, health authorities took corrective action. Cafeteria workers suffering from diarrhea were not permitted to return to their jobs until they were symptom-free. All of the workers were instructed on proper hand washing and personal hygiene. They were also taught to thaw frozen meat in the refrigerator, to always check the internal temperature of cooked meat with a meat thermometer, and to store cooked foods either above 140°F [60°C] or below 40°F [4.5°C] to minimize bacterial growth.

The cafeteria workers should have been taught these simple rules long before the outbreak. Had they been properly trained when they were first hired, two hundred people most likely would have been spared the agonies of *Salmonella* food poisoning. Students and teachers would not have missed classes, and the school's insurer would not have been out $40,000 in medical expenses.

Degrees of Confusion

It would take an exceptional microbe to withstand 350°F [177°C], even for a second or two. So, how can a pathogen such as *Salmonella* (which isn't especially heat-tolerant) survive two hours or more in a hot oven? In fact, the only thing inside an oven that reaches the nominal set temperature is the air. A roast leg of lamb, for example, is considered to be "well done" when its internal temperature hits 170°F [77°C].[2] Even water only reaches 212°F [100°C] before it boils.

An oven's temperature setting is a very poor predictor of the final core temperature of the food. Several additional factors influence the outcome of a cooking procedure, including: the uniformity of heat distribution in the oven, the density and thickness of the food being cooked, the length of time allowed for cooking, the ability of air to circulate around the food and the reliability of the oven thermostat.

A thermostat that is out of calibration by even 25°F [14°C] will alter noticeably the length of time required to cook a food.

Many ovens, especially older ones, suffer from uneven heat distribution. The baking element is usually at the bottom of the oven. When the oven thermostat calls for heat, the element comes on, and remains on until the thermostat senses that the set temperature has been reached. Because the thermostat usually is placed at or near the top of the oven chamber, this produces a temperature gradient inside the oven, with the hottest area near the bottom. Convection ovens, which incorporate a fan to circulate the air, reduce or even eliminate uneven heat distribution, although some designs work better than others.

The way in which food is placed inside an oven also affects heat distribution. Large trays or pans that fill entire shelves right to the oven walls impede air circulation, even in a convection oven. Lining shelves with aluminum foil to catch drips and splashes also inhibits airflow, and produces uneven heating. Squeezing as much food as possible into a cooking pan, or covering the pan tightly with foil, prevents air from circulating efficiently around the food. Finally, evaporative cooling – the reduction in temperature that takes place when water evaporates – lowers the surface temperature of food, slowing the rise in the food's internal temperature.

Ensuring that food has been cooked to a safe internal temperature is more complicated than putting the food into a pan, setting the oven temperature and cooking the food for a fixed time. Relying solely on past experience to determine when food should be removed from an oven is truly a recipe for disaster. The only way to be certain that food has been cooked adequately is to use one or more meat thermometers, placed in thickest, most dense parts of the food – the areas that are likely to be the last to reach the target temperature.

Unfortunately, lack of proper instruction for food service workers often is the rule, rather than the exception. Consequently, outbreaks

due to errors in food handling take place with sickening regularity. The customers and owner of Danny's Deli found this out the hard way in 1993.

Danny's Deli

St. Patrick's Day is a major event for a catering delicatessen famous for its corned beef. Danny's Deli was known throughout Cleveland for the quality and flavor of its signature meat. On March 12, 1993, the deli began to prepare and stockpile meat for the anticipated St. Patrick's Day demand.

Danny's cooked corned beef briskets by boiling them for three hours.[3] The cooked meat was allowed to cool at room temperature, after which it was refrigerated until the St. Patrick's Day "rush" on March 16th and 17th. To prepare the corned beef for serving, briskets were removed from the refrigerator as needed and placed in a warming tray maintained at 120°F [49°C]. Each brisket was sliced and either served immediately, or used on March 17th to prepare sandwiches for catered events. The sandwiches were made around 11 a.m. and held at room temperature until they were eaten during the course of the afternoon.

On March 18th, the phone started ringing at the Cleveland City Health Department. In all, 15 calls were made to the department that day, reporting approximately 150 cases of food poisoning involving Danny's Deli. Health officials responded by closing the restaurant temporarily pending a full inspection of the facilities and a review of its food-handling practices. The deli was permitted to reopen for business the following day.

The Ohio Department of Health, which analyzed the suspect meat, reported that it contained a high concentration of *Clostridium perfringens,* a species of bacteria known to cause food poisoning and often associated with this type of outbreak. These bacteria produce heat-resistant spores that could easily have survived the three-hour boiling process used to prepare the corned beef. Even so, those

spores wouldn't have caused a problem, had the boiled meat been refrigerated immediately after cooking.

A reporter from *The Plain Dealer*, a Cleveland daily newspaper, interviewed Danny's owner, George Georges, on the day the deli reopened.[4] According to Mr. Georges's explanation, the food poisoning was caused by his having refrigerated the meat too soon after cooking. He told the reporter that, "*an inspector who visited the site Thursday told [me] the problem might have been the result of not allowing cooked corned beef to stand before refrigerating it.*" The reporter added that, in the owner's opinion, "*about 60 pounds of the meat apparently was refrigerated too soon after cooking. By doing that, the cooking process stopped before all the bacteria were destroyed.*"

In fact, Mr. Georges had it backwards. Spores are a survival mechanism designed to endure harsh conditions such as high temperatures, and to germinate and grow when the conditions are favorable. Had the meat been refrigerated immediately after cooking, the spores would have remained inactive, and the meat would have been safe to eat. By cooling the cooked corned beef at room temperature, the deli ensured that the food remained at a favorable bacterial growth temperature for long enough to produce a dangerous level of *C. perfringens* in the meat. Once the chain of events leading to the outbreak was established, representatives from Cleveland's health department provided recommendations to the deli on how to improve their handling practices.

