
Navigating through Food Safety Challenges

In June 2009, Scott Tucker, co-president of Maple Leaf Farms Inc. and grandson of the company's founder, was examining the production line that pumps out high-tech, not-ready-to-eat (NRTE) stuffed chicken products. From the forming equipment, the product is breaded, par-fried, frozen, and packaged. Chicken Kiev and Chicken Cordon Bleu are two of eight NRTE stuffed chicken products sold under the Milford Valley Farms label the company produces to meet consumer demand for convenient, value-added, upscale, and flavorful entrees (Exhibit 1). They also generate healthy margins for the company.

Maple Leaf Farms' NRTE stuffed chicken products are manufactured from frozen, raw chicken procured from several of the nation's major chicken processors. Chickens naturally contain *Salmonella* bacteria. Currently, the total elimination of all live *Salmonella* cells from raw chicken is technologically infeasible without destroying the product's functional and organoleptic properties. Therefore, cooking chicken products prior to consumption is essential to ensure the food's safety.

Since Maple Leaf Farms' stuffed chicken products are par-fried, they appear cooked. To avoid mishandling by the consumer, the package labeling has undergone a number of changes over time. Following a *Salmonella* outbreak in 2006, the U.S. Department of Agriculture (USDA) issued a new policy on enhanced labeling to improve consumer comprehension, and the industry transitioned their packaging accordingly.

Unfortunately, not all consumers took note of these changes. It became obvious that members of a generation reared on ultra-convenience, accustomed to microwaving and ignoring cooking instructions, can be oblivious to details contained in the fine print, even when that fine print is bold and a half-inch tall on the package. For this reason, an industry group (Barber Foods, Maple Leaf Farms, Koch Foods, and Tyson), in cooperation with the National Chicken Council (NCC), started researching additional labeling options to improve comprehension and reduce the likelihood for product mishandling by the consumer.

The NCC/industry group performed consumer research on and agreed to nine separate packaging changes (Exhibit 2). The consumer research was clear that the new packaging would communicate the product's raw state more effectively. Recall of the word "raw" nearly doubled (42 percent with old

This case study was prepared by Kenneth McCorkle, executive vice president, Agricultural Industries, Wells Fargo Bank, as a basis for class discussion and represents the views of the author, not the university. The author would like to thank Scott Tucker, co-president of Maple Leaf Farms, for participating in this case. No part of this publication may be reproduced or transmitted in any form without written permission from Purdue University.

packaging, compared to 82 percent with new packaging), and the overall understanding of the raw product state increased by 38 percent. All primary manufacturers of NRTE stuffed chicken products that appear ready to eat (RTE) agreed to transition all package labeling by the end of 2009. Maple Leaf planned to have all Milford Valley Farms NTRE products transitioned by the end of July 2009.

Thus, Scott faced a dilemma. On one hand, he wanted to continue offering his customers these popular, innovative, convenient, flavorful, and semi-gourmet products. His consumers liked them, and they generated production and marketing synergies with the company's primary line—the Maple Leaf Farms' duck products. On the other hand, given the consumers' increasingly casual adherence to, and in some cases, ignorance of sound food safety practices, these products represented a risk to consumers who mishandle them. Risk to consumers, in turn, represented risk to the company.

Beginning in March 2006, this risk began rising, not because the products had become less safe, but because the government began re-examining its regulation of such products. The Food Safety Inspection Service (FSIS) is the public health agency of USDA responsible for ensuring that the nation's supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Over the past three-and-a-half years, the agency has taken an increasingly active role toward tightening the food safety standards for these products.

During the summer of 2009, the FSIS proposed that *Salmonella* in NRTE stuffed chicken products that appear RTE be designated as a food adulterant. If this proposal became law, these products would be subject to recall whenever the raw product tested positive for *Salmonella*. This regulation would initially apply just to stuffed, breaded NRTE chicken entrees, but was likely to open the door to further regulation of all NRTE poultry products. Consequently, major chicken processors were wary that further regulatory changes could negatively influence the production of higher-volume NRTE products, such as chicken nuggets, and ultimately, impact raw chicken production methods industry-wide. It would not apply to raw fresh poultry.

While Scott took an active role in industry efforts to favorably shape the regulation, he also recognized he must develop a strategy that would succeed regardless of the FSIS decision and resulting action. To that end, he developed a list of alternatives that would ensure success. The list included:

1. Working with chicken suppliers to further reduce the *Salmonella* levels in the raw material.
2. Exploring and developing intervention technologies to reduce or eliminate *Salmonella* from the final product.
3. Converting from a par-fried NRTE product to a cooked RTE product.
4. Exiting the par-fried NRTE stuffed chicken business altogether.

