# From Farm Gate to Dinner Plate

# TAINTED

FIFTY YEARS OF

**FOOD SAFETY FAILURES** 

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# Abbreviations & Acronyms

# **Agencies and Countries**

American Dietetic Association
US Centers for Disease Control and Prevention
California Department of Public Health
Canadian Food Inspection Agency
US Environmental Protection Agency
European Union
Food and Agriculture Organization of the United Nations
US Food and Drug Administration
Food Safety and Inspection Service, US Department of Agriculture
US Government Accountability Office
Georgia Department of Agriculture
Health Protection Branch, Health and Welfare Canada

MDA Minnesota Department of Agriculture

MDH Minnesota Department of Health

**MOE** Ontario Ministry of the Environment

MOSPL Microbial Outbreaks and Special Projects Laboratory

(within USDA)

**NACMCF** National Advisory Committee on Microbiological Criteria

for Foods (within USDA)

NASA US National Aeronautics and Space Administration

**NFPA** National Food Processors Association

**NIH** US National Institutes of Health

NRC US National Research Council

OIG Office of Inspector General

**PUC** Public Utilities Commission (Walkerton, Ontario,

Canada)

UK United Kingdom

**US or USA** United States of America

USDA US Department of Agriculture

WHO World Health Organization

WSDA Washington State Department of Agriculture

#### 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* 

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 return 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.

Multiple pairs of eyes are essential in the copy-editing and proofreading phases of a book's production, especially for a fact-packed non-fiction. 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 an 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.

I am grateful to the various public service employees in federal and state agencies across the United States for fulfilling a multitude of Freedom of Information Act requests.

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

By the time *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.

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 into a field of spinach one mile away. That outbreak was responsible for 205 illnesses and three deaths.

I realized that I couldn't remain on the sidelines while the problems I had written about in *Old Habits* were still very much alive.

Thus began the *eFoodAlert* blog.

I have been reporting on food-safety issues—on *eFoodAlert* and elsewhere—for almost thirteen years (with time off in 2013 and 2014 to jump-start my fiction writing), but my personal 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 Quebec Region microbiology group.

The Regent Chocolate *Salmonella* outbreak took place while I was working in Winnipeg, and the investigation into the source of repeated contamination of milk-powder production plants with *Salmonella* was carried out while I was in Montreal. Many of the details included in the descriptions 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 is based on first-hand information. I was the consultant hired by the company to determine the source of their ongoing, post-process contamination problem.

In 2003, I wrote a series of articles on food safety for the *Del Mar Times*, a weekly newspaper. Some of the information and anecdotes that appeared in those articles are scattered through this book. Notably, the story of Kevin Kowalcyk and portions of the discussion of the BARF (raw food) diet for companion animals first appeared in those *Del Mar Times* articles. The story about Blitz is shared with kind permission of his owner.

When ASM Press ceded back 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. It occurred to me that, with some revision and updating, this book had a story to tell to the general public.

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 replaced with more current material. I deleted two of the original chapters, added two new ones, simplified most of the technical explanations, and removed the all of the charts, tables and graphs.

In writing both *Old Habits* and *TAINTED*, I have drawn upon scientific literature reports, news stories, material obtained from

government agencies in response to Freedom of Information Act requests, and my own personal experiences. Readers who are interested in the sources of my information can consult the detailed list of references contained in Appendix B. Website addresses cited in Appendix B were verified on the dates shown. Given the ephemeral nature of the Internet, these are subject to change.

What is not—and never should be—subject to change is the responsibility of food producers and processors to put food safety 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 food companies. Yet these choices are made time and again—not just by small food processors, but also by major, multinational food companies.

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 many drivers will be tempted to exceed 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, 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 sometimes 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 others, I alone am responsible for the accuracy and completeness of the contents of this book, and for any opinions expressed herein.

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

PHYLLIS ENTIS

## *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 dictates.

*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 foodborne 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 before my personal food-safety credo becomes a reality.

Want to know more? Then please read on.

## 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.

"I really don't know," Martha 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 use 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!"

"There's no secret, Sweetheart," Nana replied with a chuckle. "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's 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 loaded into pans of water and baked in a 350°F [177°C] oven.