Fortunately for the victims and for Danny's Deli, *C. perfringens* is a relatively mild food poisoning bacterium. Its main symptoms are acute diarrhea, abdominal cramps and vomiting, and illness typically runs its course in about 24 hours. Nevertheless, the experience can be agonizing. In describing her illness to a reporter, one victim said, "*It was pretty bad. I was crawling on the floor saying, 'God, if you just let me live I'll be a better person'.*"[5]

No one died as a result of this outbreak. No one was even hospitalized. However, more than 150 individuals and their families were severely inconvenienced, and many probably lost a day of work.

The public expects restauranteurs to know how to handle and prepare food safety, and depends upon local health departments to communicate effectively with food handlers. Yet the owner of Danny's Deli misunderstood the health inspector to say that the corned beef was refrigerated too soon, rather than not soon enough. Clearly, the substance of the inspector's message was not coherent.

We expect our health professionals to have mastered their profession and the ability to assimilate important safety information into their daily work routines. Nevertheless, even health care workers have been known to engage in outdated and unsafe practices.

Nourishing the Newborn

In March 2001, a baby boy was delivered prematurely by caesarean section in Tennessee and admitted to the hospital's neonatal intensive care unit (NICU).[6] By the time he reached the age of eleven days, he was suffering from a variety of symptoms, including fever and neurological abnormalities. Lab cultures established that he had contracted meningitis caused by *Cronobacter sakazakii* (formerly known as *Enterobacter sakazakii*). His doctors tried to treat the infection with antibiotics, but he died in April 2001 at the age of 20 days.[6]

On learning of the infection, hospital personnel screened the other 48 infants in the NICU to find out whether any of them were infected with the microbe. The bacterium was found in specimens from nine of the 48 infants tested, including from the baby boy who died.

Premature and underweight infants represent one of the most susceptible populations to infection. The hospital had to uncover the source of the bacteria without further delay, to prevent other babies from becoming ill.

The first step was to compare the records of the nine infected infants with those of the 40 infants who were patients in the NICU at the same time but showed no sign of infection. After reviewing all the possible variables, hospital personnel could find only one thing that the nine babies had in common. They had all been fed Portagen, a powdered infant formula product made by Mead Johnson. But 21 of the 40 healthy babies had also received Portagen. The search continued.

Everything used to prepare the powdered formula for feeding came under scrutiny. Microbiology lab personnel tested the water in which the powder was dissolved. They analyzed samples from opened cans of two different batches of formula that had been in use in the NICU during March and April. They also sampled unopened cans from both batches and looked for *C. sakazakii* on the countertops where the formula had been prepared. While the lab tests were underway, hospital personnel carried out an intensive examination of all infection-control practices in the NICU, and reviewed all preparation protocols and records for the powdered formula.

The review of practices and procedures turned up nothing. Everything had been done by the book. Formula had been prepared and stored according to the manufacturer's instructions. The infant who died from meningitis had been fed the formula continuously by tube, and the time that a container of formula was allowed to remain at room temperature during feeding had not exceeded the eight hours specified in hospital policy.

Fortunately, the lab investigation provided answers. Although all of the environmental samples were negative, as was the water used to prepare the formula, one of the two batches of Portagen in use in the NICU during the time of the outbreak contained *C. sakazakii*. The

microbe was present even in sealed cans of the powdered infant formula. On learning these results, the hospital immediately made several changes to its practices, switching from powdered formula to a ready-to-use liquid product, limiting the use of powdered formula to certain specific situations, and reducing the hang time for continuous tube feeding of formula to 4 hours from 8 hours.

Mead Johnson eventually recalled the contaminated batch of Portagen on March 29, 2002, nearly one full year after the initial outbreak.[7] No explanation was ever given for the delay.

Very few people outside of the microbiology community had heard about *C. sakazakii* at the time this outbreak took place. But the microbe, and the harm it could cause, was well known for many years. Several researchers in North America and Europe had made the connection between infant formula, *C. sakazakii,* and meningitis in infants long before 2001.

The very first reports linking meningitis in infants to this microbe appeared in the early 1960s.[8] By 1981, the ability of *C. sakazakii* to cause fatal meningitis was confirmed by researchers at the Indiana University School of Medicine.[9] In 1983, a group of Dutch researchers drew the first tentative conclusion linking the infection to infant formula.[10] This was corroborated by the results of a detailed investigation of an Icelandic outbreak, carried out with the cooperation of a representative of the US Centers for Disease Control and Prevention (CDC).[11]

How common is *C. sakazakii*? A 1988 study evaluated 141 different samples of powdered formula obtained in 35 different countries.[12] The researchers found low levels of the microbe in twenty of those samples, from thirteen countries. None of the results exceeded the standards of the Food and Agricultural Organization of the United Nations (FAO) in force at that time for powdered infant formula. However, even very low levels of a dangerous bacterium can grow to high numbers when the conditions are right.