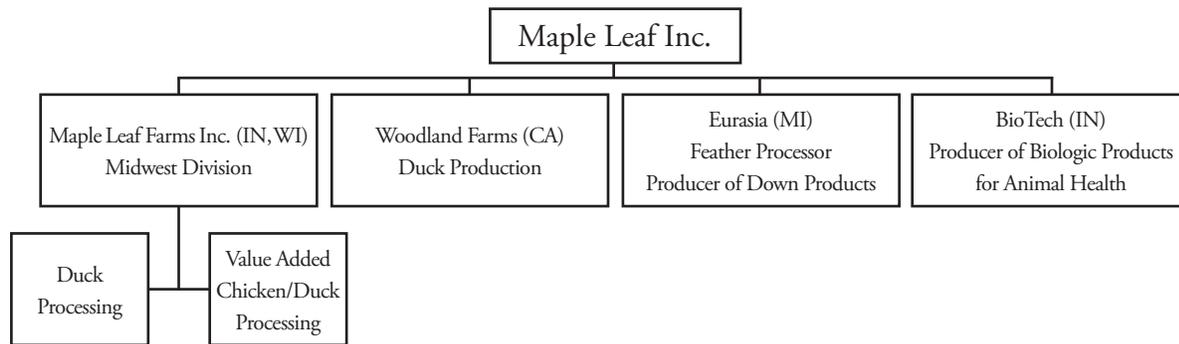
In the event he chose the fourth alternative, he considered what alternative products he might produce to fill the void.

Finally, Scott reviewed his primary business—vertically integrated production, processing, and marketing of high-quality, premium-priced duck products. Under Maple Leaf Farms' leadership, the industry was blossoming. However, managing the political process of establishing reasonable standards under which the NRTE stuffed chicken products could be safely marketed was taking

much of his time and focus. Given the strength of the Milford Valley Farms brand and the product quality, consumer acceptance, and profitability of these products, he was not ready to abandon them. However, Scott knew he must shift his time and effort to the duck business and determine how the NRTE stuffed chicken business fit into the overall company strategy.

Maple Leaf Inc.

Maple Leaf Inc. is the parent company of four operating divisions: a Midwest-based vertically integrated food production, processing, and marketing company specializing in duck and value-added poultry products; a California-based duck production company serving Asian clientele; a duck feather and down processor based in Michigan; and an animal-health products company based in Indiana.



Maple Leaf Farms Inc. Midwest Division

This division focuses primarily on duck products (80 percent frozen, 20 percent fresh) complimented by frozen chicken entrees, patties, strips, and nuggets. Sales are primarily to upscale retail and food service markets. Approximately 80 percent of company sales are duck products, the other 20 percent chicken products. Despite the lower volume of chicken-product sales, they are important to the company. The products are high value-added and high margin; they utilize available capacity; and they have an established branded market presence within the industry.

The Maple Leaf Farms Division is vertically integrated from duck genetics through value-added product marketing. Its facilities, located in Indiana and Wisconsin, include duck research and breeding operations, three hatcheries, two feed mills, company-owned grow-out farms, a duck processing plant, and a further processing plant (Serenade Foods) for value-added fresh and frozen duck and frozen chicken products.

Its duck research and breeding activities have developed world-class White Pekin duck genetics, a major strength of the company. Maple Leaf Farms Division is in the early stages of capitalizing on this strength. It has established a joint venture with a British firm to supply improved duck breeds to the European market and is exploring opportunities to set up similar relationships in China, the world's largest duck market. As one of the few primary duck breeders in the world, Maple Leaf is fully capable of providing successive generations of duck with improved performance characteristics without sacrificing competitive advantage for their own operations. Both European and Chinese duck genetics lag well behind those of Maple Leaf Farms; consequently, these markets represent significant growth opportunities.

The company has invested heavily in personnel, research, and facilities to develop optimal feed rations and growing conditions to maximize meat production. Maple Leaf produces all of its own feed requirements for both its company-owned and contracted grow-out facilities. Its contract growers consist largely of Amish farmers whose proximity to the company's facilities, work ethics, and lifestyles are well suited to raising duck.

The company's two processing facilities are physically separate and located across the street from one another. The duck slaughtering and primary processing facility transforms ducks into marketable fresh and frozen whole birds and parts, and generates front halves and other raw material for deboning and further processing at its value-added plant across the street. The value-added plant, known as Serenade Foods, converts duck meat and chicken meat (purchased from outside poultry processors) into a wide array of further processed ready-to-cook (RTC) and RTE products. Maple Leaf Farms' products are sold to large food service companies and retail customers.

Woodland Farms Division

This division, located in southern California, produces duck products primarily for the more price-competitive Asian market. Unlike the Maple Leaf Farms Division, Woodland Farms does not produce its own feed, nor does it fabricate a wide variety of products. Its primary products are fresh head-on-foot-on (HOFO) whole body duck and frozen duck.

Eurasia Division

The Eurasia division, located in Michigan, produces top-of-bed products made of duck down and feathers. It acquires feathers from the Midwest division, sanitizes the feathers, and uses them to produce pillows, comforters, and similar products. Eurasia serves three primary customer segments: business-to-business catalog customers, hospitality customers, and large retail stores. Feathers processed in excess of its primary domestic markets are exported, typically to Asia and Europe.

Biotech Division

This division is an Indiana-based company that specializes in animal health and nutrition. It produces and markets biological products (probiotics) promoting a healthy digestive tract across various animal species. It also offers toxicity testing services to protect animals from ingesting toxins.

Maple Leaf Farms was founded in 1958 by Donald Wentzel near Milford, Indiana. During its first year of operation, the company produced 280,000 ducks. In 1963, Terry Tucker, Donald's son-in-law, joined the company and led it to significant growth. Today, Terry's two sons, John and Scott Tucker, run the company as co-presidents.