The oven heat was turned off after two hours, and the chicken was left to sit overnight in the warm oven. The kitchen workers cooked the

rest of the chicken in a steam cooker for two hours, then readjusted the temperature to the lowest setting and left the food in the warm steam 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 and 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 infected with *Salmonella*, courtesy of the chicken. Fortunately, everyone survived their ordeal.<sup>1</sup>

How could this have happened? Chicken cooked for two 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 warms 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 two-hour cooking period. Nor do we know how full the steam cooker was, or how evenly the heat was distributed through the chicken either in the oven or in 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 twenty to thirty minutes.

When conditions are right, a single *Salmonella* is able to generate more than ten million offspring in twelve 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 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 free of symptoms.

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, 200 people most likely would have been spared the agonies of a *Salmonella* infection. 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].<sup>2</sup> 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 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 and the thermostat near the top. When the oven thermostat calls for heat, the element comes on, and stays on until the thermostat senses that the set temperature has been reached. 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.

The practice of lining shelves with aluminum foil to catch drips and splashes also inhibits airflow, producing 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, and outbreaks due to errors in food handling take place with sickening regularity. The customers and the 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 its corned-beef briskets by boiling them for three hours.<sup>3</sup> 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 on March 16th, or used on March 17th to prepare sandwiches for catered events. The sandwiches were made around 11:00 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, fifteen 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 (C. perfringens), a species of bacteria known to cause food poisoning, and one 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 cook 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.<sup>4</sup> According to Mr. Georges's explanation, the food poisoning was caused by his having refrigerated the meat too soon after cooking.

Georges 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 temperature for bacterial growth 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 the illness typically

runs its course within about twenty-four hours. Nevertheless, the experience can be agonizing.

In describing her symptoms 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.'"<sup>5</sup>

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's explanation of what caused the outbreak. Clearly, the substance of the inspector's message was not delivered clearly.

We expect our health professionals to have mastered their profession and 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).<sup>6</sup> 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 the infant had contracted meningitis caused by *Cronobacter sakazakii* (*C. 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 twenty days.<sup>6</sup>

On learning of the infection, hospital personnel screened the other forty-eight 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 forty-eight infants tested, including from the baby boy who died.

Premature and underweight infants constitute 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 forty 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 infected babies had in common. They had all been tube-fed Portagen, a powdered infant formula made by Mead Johnson. But twenty-one of the forty healthy babies had also received Portagen.

The search continued.

Everything used to prepare the powdered formula for feeding came under scrutiny. Lab personnel tested the water that was used to dissolve the powder. 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, including, switching from powdered formula to a ready-to-use liquid product, limiting the use of powdered formula to certain specific situations, and cutting in half the maximum length of time for continuous tube feeding of formula from eight hours to four.

Mead Johnson eventually recalled the contaminated batch of Portagen on March 29, 2002, nearly one full year after the initial outbreak.<sup>7</sup> 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.<sup>8</sup> By 1981, the ability of *C. sakazakii* to cause fatal meningitis was confirmed by researchers at the Indiana University School of Medicine.<sup>9</sup>

In 1983, a group of Dutch researchers drew the first tentative conclusion linking the infection to infant formula.<sup>10</sup> 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).<sup>11</sup>

How common is *C. sakazakii*? A 1988 study evaluated 141 different samples of powdered formula obtained in thirty-five different countries. <sup>12</sup> The researchers found low levels of the microbe in twenty 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 eight 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.<sup>13</sup> 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 US 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 Nestlé's "Beba" powdered formula. Nestlé recalled two production lots of the formula in May 2002.<sup>14</sup>

The FDA responded to the lessons learned from the Tennessee outbreak by increasing surveillance of infant-formula manufacturers, with specific emphasis on *C. sakazakii*. The heightened awareness resulted in at least one recall, encompassing 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 became infected.<sup>15</sup>

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 maximum time to hold the reconstituted formula at room temperature from eight hours to four.<sup>16,17</sup>

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.<sup>18</sup>

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.<sup>19,20</sup>

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.<sup>21</sup>

A 2019 survey of four Chinese factories that manufactured powdered infant formula found *C. sakazakii* in forty-two samples from multiple locations in all four facilities. Some of the bacteria were recovered from designated 'clean work' areas.<sup>22</sup>

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 practice, 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.