At the time of the Tennessee outbreak, standard practices allowed for reconstituted powdered formula to remain at room temperature for up to 8 hours while an infant was being fed continuously by tube. Yet in 1997, Canadian researchers reported that *C. sakazakii* could begin to multiply in reconstituted formula after only 2.7 hours at room temperature.[13] In addition, once it began to grow, *C. sakazakii* could double in population under these conditions every forty minutes. Allowing for the 2.7-hour lag time, a single *C. sakazakii* cell could produce as many as 256 offspring under the conditions of use still recommended in 2001 by the American Dietetic Association (ADA) and the U.S. Food and Drug Administration (FDA). If a four-hour limit had been in effect at the time of the 2001 outbreak, that same *C. sakazakii* cell would only have had time to produce four offspring.

While the results of a single research report would not ordinarily be enough to warrant a major policy shift, the Canadian research had been triggered by several clinical reports, issued over a period of years, of death or lifelong disability resulting from *C. sakazakii* infections. These reports, and the results of the Canadian research study, appear to have passed beneath the radar screens of the ADA, food safety regulators, and infant formula manufacturers both in North America and in Europe. One year after the Tennessee outbreak, a Belgian baby became infected with *C. sakazakii*, developed meningitis, and died shortly after being released from the hospital at five days of age. The source of the baby's infection was traced to a batch of Nestle's "Beba" powdered formula. Nestle recalled two production lots of the formula in May 2002.[14]

The FDA responded to the lessons learned from the Tennessee outbreak by increasing surveillance of infant formula manufacturers, with specific emphasis on *C. sakazakii*. This heightened awareness resulted in at least one recall, comprising several lots of powdered formula produced by Wyeth Nutritionals and sold under various brand names. This time, the FDA caught the problem before any infants were put at risk.[15]

In 2002, as a result of the fatal Tennessee outbreak, both the FDA and the ADA modified their recommendations for preparation, use and storage of reconstituted powdered formula, and shortened the recommended room temperature holding period from eight hours to four.[16,17] In addition, FDA microbiologists developed a procedure for detecting *C. sakazakii* in powdered infant formula and published the details on the agency's web site. At the same time, the FDA let it be known that testing for this microbe would become part of their standard protocol when inspecting infant formula manufacturers.[18]

In 2007, the World Health Organization (WHO) recommended a further reduction in holding time for reconstituted powdered infant formula from four hours to a maximum of two hours, and in 2014, the FDA implemented stringent new quality control standards for the manufacture of powdered infant formulas.[19,20]

More than thirty years after the Tennessee outbreak, the threat of *C. sakazakii* still lingers. A recent survey of 128 samples of powdered infant formula from Chile, Mexico, the Netherlands and Brazil discovered low levels of *C. sakazakii* in samples of four different Chilean products and one Mexican product.[21] A 2019 survey of four Chinese powdered infant formula factories found forty-two *C. sakazakii* isolates from multiple locations in all four facilities. Some of the isolates were recovered from designated 'clean work' areas.[22]

All of us, whether we are consumers, food handlers or food safety professionals, are subject to the "Old Habits" syndrome, and we cannot afford to let down our guard. To ensure the safety of our food and water supply, we must always learn and use the best and safest ways to produce, prepare and store food. We don't have to cut the end off the brisket, just because Nana's pot was too small.

Chapter 2
Recipes for Disaster

Whether for eliminating pesky facial imperfections, reducing excessive underarm sweating, treating muscle spasms, or mitigating migraines, Botox® has become a bandwagon with an ever growing population of adherents ever since its initial approval by the FDA in 2002.[1,2,3,4] But this potent neurotoxin and Clostridium botulinum, the microbe that produces it, can also wreak havoc in our food supply when we least expect it.

The Fatal Error

Hazelnut was a common yogurt flavor in the United Kingdom (UK) in the 1980s. Hazelnut conserve was prepared from a puree of roasted hazelnuts, water, starch and sugar. The ingredients were mixed, heated together in a large vat, and pumped into cans. The cans were then sealed and placed in a boiling water apparatus for 20 minutes, after which they were cooled and stored at room temperature. Yogurt manufacturers purchased the conserve, mixed it with plain yogurt, and packaged the product into retail containers. All went well until consumers demanded a sugar-free variety.

The supplier of hazelnut conserve responded by substituting aspartame for sugar in his formula. Little did he realize that, in doing so, he had opened Pandora's box. In May and June 1989, 27 people living in Northwest England and North Wales developed symptoms of botulism: weak limbs, impaired speech, double vision, difficulty swallowing, and weak respiratory muscles. One person died from aspiration pneumonia, and twenty-five others were hospitalized. Of the 27 victims, 25 reported having eaten the same brand of hazelnut yogurt.[5]

Investigators found *C. botulinum* toxin in unopened packages of the yogurt. After having inspected the production plant, they

concluded that the yogurt manufacturer was maintaining an adequate level of hygiene, and turned their attention to the hazelnut conserve. The year before, in response to complaints of swollen cans, the manufacturer added potassium sorbate to his formula in an attempt to control the growth of yeast, which he assumed to be the cause of the swelling. As it turned out, yeast contamination wasn't the problem. *Clostridium botulinum* was.

When investigators tested a badly swollen can of the conserve, they found that it contained the same toxin that was present in the yogurt. On reviewing the manufacturer's production process, they realized that the heating step was not harsh enough to kill *C. botulinum* spores. Worse, the level of acidity (pH) of the conserve was well within the range that the microbe could tolerate.

By switching from sugar to aspartame without making any other adjustments to his process, the conserve manufacturer had set himself up to fail. The high sugar content of the original formula had prevented *C. botulinum* from growing. Once the sugar was removed, so was the only barrier to a serious outbreak. The manufacturer forgot – or never realized – that he was walking a food safety tightrope.