The company produces 12-15 million ducks per year, approximately 60 percent of the domestic industry's production. While Maple Leaf Farms owns and manages the entire process from hatchery to processing/marketing, most of the ducks are grown on a contract basis. In the Midwest, these ducks are raised primarily by Amish farmers in the area.

The duck industry is a relatively small, niche business. Per capita consumption was rising steadily over the past decade and reached 0.45 pounds in 2006 before declining somewhat in 2007-2008, the result, in part, of higher grain and duck prices and lower chicken and pork prices. Increased consumption reflects increased health awareness (duck is low in fat); increased income growth (these

products are often consumed in higher-end restaurants); and increased availability of convenient, value-added duck products that has broadened the market to include home consumption.

Maple Leaf Farms' strengths include its family ownership, experienced management team, established, loyal customer base, marketing and distribution capabilities, vertically integrated operations with industry leadership at each level of production and distribution, the stature of its brands, and its product quality. Management believes the company maintains a substantial cost and quality advantage over its competitors as a result of its advanced genetics, science-based feed rations, and economies of scale. It also markets the industry's top-selling duck brand, Maple Leaf Farms.

Foodborne Illness in the United States

Despite their low incidence in the United States, foodborne diseases remain an important domestic public health problem. The Centers of Disease Control and Prevention (CDC) estimates that, each year, 76 million people become sick, 325,000 are hospitalized, and 5,000 die as a result of more than 250 known foodborne diseases. The three most common bacterial foodborne pathogens are *E. coli* 0157:H7, *Campylobacter*, and *Salmonella*. The CDC estimates the economic cost of these diseases (medical expenses, lost productivity, etc.) to be about \$23 billion per year.

Based on recent media coverage, foodborne illnesses seem to be more prevalent over the past several years. Cases of *E. coli* infections in spinach, lettuce, ground beef, and cookie dough; *Salmonella* infections in almonds, pistachios, peanuts, alfalfa sprouts, green onions, peppers, and chicken products; *Listeria monocytogenes* in meat products; and even *Botulism* in chili and juice products have all appeared within recent years.

While the industry has made progress during the past decade in reducing incidences of foodborne diseases, the progress has not been consistent over all pathogens; most of the progress occurred early in the decade as shown in Exhibit 3. In 2008, the estimated incidence of infections caused by *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Escherichia coli* 0157, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia* did not change significantly when compared with the preceding three years. The lack of recent progress suggests, to some, deficiencies in the current food safety system and the need to continue to develop and evaluate food safety practices as food moves from farm to table.

Part of the apparent lack of progress in reducing foodborne illness may be the result of improvements in the science of epidemiology. Today's enhanced detection methods, coordinated federal and state responses, and rapid dissemination of outbreak information facilitates clearer and more timely identification of disease patterns. More stringent quality assurance programs, including detailed HACCP programs, implemented to reduce the likelihood of foodborne diseases and improve product traceability, ironically may be contributing to a perception that these diseases are more prevalent today than in the past. Since the CDC has better tools to detect problems early and issue timely alerts, it may appear foodborne diseases are a larger problem today than before.

Another probable contributor to the increased risk of foodborne illnesses is the slew of creative new products and packaging reaching the market each year. Some of these products, such as packaged fresh vegetables and fruits, push the limits of food safety, particularly those to be consumed uncooked and reliant on proper handling throughout the supply chain.

Regardless of whether foodborne illnesses are truly on the rise or the public is just more aware of and less tolerant of food contaminations, the current administration is determined to more closely regulate the food industry with respect to food safety. Furthermore, as the ability to trace products through the supply chain improves, the liability for processing/handling errors is increasingly being assigned to the responsible party, creating a powerful incentive for all parties to improve.

Because of widespread media coverage of each outbreak incident, today's consumers may be more aware of, but less skillful at, avoiding foodborne illnesses. Home economics, once a course required for high school graduation, has gone the way of physical education and wood shop. Consumer cooking skills have declined as the time involved in food preparation has declined. The majority of consumers have lost their connection with the food supply, increasingly relying on quickly prepared, microwaveable foods at home and fast foods on the road. At the same time, consumers have zero tolerance for foodborne diseases.

Not surprisingly, the government has stepped in to fill the role once occupied by common sense, protecting an increasingly naïve consumer. The government's approach has been to tighten regulations; thus, the food manufacturer assumes more responsibility to protect even the most careless consumer.

Maple Leaf Farms NRTE Stuffed Chicken Entrée History

The not-ready-to-eat (NRTE) entrée category has been part of the American menu since its introduction in the mid-1970s. For its first 50 years on the market, the product was considered safe by manufacturers, consumers, and regulators. The product line has been popular among convenience-oriented consumers, and sales growth for these products has been brisk.

However, in March 2006, the USDA ordered its first NRTE stuffed chicken entrée recall (Exhibit 4). The basis for the USDA recall was two outbreaks attributable to consumers using a microwave, rather than an oven, to cook the product. The recall was not based on the fact that the product contained *Salmonella* (because it is widely accepted that there is a high prevalence of *Salmonella* in raw chicken, it is currently not considered an adulterant), but rather that these par-fried products appear to be cooked and ready to eat, thus posing a potential food safety hazard. The USDA's Food Safety Inspection Service concurrently issued a new policy for labeling these products to reduce the risk of consumer mishandling. Two producers of the product, Koch Foods and Maple Leaf Farms, were initially implicated in the recall. A third producer, Barber Foods, was later implicated. Maple Leaf's cost to remove all product distributed to Wal-Mart alone totaled \$10 million.

Within one week of the recall, Wal-Mart decided to remove all NRTE stuffed chicken products that appeared to be ready-to-eat from its shelves and informed the product manufacturers that only fully cooked entrées would be restocked on their shelves. Maple Leaf and others quickly responded by developing and introducing fully cooked stuffed replacement entrées. Market acceptance, however, was poor, and the product line eventually failed, sending a clear message to producers that consumers wanted ready-to-cook, not ready-to-eat, products.

Hoping to avoid further costly disruptions, the poultry industry worked with USDA regulators to make adjustments to manufacturing processes that would decrease the likelihood of future problems.

These changes appeared sufficient as no instances of *Salmonellosis* outbreaks attributable to NRTE stuffed chicken entrées were reported from July 2006 through February 2008.

However, in March 2008, another *Salmonella* outbreak was reported in Minnesota (Exhibit 5). Serenade Foods was the source of the product. The relationship between manufacturers of NRTE chicken products and government regulatory agencies grew increasingly intense over the next 18 months. The recent history of the company's interaction with government officials toward solving the *Salmonella* problem in NRTE chicken products is detailed in Appendix A.

Alternatives

Scott Tucker identified four alternative strategies for dealing with the challenges in the NRTE category.

Labeling

The poultry industry had been making the case that the food safety challenge in NRTE stuffed chicken products was a labeling, rather than an adulterant, issue. The industry had proposed more prominent and definitive labels to alert the consumer that the product is raw and needs to be cooked (Exhibit 2). By prominently labeling the chicken products as “raw” and “do not microwave,” Scott anticipated that consumers would heed the labels and properly and safely prepare the product. The responses from FSIS have been mixed, best summarized as “helpful, but not sufficient.” Scott was uncertain whether labeling alone would eventually satisfy the FSIS.

Cooking

If the FSIS issued a fiat banning the sale of NRTE chicken products in the United States, Scott's answer would be easy. Instead of par-frying the product, Maple Leaf would convert to a fully cooked product, thereby ensuring all bacteria were killed. Consumers would have a safe, nearly foolproof product. Demand might decline since the product lacked the NRTE quality, but at least no NRTE stuffed product would be on the shelf competing at a lower price point.

But, FSIS was not inclined to ban these products from the marketplace. Rather, the regulatory body defined its role as recommending to lawmakers appropriate standards and enforcing compliance with those standards once they become law. As of June 2009, FSIS was expected to label *Salmonella* an adulterant and require the NRTE products be subject to the “non-detectable quantity” *Salmonella* standard. Products failing to meet this standard would be considered adulterated and subject to recall.

Each of the four competitors marketing retail NRTE stuffed products knew this standard was unachievable. But as long as one company produces a NRTE product, the more expensive, fully cooked RTE product would be unable to effectively compete for shelf space.

Alternative technologies

Scott had experimented with a broad range of alternative technologies to develop a near *Salmonella*-free product. Irradiation, while successful at eliminating *Salmonella*, denatured the chicken's proteins, rendering it unacceptable. The relatively new technology—high-pressure pasteurization—proved somewhat effective at reducing *Salmonella* populations, but severely denatured the material and adversely affected the product's texture, moisture, and physical appearance. Chemical intervention—spraying a buffered acid rinse over the chicken's surface—showed promise, but lacked the perfection required in the proposed regulation. Clearly, any successful strategy for intervention must include the poultry suppliers.

Exit NRTE segment

Scott could exit the NRTE stuffed chicken category. This alternative would result in lost sales volume (approximately \$40 million), lost margin, and lost overhead coverage contributed by this product line. This alternative would create excess processing capacity and significantly impact the profitability of the company. Given the company's investment of capital and management time in the product line and its established brand label and widespread distribution, Scott would only select this alternative if the risks to the company became too great.

Other extruded products

Scott researched other product opportunities that would absorb the plant capacity should Maple Leaf chose to exit the NRTE chicken business. One idea was to enter the seafood industry. These products could be produced either as an extension of the company's existing branded lines or on a toll-processing basis. One advantage of the toll-processing arrangement was that this line could be curtailed as Maple Leaf's duck value-added business consumed an increasing percentage of the plant's capacity.

As Scott contemplated his options, he reflected on the situation and what he had learned thus far from the experience with NRTE stuffed products. It was clear that he, his company, and his industry must continue to proactively engage with the appropriate federal and state regulators. These individuals had perspectives and information Scott needed to understand in order to move toward an acceptable solution. Conversely, the regulators needed to better understand the technological limitations of food processing, the industry challenges in producing NRTE poultry products free from detectable *Salmonella*, and constraints in complying with regulations. Thus, there was a need for mutual education in the process.

Engaging the regulatory agencies was also important to overcome the natural skepticism of the enforcement agencies. Ultimately, the regulator is responsible for protecting the consumer, not the producer. In this role, the regulator will err on the side of the consumer.

Scott also recognized the importance of anticipating what the issues would be and addressing those issues preemptively. He admitted that the NRTE stuffed chicken sector was currently behind in adopting appropriate procedures and packaging and must quickly catch up.