Long associated with inadequately processed canned food, *C. botulinum* has appeared in a variety of new places in recent decades. Uneviscerated salted fish, fermented beaver tails, and oil-packed condiments such as chopped garlic, roasted eggplant, and sautéed onions have all been linked to botulism.[6,7,8,9,10,11] In 1994, foil-wrapped baked potatoes were responsible for the third-largest outbreak of botulism in US history.

Foiled

The story began to unfold early on the morning of April 10, 1994, when a father and his teenage son turned up in an El Paso, TX hospital complaining of botulism-like symptoms.[12] In the days before their arrival at the hospital, they had shared a meal at Tassos,

a local Greek restaurant.[13] The hospital notified local health authorities who, in turn, alerted the other six hospitals in the area. Within hours, four additional victims were identified. All of them had eaten at Tassos.

Faced with an incipient *C. botulinum* outbreak, the El Paso health department immediately ordered the restaurant to remain closed that day, to allow health officials time to interview the outbreak victims. All of the people who showed symptoms of botulism had visited the restaurant on either April 8th or 9th, and most of them had eaten one of two appetizers made from baked potatoes: skordalia (a potato dip) and melitzanosalata (a potato/eggplant dip). Four of the victims who hadn't eaten either dip were restaurant employees, and had handled both appetizers while on the job April 8th and 9th.

Investigators tested leftover potato dip and confirmed that it contained high levels of botulinum toxin. The restaurant had no eggplant dip left over, but some was found discarded in a garbage can at the home of one of the patients. It, too, was positive for the same toxin. The pH of the potato dip was 3.7 – too acidic for *C. botulinum* to grow. Investigators concluded that the toxin must have come from one of the ingredients.

Six ingredients were common to both dips: oil, vinegar, raw onion, raw garlic, feta cheese and baked potato. The potato dip also contained French bread, and the eggplant dip contained baked eggplant. While there was no leftover baked potato or eggplant available for testing, all of the other dip ingredients were tested and contained no toxin.

The potato dip had been prepared using two potatoes that were wrapped in aluminum foil and baked at 450°F [250°C] for about 2 hours on April 7th. Still wrapped in the foil, the baked potatoes were stored for 18 hours at room temperature. The eggplant dip was made on April 5th using one potato and some eggplant that had been baked earlier in the evening. It was served to diners on April 6th or

7th, with no apparent ill effect. However, 5 people who were served portions of the same batch of eggplant dip on April 8th became ill.

Lab investigations confirmed that *C. botulinum* spores could have survived baking inside a foil-wrapped potato, and could have germinated, multiplied, and produced toxin in the baked potato while it was stored at room temperature. The toxin also remained stable and active in the acidic environment of the potato dip. The two implicated appetizers had been stored side-by-side in the restaurant's refrigerator, and the same utensils were used for both dishes. Investigators concluded that a serving utensil had transferred toxin from the potato dip to the eggplant dip.

The foil wrapping on the baked potatoes was the key to this outbreak. In a trial baking study, the internal temperature of foil-wrapped baked potatoes only reached 205-207°F [96-97°C], a temperature that *C. botulinum* spores could easily have survived. After baking, the foil acted as an oxygen barrier, creating near-perfect anaerobic conditions under which the organism could grow and produce its deadly toxin. The chef's decision to store the baked potatoes at room temperature for 18 hours was the final ingredient in the *C. botulinum* recipe. Had he refrigerated the baked potatoes, there would have been no outbreak.

Have Eggs Instead?

Pity the poor egg. Once hailed as one of nature's perfect foods, it has fallen on hard times. First it was ostracized due to our fear of cholesterol. Then, in the late 1980s, *Salmonella* further poisoned the egg's reputation. Reports of foodborne *Salmonella* outbreaks – many of them traced to eggs served at foodservice locations such as cafeterias, hospital kitchens, and restaurants – started flowing into government health departments in several countries, including the United States.

The breakfast buffet was a popular fixture at a Maryland restaurant chain.[14] But in the summer of 1985, it offered an

unexpected and unwelcome ingredient. That August, one employee and 3 patrons of a restaurant in the chain were stricken with *Salmonella* Enteritidis. Even though county health authorities investigated the restaurant and interviewed the victims and other patrons, they couldn't determine which food had caused the outbreak. There were not enough victims, and just too many individual food items, to allow investigators to pinpoint the source.

In the first half of September, five customers of a second restaurant belonging to the same chain became ill. That same week, 113 people who had eaten at a third restaurant in the chain contacted their local health department to complain about diarrhea, cramps and fever. Seventeen of the 113 ended up in the hospital. Once more, *Salmonella* Enteritidis was the uninvited guest at the table. This time, however, investigators were able to identify the offending food. Scrambled eggs offered in the breakfast buffet.

All three restaurants used Grade A shell eggs to prepare their scrambled eggs. Employees cracked the eggs by hand, with up to 1800 eggs combined into a single batch. The scrambled egg mixture sometimes sat at room temperature for as long as 6 hours before being cooked, and the kitchen staff was trained to undercook the eggs. Otherwise, the scrambled eggs would dry out in the breakfast bar's warming tray. Indeed, several of the food poisoning victims at restaurant #3 reported that the eggs appeared underdone.

It looked like a coincidence that all 3 locations were hit with a *Salmonella* outbreak in the space of just a few weeks, except that lab tests found that the identical strain of *Salmonella* Enteritidis was responsible for all of the illnesses. An in-depth investigation determined that the three affected restaurants purchased their eggs from the same distributor. Contaminated eggs combined with poor handling and cooking procedures made these outbreaks all but inevitable.