Scott was producing a product line on which he must guarantee safety, not just when it leaves the plant, but throughout the supply chain to the point of consumption. However, the same factor that created the demand for these convenience products—a consumer base that had largely lost cooking skills—also contributed to the increased risk of mishandling and illness. He had to determine how best to manage this risk.

Discussion Questions

1. Where does the food manufacturer's responsibility end and the consumer's responsibility begin in regard to food safety?
2. Should the government ban par-fried poultry products? If so, why? If not, why not?
3. Which option under consideration, if any, do you support and why?
4. What lessons can you glean from Scott's experiences for dealing effectively with government regulatory agencies?

Exhibit 1

COOKING INSTRUCTIONS

CONTAINS UNCOOKED POULTRY. For safety, must be cooked thoroughly. Always cook to an internal temperature of 165°F as measured by use of a thermometer, check in several places for final temperature reading. This product is not intended for use in microwave or toaster oven.

Conventional Oven

Cook from frozen. Remove breast from protective pouch. Place in a shallow oven safe dish. Place on the center rack in the middle of the oven. Bake in a 375°F preheated oven for 35 minutes. Cook to an internal temperature of 165°F. Let stand for 2 minutes before serving.



SAFE HANDLING INSTRUCTIONS

THIS PRODUCT WAS PREPARED FROM INSPECTED AND PASSED MEAT AND/OR POULTRY. SOME FOOD PRODUCTS MAY CONTAIN BACTERIA THAT COULD CAUSE ILLNESS IF THE PRODUCT IS MISHANDLED OR COOKED IMPROPERLY. FOR YOUR PROTECTION, FOLLOW THESE SAFE HANDLING INSTRUCTIONS.

- KEEP REFRIGERATED OR FROZEN. THAW IN REFRIGERATOR OR MICROWAVE.
- KEEP RAW MEAT AND POULTRY SEPARATE FROM OTHER FOODS. WASH WORKING SURFACES (INCLUDING CUTTING BOARDS), UTENSILS, AND HANDS AFTER TOUCHING RAW MEAT OR POULTRY.
- COOK THOROUGHLY.
- KEEP HOT FOODS HOT. REFRIGERATE LEFTOVERS IMMEDIATELY OR DISCARD.

Part # 307675



UNCOOKED. For food safety, cook to a minimum internal temperature of 165°F measured by a thermometer.

Nutrition Facts

Serv Size 1 Container (170g)
Servings 1
Calories 340
Fat Cal 170

Amount/Serving	%DV*	Amount/Serving	%DV*
Total Fat 19g	29%	Total Carb 17g	6%
Sat Fat 6g	30%	Fiber 2g	8%
Trans Fat 0g		Sugars 2g	
Cholest 45mg	15%	Protein 24g	
Sodium 870mg	36%		

* Percent Daily Values (DV) are based on a 2,000 calorie diet. Vitamin A 2% • Vitamin C 0% • Calcium 4% • Iron 4%

INGREDIENTS: BONELESS BREAST OF CHICKEN WITH RIB MEAT (CONTAINING UP TO 14% OF A SOLUTION OF WATER, SALT, SODIUM PHOSPHATE, DRY CHICKEN STOCK, SUGAR, ONION POWDER, GARLIC POWDER, FLAVORING), WATER, BLEACHED WHEAT FLOUR, SMOKED HAM WITH NATURAL JUICES CHOPPED AND FORMED (HAM, WATER, SALT, DEXTROSE, SODIUM PHOSPHATES, SODIUM ERYTHORBATE, NATURAL FLAVORING, SODIUM NITRITE), PASTEURIZED PROCESS SWISS CHEESE (SWISS CHEESE (CULTURED MILK, SALT, ENZYMES), WATER, SODIUM PHOSPHATE, SALT, MAY CONTAIN: CREAM, MILKFAT, SORBIC ACID (PRESERVATIVE), ENZYME MODIFIED CHEESE (CULTURED MILK, WATER, CREAM, SODIUM CITRATE, SALT, SODIUM PHOSPHATE, ENZYMES, SORBIC ACID (PRESERVATIVE), ACETIC ACID), CONTAINS 2% OR LESS OF MODIFIED FOOD STARCH, CORN FLOUR, DEXTROSE, SALT, PAPRIKA, PALM OIL, SPICES, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE, SODIUM ALUMINIUM PHOSPHATE), NATURAL FLAVORS, NONFAT MILK, METHYLCELLULOSE, SOYBEAN OIL, PRE-BROWNED IN SOYBEAN OIL.
ALLERGEN INFORMATION: CONTAINS WHEAT, MILK.

MAPLE LEAF FARMS, INC. • P.O. BOX 308, MILFORD, IN 46542-0308, U.S.A. • © 2008 Maple Leaf Farms, Inc. • 1-800-382-5546

Exhibit 3

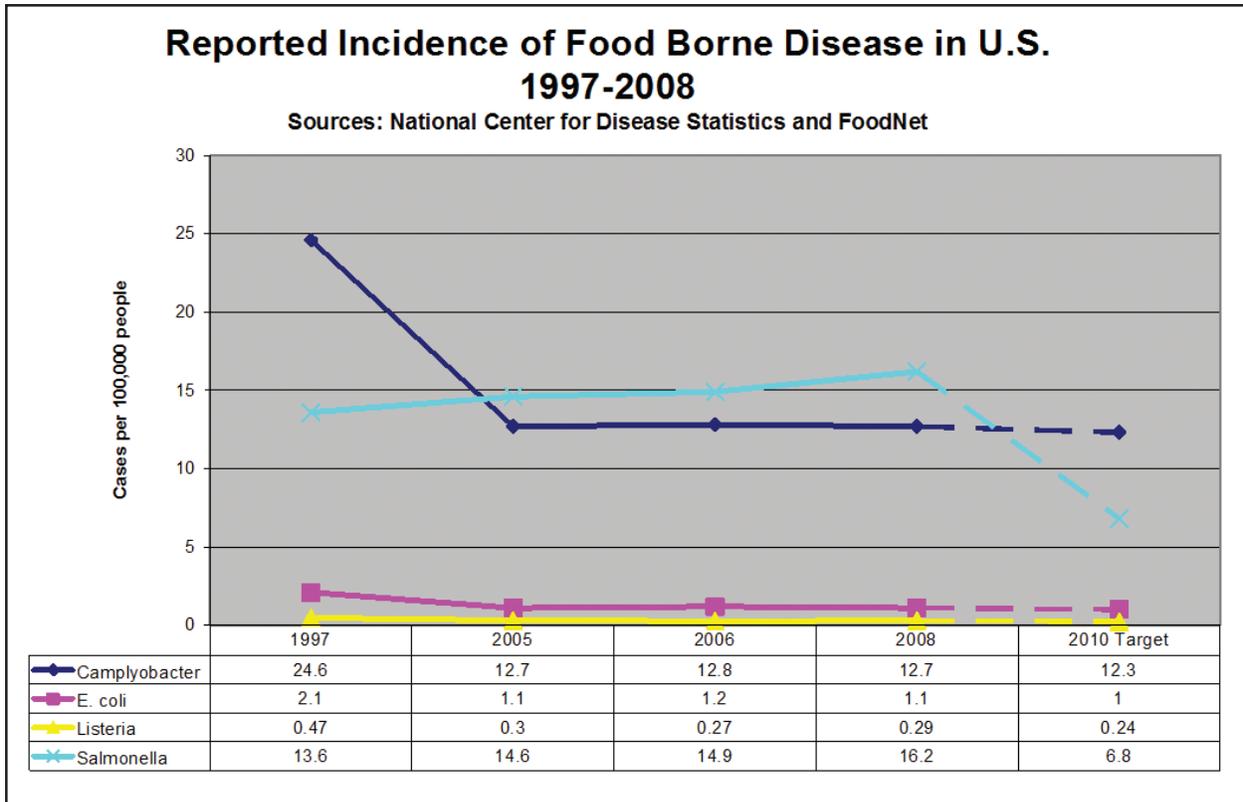


Exhibit 4

Minnesota *Salmonella* Cases Linked to Frozen Chicken Entrees

07/26/2006

Two recent outbreaks of salmonellosis in Minnesota with a total of 29 cases have been linked to frozen, pre-browned, single-serving, microwaveable stuffed chicken entrees, state health and agriculture officials said today.

These are the third and fourth outbreaks of salmonellosis in Minnesota linked to these types of products since 1998. The findings prompted the officials to urge consumers to make sure that all raw poultry products are handled carefully and cooked thoroughly, and to strongly discourage the use of the microwave to cook raw chicken products.

Investigators from the Minnesota Department of Health (MDH) and the Minnesota Department of Agriculture (MDA) determined that 26 cases of *Salmonella* infection from August 2005 through June 2006, were due to the same strain of *Salmonella* Enteritidis. “DNA fingerprinting is used in these investigations; the illness cases all had the same strain of *Salmonella*, and the same strain was found in product that customers still had in their freezers,” said Dr. Kirk Smith, supervisor of the Foodborne Disease Unit at MDH.

In March 2006, the United States Department of Agriculture (USDA) issued a limited recall in response to the identification of the outbreak. However, epidemiologists have found that new cases of illness continue to occur. Case findings indicate problems stemmed from products primarily produced by two different manufacturers, Aspen Foods of Chicago (USDA plant P-1358) and Serenade Foods of Milford, Ind. (USDA plant P-2375) and sold under a variety of brand names including store brand names.

“In addition, since April 2006, we have seen three cases of *Salmonella* Typhimurium infection with the same DNA fingerprint,” Smith said. “This strain of *Salmonella* also has been found in products obtained from the homes of the illness cases.” The products eaten by these three individuals were produced by Aspen Foods and sold under a store brand name. This outbreak prompted the USDA to issue a consumer advisory on July 3, 2006.

Salmonella is sometimes present in raw chicken, which is why it is important for consumers to follow safe food handling practices. This includes cooking all raw poultry products to an internal temperature of at least 165 degrees Fahrenheit. “The problem arises when consumers don’t realize that they are preparing a raw product,” according to MDA dairy and food inspection director Kevin Elfering.

“The frozen chicken entrees in these outbreaks are breaded, pre-browned and individually wrapped, so it’s likely most ill consumers mistakenly assumed they have been pre-cooked,” Elfering said. “Although the wrapper includes instructions to fully cook the product, some consumers might have overlooked that information and simply heated it in a microwave.”