State health officials were unable to find *Salmonella* in other batches of eggs from the distributor. As a result – despite strong

circumstantial evidence – they couldn't confirm unequivocally that eggs from that distributor were the source of the outbreaks. Officials had to content themselves with explaining to the restaurant management how to prepare and serve scrambled eggs safely.

The 1985 Maryland outbreaks were early harbingers of a much larger problem. That same year, *Salmonella* Enteritidis became the most commonly reported *Salmonella* serotype in three US states: New Hampshire, New Jersey and New York. The trend of ever-increasing reports of illness due to *Salmonella* Enteritidis continued in 1986. Sources of the outbreaks included a wide variety of foods. Scrambled eggs, pasta (both homemade and commercial), hollandaise sauce, rice balls, protein supplement, and roast beef were all implicated, but there was no apparent connection to explain the emergence in the US Northeast of *Salmonella* Enteritidis as a serotype to be reckoned with.[15]

Then tragedy hit the Coler Memorial Hospital on Roosevelt Island, New York.

On Friday July 31, 1987, the headline on page B3 in the *New York Times* read "Tainted Food Possible in Patient's Death." The outbreak had begun on Tuesday of that week, and by late Thursday more than 175 people had developed gastroenteritis.[16] By the time the outbreak was over, 274 hospital patients were diagnosed with salmonellosis caused by *Salmonella* Enteritidis, and nine patients had died.[17]

Hospital officials worked feverishly to track down the source of the *Salmonella* before the outbreak could spiral out of control. They quickly discovered that the contaminated meal had been served at lunch on July 28th. Based on a review of medical records, their attention focused on a tuna-macaroni salad containing hospital-prepared mayonnaise which was made on July 27th using raw Grade A shell eggs. It was mixed with the other ingredients the morning of July 28th, and the finished salad sat at room temperature for 5 hours before being served with lunch.

The hospital lab tested remnants of the tuna-macaroni salad and found *Salmonella* Enteritidis. They also recovered the same microbe from pooled batches of eggs. Just to tie up the final loose ends, cultures of hen ovaries from the farm that had produced the eggs were positive for the same strain of *Salmonella* Enteritidis that had been found in the patients and in the salad.

Coincidentally, *Salmonella* Enteritidis was also turning up in the UK at an alarming rate. Illness due to *Salmonella* Enteritidis increased more than six-fold from 1101 to 6858 cases in the period between 1982 and 1987. While some cases of salmonellosis were traced to poultry meat, many others were tied to a variety of foods containing raw or partially cooked eggs.[18]

Inexorably, year after year, *Salmonella* Enteritidis contamination of shell eggs extended its reach to other countries, as well as to other regions of the United States. Japan was hit in 1989.[19] *Salmonella* Enteritidis was responsible for outbreaks in Canada in 1991, in Italy in 1993 and in California in 1996.[20,21,22] Reports submitted to the WHO between 1979 and 1987 by thirty-five countries highlighted the magnitude of the problem. The percentage of *Salmonella* Enteritidis isolations increased by at least 25% in twenty-one of the thirty-five countries, and more than doubled in fifteen of them.[23] And the number of victims continued to grow. Time and again, *Salmonella* Enteritidis outbreaks were traced to foods containing raw or undercooked eggs.

Hollandaise sauce, Caesar salad, ice cream, cake frostings, meringue pies, cheesecake, scrambled eggs, and mayonnaise. The list of dishes and desserts that traditionally use raw or partially cooked eggs goes on and on. Every now and then, the recipe comes with a microscopic bonus in the form of *Salmonella* Enteritidis. Microbiologists once thought that *Salmonella* could not penetrate into an egg unless the shell was damaged. But if that were true, how was the microbe finding its way into eggs? More importantly, what could be done about it?

To answer these questions, the CDC organized a working group in cooperation with state epidemiologists in November 1986.[15] After reviewing sixty-five outbreaks that had occurred over a 2½-year period beginning in January 1985, the group came to a startling conclusion. Infected hens were contaminating the eggs with *Salmonella* while the immature eggs were still in the oviduct.[24] Not everyone agreed with this assessment at first.[25] But over the next few years, evidence piled up in support of the theory.[26]

Egg production begins in the ovary, which is filled with immature eggs. As an egg matures, it pops out of the ovary and enters a tube known as the oviduct. At this stage, the egg is a tiny, naked yolk. As it travels down the oviduct, the egg increases in volume. Once it reaches full size, the egg yolk is surrounded by the vitelline membrane, around which is deposited a layer of albumen (egg white). Two pieces of fibrous material called chalaza attach the albumen to the vitelline membrane. Finally, the shell membrane and eggshell are deposited around the exterior of the now-complete egg.

An infected hen can carry *Salmonella* in several parts of its body, including the ovary and the oviduct.[27] Until an egg receives its protective shell, it is susceptible to *Salmonella* contamination. The microbe can either travel down the oviduct from an infected ovary, or up the oviduct from the cloaca. If the oviduct itself is contaminated, *Salmonella* can be transferred directly to the egg as it passes through on its way to the cloaca.[28]

Knowing how the egg becomes infected is only one part of the battle – the easiest part, at that. Preventing the infection is far more difficult. The only way to ensure that eggs don't become contaminated with *Salmonella* before they are laid is to start with a *Salmonella*-free flock of laying hens and work to keep it that way.

Which came first – the chicken or the egg?

While a *Salmonella*-free breeding hen produces *Salmonella*-free chicks, that's only the first step. Because newborn chicks are highly susceptible to infection with *Salmonella* Enteritidis and other salmonellae, decades of research have gone into strategies to keep chicks free from infection as they mature and develop into laying hens.

In 1971, Finland was hit with a massive outbreak of *Salmonella* Infantis in its broiler flocks. The economic damage was huge, and 277 people were stricken with salmonellosis.[29] In order to prevent a recurrence, Finnish scientists looked for ways to protect their flocks. They observed that 2- to 3-day old chicks were highly susceptible to *Salmonella*. But by feeding the baby chicks a mixture of the intestinal contents of a healthy adult chicken, the babies were prevented from succumbing to infection.[30] The researchers theorized that some component of the natural bacterial flora of *Salmonella*-free birds blocked *Salmonella* from colonizing the chickens' guts. They named the phenomenon "competitive exclusion."

Finland and Sweden, were among those countries that, in the early 1980s, incorporated competitive exclusion into an overall strategy which included using *Salmonella*-free feed and maintaining a clean henhouse environment. The contamination rate of chicken carcasses in Finland dropped to just 5-10% in 1992. That same year, only 1% of Swedish chickens tested positive for *Salmonella*.[31,32]

Competitive exclusion alone is not enough to eradicate *Salmonella*.[19,33] As the Scandinavians have learned, however, it can be very effective when used in conjunction with other control measures. One such method is vaccination.

The idea of vaccinating chickens against *Salmonella* was first explored as a means of preventing fowl typhoid, a disease of poultry caused by *Salmonella* Gallinarum.[34] Early experiments with vaccines made from killed *Salmonella* proved fruitless. Then, in 1956, the first successful vaccine – this one using a live, attenuated culture – was

announced.[35] Until recently, however, the use of poultry vaccines was never extended beyond control of *Salmonella* Gallinarum.

As regulators struggled in the 1980s and 1990s to contain the sudden eruption of egg-associated *Salmonella* Enteritidis outbreaks, poultry scientists revisited vaccination as a control strategy. In 1994, Hassan and Curtis introduced a live vaccine that protected chickens from infection by a variety of salmonellae, including *Salmonella* Enteritidis.[36] Their vaccine came with a bonus. The baby chicks born from vaccinated hens were more resistant to *Salmonella* infection than chicks from unvaccinated hens.[37]

In spite of the promising results obtained from vaccination and competitive exclusion research, egg farmers cannot rely exclusively on these approaches to keep their poultry *Salmonella*-free. Several environmental factors conspire to expose laying hens to infection throughout their lifespan. Often, feed is already contaminated with *Salmonella* when it arrives at the farm.[22] Mice carry *Salmonella* Enteritidis from henhouse to henhouse, spreading contamination with their droppings.[38] Also, *Salmonella* can attach to dust in the henhouse and circulate through the air, especially in windowless, environmentally controlled facilities.[19] Therefore, rodent control and careful attention to sanitation and disinfection must be part of the poultry industry's anti-*Salmonella* arsenal.

Nor is it enough to focus exclusively on the laying hens while ignoring the eggs. Hens expel their eggs through the cloaca – the same opening through which they eliminate feces. Thus, even at the instant a mature egg is laid, it is exposed to the risk of *Salmonella* contamination from an infected hen.[39] Once laid, every step in an egg's voyage to the breakfast plate provides another opportunity for *Salmonella* to hitch a ride.

Modern egg farms are highly automated and comprise multiple henhouses. When a hen lays her egg, a conveyor belt carries it out of the henhouse. Often, the same belt passes through each house in

sequence, accumulating eggs, debris, feces and, sometimes, *Salmonella* along the way.[40] Being fragile, some eggs develop hairline cracks, or even break open, during the collection process. Although cracked or broken eggs are either discarded or diverted, egg yolk and albumen leaking from the damaged eggs can coat the shells of intact eggs, and act like flypaper to trap stray *Salmonella*.

While studies have confirmed that caged hens in high population density facilities produce *Salmonella*-contaminated eggs, free-range and cage-free hens aren't exempt from this problem. Free-range hens have access to the outdoors for at least part of the day; cage-free hens, while not housed in cages, do not necessarily have outdoor access. Both spend at least part of their time indoors. Free-range hens are just as susceptible to *Salmonella* infection as their caged cousins, especially when a poultry farm is located near a sewage runoff creek.[21,41,42]

In the US, once intact shell eggs arrive at an egg-processing facility, they are washed with a sanitizing solution, and coated with a light mineral oil to seal the pores of the shell.[43] Washing and sanitizing removes visible soil and reduces the bacterial population on the outside of the shell. But detergent strips the natural protective coating from the shell, potentially enabling *Salmonella* to penetrate into the albumen.[44] Due to this perceived risk, several countries – including the UK and many members of the European Union (EU) – do not wash eggs.[45,46]

Temperature change is also an important factor in egg contamination. When an egg cools, either after having been laid or after washing, the contents shrink slightly. This creates a vacuum, which can suck into the egg any bacteria that may be present on the outside of the shell.[47]

Once it enters an egg, all that *Salmonella* needs in order to multiply is enough time and the right temperature. *Salmonella* Enteritidis barely grows at refrigeration temperature, but multiplies

readily in eggs that are stored at room temperature.[48,49] The older the egg, the better able it is to support the growth of *Salmonella*. Furthermore, the aging effect is hastened by storing eggs without refrigeration.[50] Unlike the UK, member countries of the EU, and many other developed countries, the US and Canada require that eggs be held at or below 50°F [10°C] through the entire length of the supply chain from collection at the hen house to retail display.[51,52]