Even though these products are labeled as microwaveable, both the MDA and the MDH strongly advise against cooking these products in the microwave. Microwaves vary in strength and tend to cook products unevenly; therefore, they are not appropriate for the primary preparation of raw meat and poultry. Additionally, the cooking instructions for many of these products may not be sufficient for killing *Salmonella*; therefore, consumers should ensure that they have fully cooked the products before eating them.

Other important food handling practices include washing your hands before and after handling raw meat, keeping raw and cooked foods separate to avoid cross-contamination, and placing cooked meat on a clean plate or platter before serving. Consumers can find more information about safe food-handling practices on the MDA Web site at <http://www.mda.state.mn.us/foodsafte.htm>.

It's important to note that because *Salmonella* is not considered an adulterant in raw poultry, no recall is required according to federal guidelines. Consumers with the products in their freezers, if they choose to use them, should cook them thoroughly, MDA and MDH officials advised.

“Salmonellosis outbreaks due to this type of product keep occurring, despite public notifications, so it is time to take more stringent action,” Elfering said. State officials have asked the U.S. Department of Agriculture to consider requiring individually wrapped, breaded, raw chicken products to include more prominent label information clearly stating they are raw products.

“USDA is in the process of requiring all manufacturers to change the labels of these products to better inform consumers and requiring companies to validate cooking instructions. However the process of approving new labels takes time, and it appears that these products will still be allowed to be marketed as ‘microwaveable.’ Therefore, MDH and MDA decided to issue this advisory in an attempt to try to prevent further illnesses,” he said.

Symptoms of salmonellosis include diarrhea, abdominal pain and cramps and fever. Symptoms usually begin within 12 to 72 hours after exposure, but can begin up to a week after exposure. *Salmonella* infections usually resolve in five to seven days, but approximately 20 percent of cases require hospitalization. In rare cases, *Salmonella* infection can lead to death, particularly in the elderly or those with weakened immune systems.

Approximately 575 to 700 cases of salmonellosis are reported each year in Minnesota.

Source: Minnesota Department of Health

Exhibit 5

Frozen chicken entrees linked to *Salmonella* outbreak

by Lorna Benson, Minnesota Public Radio

March 28, 2008

St. Paul, Minn. — Raw, frozen chicken entrees once again have been linked to a *Salmonella* outbreak in Minnesota.

The Minnesota Department of Health said two people were sickened after eating breaded, pre-browned chicken cordon bleu produced by Milford Valley Farms.

Food-borne diseases specialist Kirk Smith said one of the victims prepared the frozen entree in a microwave, even though that method of preparation is not recommended on the package.

“People are used to cooking these things in a microwave,” Smith said. “So even though they’re not being marketed as microwaveable anymore and there are not microwave cooking instructions on the label anymore some people are probably going to microwave these things. And that’s really what we want to get away from.”

Smith said entree manufacturers no longer market these types of products as microwaveable. But he says some consumers might not be reading the instructions closely enough.

“After you cook it with a microwave the product might be plenty hot enough to kill *Salmonella* in one part, but an inch away it might be cool and the *Salmonella* survives,” he said. “And also because this stuff is breaded and pre-browned it looks cooked.”

Smith said this is the fifth such *Salmonella* outbreak since 1998 linked to these types of frozen chicken products. He said the Health Department is working with the U.S. Department of Agriculture to determine whether to issue a voluntary recall on the products. Both Minnesota victims were hospitalized, but have since recovered.

Appendix A

Following the March 2008 *Salmonella* outbreak in Minnesota traced to Serenade Foods' NRTE chicken products, the FSIS conducted a full review to determine the problem's scope. The investigation concluded that the company's HACCP systems and processes were sufficient and being followed and that the company was "doing everything right and more." In a subsequent meeting with the company, the FSIS made no recommendations for process or product changes, but suggested the agency may need to address policy "through the regulatory process."

In June 2008, Maple Leaf Farms launched a new product formulation converting to 100 percent frozen chicken that, among other things, helped to lower the microbial load in the chicken raw materials. In addition, the company increased the moisture content of the product, which resulted in higher finished product temperatures when it was cooked according to the instructions. Both changes reduced the food safety risk with the product.

In October 2008, a second *Salmonella* case in Minnesota was traced to Maple Leaf and two other manufacturers (Barber Foods and Tyson Foods) NRTE stuffed chicken products. The FSIS did not issue a recall. The Maple Leaf product implicated was produced in early 2008, before the company's formulation changes in June. However, the FSIS and the Minnesota Department of Health both expressed concern about the product's history, and the FSIS again indicated possible policy changes in the future.

In November 2008, the FSIS conducted an extensive Food Safety Audit of Maple Leaf's Serenade plant, taking hundreds of samples. While these samples produced no positives for *Salmonella*, FSIS, nevertheless, issued the company a Notice of Intended Enforcement (NOIE) on November 21, 2008. Within five days, the company responded with a multi-faceted approach to resolve the issues raised in the NOIE.

Communication between the company and FSIS over the next month confirmed the FSIS was satisfied with the company's corrective action plan, and no major concerns were noted by FSIS.