Notwithstanding all of the things that can go wrong at each step in the egg production, distribution, and marketing chain, the risk of finding a contaminated egg was thought to be small. Using information based on the theoretical rate of infection of US laying hens at various stages in their productive lives, a risk-assessment team operating under United States Department of Agriculture (USDA) auspices calculated that only 0.005% of eggs (just one egg in 20,000) were likely to contain *Salmonella* Enteritidis.[53]

This study, which was published in 2000, provided a false sense of security to consumers. It was a numbers game, based on a series of assumptions regarding the relative prevalence of *Salmonella*-negative laying flocks and flocks with low (~1 contaminated egg in 17,000) or high (~1 contaminated egg in 1400) rates of *Salmonella*-positive results.[54] As regulators and consumers would find out a decade later, a single out-of-control hatchery could wreak havoc with public health and the egg distribution system.

The presence or absence of *Salmonella* inside an egg is not the only consideration. Quantity counts. The number of live bacteria in a contaminated egg can become dangerously high if the egg has been mishandled—high enough that traditional cooking methods may not kill all of the *Salmonella*.[55] *Salmonella*-positive eggs also present a risk of cross-contamination during food preparation. Cracking, separating or beating an egg can spread *Salmonella* over a wide area, contaminating work surfaces, utensils, mixing bowls and hands.[56] It's just as important to clean up the kitchen thoroughly after working with eggs as it is after handling raw chicken.

Sadly, food handlers – even those who work in hospitals – sometimes forget the risks associated with raw eggs. In 1993, a group of fourteen people, including seven children, who attended a cookout at a psychiatric hospital in Florida learned about the connection between *Salmonella* Enteritidis and eggs the hard way. Five of the seven children and all of the adults developed gastroenteritis within twenty-four hours of attending the party. Eleven of the twelve victims had eaten homemade ice cream made especially for the cookout.[57]

Investigators found *Salmonella* Enteritidis in the leftover ice cream and also recovered the microbe from three of the victims. The ice cream had been prepared the morning of the cookout using six raw eggs. There were no obvious preparation, sanitation or temperature control errors. Raw eggs represented the one fatal flaw in the recipe.

The USDA tried, without success, to trace the producer of the eggs. The hospital was able to point investigators to their supplier, but the distributor had purchased eggs from many different sources. As the agency had no authority to test poultry flocks for *Salmonella* unless the evidence clearly implicated one specific flock as being the source of an outbreak, the USDA was unable to pursue its investigation to a logical conclusion.

As long as people want to enjoy homemade ice cream, hollandaise sauce, sunny side up eggs, and Caesar salad, outbreaks of *Salmonella* Enteritidis gastroenteritis will continue to pop up like thunderstorms on hot, humid days. But, unlike the weather, we can control *Salmonella* if government agencies, the egg industry and food handlers are prepared to make the effort.

This effort has been made, and has borne fruit, in some countries. More than 80% of retail shell eggs in the UK now come from flocks that have been vaccinated against *Salmonella* Enteritidis.[46] The British government mandated *Salmonella* testing of all breeder flocks, and introduced new codes of practice for infection control and hygiene. As a result, reported cases of *Salmonella* Enteritidis infection

in the UK declined from a peak of nearly 30,000 cases in 1997 to fewer than 2,200 *Salmonella* Enteritidis infections reported during all of 2019, excluding a single four-week period for which data were unavailable.[58]

The US took a somewhat different approach, emphasizing the egg as well as the chicken. The President's Council on Food Safety issued its Egg Safety Action Plan in December 1999.[59] The Council established an interim goal of reducing *Salmonella* Enteritidis illness linked to eggs by 50% by 2005 and eliminating it completely by 2010. Yet, in 2018, cage-free eggs from a single producer were responsible for an outbreak of forty-four *Salmonella* Enteritidis illnesses in eleven US states.[60]

The 1999 Action Plan identified the stages of egg production for which improvements were needed, including breeder flocks and poultry feed, shell-egg processing procedures, improved package labeling, proper storage, shipping and display temperatures, and better education of food handlers, whether commercial, institutional or in the home. The plan also highlighted the need for improved outbreak surveillance and for a national system to enable investigators to trace a contaminated batch of eggs through the distribution system back to the flock that produced it. Finally, it called for additional research into all aspects of *Salmonella* Enteritidis and its association with poultry and eggs, including development of improved vaccines and competitive exclusion products, and in-shell pasteurization of eggs.

In 2000, the FDA published a Final Rule requiring that all consumer packages of shell eggs be labeled with instructions for safe handling and storage of the eggs.[61] Then, in 2004, the FDA took a major step towards achieving the goals set forward in the 1999 Action Plan by issuing a new set of proposed rules. The FDA's proposed Egg Safety Final Rule, which targeted all egg producers with 3000 or more laying hens, encompassed rodent and pest control, biosecurity concerns, procurement of chicks and pullets,

cleaning and disinfection of poultry houses, and refrigeration of eggs at the farm, among other issues.[62,63] The comment period for the proposal was extended twice in 2005 and was not finalized until July 2009.[64,65] The compliance date established for large producers was July 2010.[66] Small producers were granted an additional two years to bring their operations into line with the new regulations.

Whether it's *C. botulinum* in eggplant or *Salmonella* Enteritidis in eggs, the challenge is the same. Recipes that do not include an adequate final cooking step have become increasingly popular with consumers, and can be a significant source of foodborne illness. The health risks associated with these recipes are magnified when ingredients are not chosen wisely, or are mishandled. Food handlers, whether manufacturers, foodservice workers, or consumers, must be prepared to adapt their techniques in the face of newly recognized pathogens—or old familiar pathogens in new settings—in order to ensure the safety of the food they prepare.

Chapter 3
Betrayal

Sarah Lewis and her entire family attended a celebratory dinner at a local restaurant on May 29, 2010, to mark her sister Stacey's college graduation. The next night, Sarah's world turned upside down.[1]

Already feeling unwell on the evening of May 30th, Sarah went to bed early. She awakened during the night, suffering from vomiting and severe diarrhea. The next day, Sarah's mother, who lived nearby, took her to an urgent care facility. Twenty minutes later, she was admitted to hospital and was later diagnosed with salmonellosis.

Badly dehydrated and in enormous pain from her inflamed bowels, Sarah was moved to the hospital's ICU. While there, she developed severe tachycardia (abnormally rapid heartbeat), and was moved to the critical care heart unit, where she spent three days.

When Sarah was finally discharged in time to attend her daughter's preschool graduation, she thought the worst was behind her.

About 2 ½ weeks later, she was back in the hospital, still suffering from severe dehydration. She was released after five days.

The antibiotics Sarah took to combat her *Salmonella* infection stripped her digestive system of its normal population of protective bacteria, resulting in her becoming infected with *Clostridium difficile* (*C. diff*), a bacterium which causes severe diarrhea and cramping. A fourteen-day antibiotic regimen took care of the *C. diff*; however, the *Salmonella* was more resilient. Four months later, Sarah still was on 5 to 10 different medications daily to combat the infection and control her symptoms.

Sarah Lewis was the first recorded California victim of a *Salmonella* Enteritidis outbreak that sickened more than 1900 people

across the United States.[2]

The restaurant where Stacey's graduation banquet was held had purchased custard tarts from a local bakery. Ordinarily, the bakery used a pasteurized liquid egg mixture to make the tarts. However, on the day they prepared the dessert items for the graduation dinner, the bakery ran out of pasteurized egg mix and used fresh, raw shell eggs instead. Eggs that most likely had come from Iowa.

Something Rotten in the State of Iowa

The CDC first became aware of an unusual rise in *Salmonella* Enteritidis infections in July 2010. Epidemiological and traceback investigations pointed the finger of suspicion at two Iowa-based suppliers of shell eggs: Quality Egg, LLC (also known as Wright County Egg) and Hillandale Farms of Iowa, Inc.[2]

Alerted by the CDC, the FDA began a detailed inspection of Quality Egg on August 12th. They encountered an egg-laying farm overrun with rodents and birds. Henhouses and buildings used to store feed grain were in a state of disrepair, with manure seeping through the concrete foundation of one of the laying houses. Uncaged chickens ambled across an 8-feet high pile of manure to access the egg laying area.[3]

The situation confronting inspectors when they began their inspection of Hillandale Farms on August 19th was just as bad. Uncaged hens were tracking manure into the henhouses, some of which had structural damage. There was standing water adjacent to the manure pit, and liquid manure was leaking into one of the henhouses.[4]

It surprised no one when environmental samples collected at both Quality Egg and Hillandale Farms tested positive for *Salmonella* Enteritidis.[3,4]

Quality Egg announced an initial limited recall on August 13th, and expanded the scope of the recall on August 18th.[5,6] Hillandale followed suit with its own recall notice on August 20th.[7]

The shell egg distribution system in the United States was (and remains) multi-tiered and complex. Eggs were distributed in bulk to packaging facilities, which packaged the eggs under multiple brand names. Often, eggs from more than one supplier were mingled together for packaging into individual cartons holding six, twelve, or more eggs.

Because there was no way to determine the source of the eggs contained in any one carton, the recalls mushroomed, and consumers lost confidence in the safety of the eggs they purchased.[8]

Too Little, Too Late

The FDA's Egg Safety Final Rule, issued in 2004, was meant to prevent exactly the kind of situation that the agency's investigators encountered at Wright and Hillandale. But bureaucratic delays prevented the rule from being enacted until July 2009. Companies with 3000 or more laying hens were given one full year from the enactment date to implement the required changes to their operations. Smaller companies were allowed even more time to comply.

Ironically, the July 2010 deadline for compliance coincided with the CDC's realization that the *Salmonella* Enteritidis outbreak was linked to eggs.

On reviewing Quality Egg's records during the course of its extensive investigation, the FDA learned that the management had known since at least 2008 that its environment was heavily contaminated with *Salmonella*, had falsified its records, and had lied both to outside auditors and to corporate customers regarding the company's sanitation and food safety practices.[1,9]

Under the fractured US food regulatory system, responsibility for grading and inspecting shell eggs rests with the USDA. On at least two occasions in 2010, the USDA inspector responsible for Quality Egg had 'red-tagged' eggs that did not meet government standards. Ordinarily, red-tagged eggs would be diverted to egg-cracking plants for processing into pasteurized egg products for commercial use. On both occasions, a company employee bribed the inspector to release the shell eggs into retail distribution, where the eggs would command a higher price, instead of requiring that they be sent to a cracking facility.[10]

Several federal charges were laid against the company, its owners and one of its employees in the aftermath of the investigation.

On September 12, 2012, Tony Wasmund, formerly an employee of Quality Egg, pled guilty to conspiracy to bribe a public official, to selling restricted eggs with intent to defraud, and to introducing misbranded food into interstate commerce with intent to defraud and mislead.[11]