But on December 23, the FSIS moved suddenly, unexpectedly, and without forewarning, indicating it had issues with company policies and procedures. The agency issued a Notice of Suspension noting "failure to sufficiently assess the foodborne outbreak data associated with your raw stuffed chicken breast entrées." In the notice, the FSIS stated that:

- It was not satisfied with the company's decision to use current FSIS *Salmonella* Performance Standards as a baseline for the products performance.
- The company should incorporate the "adverse public health data" into its decision-making process and classify *Salmonella* as a "food safety hazard" in its raw poultry products.
- The agency wanted "non-detectable levels of *Salmonella* in the company's raw products."

This Notice of Suspension closed down the plant for two production days until an Abeyance of Suspension agreement could be worked out with the agency. Under terms of the agreement, the

company could operate unless the FSIS detected something they found unsatisfactory; the company would work cooperatively with FSIS to achieve significant reduction in *Salmonella* in its chicken entrée products; the company would source chicken only from chicken suppliers meeting the highest *Salmonella* performance standards (Category 1 suppliers); the company would investigate the availability of all other raw materials meeting low-level *Salmonella* standards; and the company would implement additional measures in cooperation with the agency.

On January 6, 2009, Scott and his team took their plan for lifting the Notice of Suspension to FSIS in Washington, DC. Their 11-point approach called for reducing, but not eliminating *Salmonella* from the company's process. The plan was rejected, and FSIS's position remained that the company's operations must achieve "undetectable levels of *Salmonella*." The company rebutted that this was an unachievable standard, that this expectation was not supported by FSIS's own policy or regulations, and that Maple Leaf was being treated differently than the rest of the NRTE stuffed chicken category.

FSIS responded that it planned to issue a policy notice covering the product category and that all producers in the category would receive food safety audits by the end of January. Those that could not support non-detectible processes with their HACCP plans would be issued Notices of Intended Enforcement and be subject to suspension if they did not respond appropriately.

Two days later, Maple Leaf notified FSIS that it was taking actions to significantly reduce *Salmonella* in their NRTE stuffed chicken products. These actions included:

- continuing its exclusion of all Category 2 and Category 3 chicken providers (those with *Salmonella* detectible in more than 10 percent of their samples), and
- focusing resources on finding raw material suppliers and technologies capable of achieving this new objective.

Two weeks later, the FSIS announced that it intended to require all stuffed, ready-to-cook (raw) chicken breasts that appear to be cooked (par-fried) to be free of *Salmonella* ("non-detectable levels") in 2009. The FSIS did not, however, meet its deadline of issuing food safety audits to all producers by the end of January. But, this announcement brought the four major players (Tyson, Koch, Barber, and Maple Leaf) to the table for discussion.

On February 20, 2009, industry representatives of the four major processors met with FSIS in Washington, DC, to share all the research to date in controlling the *Salmonella* risk within the category. They also shared the most recent findings on the industry's efforts to intervene at the supplier level, which concluded that there were no immediate solutions available to the industry to completely eliminate *Salmonella* from the supply chain or from the final processing steps. All parties agreed that zero tolerance within the category was technically unattainable within a short time frame, but vowed to continue to cooperate with FSIS to address the problem through continuous improvement efforts, supported by science and based on practical, achievable targets for improvement. FSIS acknowledged during the meeting that *Salmonella* cannot be eliminated from the product.

The industry group requested that FSIS follow normal rule-making procedures defined in the Administrative Procedures Act (APA) to support this significant change in policy. Under the APA,

agencies must publish all proposed new regulations in the Federal Register at least 30 days before they take effect, and they must provide a way for interested parties to comment, offer amendments, or to object to the regulation. Some regulations require only publication (“Policy Notice”) and an opportunity for comments to become effective. Others require publication and one or more formal public hearings. The enabling legislation states which process is to be used in creating the regulations. Regulations requiring hearings can take several months to become final. The FSIS was non committal to this industry request.

From this meeting, the industry group concluded the following:

- FSIS was resolute in their position and planned to proceed with a standard unattainable for the category.
- FSIS planned to issue a notice within weeks expecting the category to reach zero tolerance during 2009.
- The industry felt FSIS should use the approved APA rule-making process that allows for public hearings, scientific input, and a reasonable implementation time frame.
- The industry was not attempting to avoid the issue; it desired and was committed to the improvement of the safety of its product; but the process should be done using common sense that is well supported and meaningful.

One week later, Scott and his team met with the district and local FSIS to provide an update on the company’s progress, to request that the company’s Suspension in Abeyance status be eliminated, and to request its normal inspection status be restored. Included in the company’s report was an update on its progress in building relationships with chicken suppliers dedicated to providing product with minimal *Salmonella* loads and research results for potential intervention processes (high-pressure pasteurization, irradiation, chemical treatments, etc.) applied at various stages of processing. While Maple Leaf was procuring only from those suppliers with the best *Salmonella* rating (Category 1 suppliers), these suppliers were currently unable to implement downstream intervention procedures within their plants.

The intervention processes Maple Leaf evaluated were generally unsatisfactory—no process was both 100 percent effective and non-detrimental to the functional or organoleptic properties of the product. However, one intervention process did show promise—buffered acids applied during the batch blending process yielded the most effective reduction. On the basis of this success, the company submitted an intervention of sulfuric acid and sodium sulfate as a processing aid for FSIS approval. Approval was granted on March 9. Maple Leaf was the first processor to use this process. An efficacy study was performed by a local university that confirmed the intervention could reduce the microbial load of the product by as much as 50 percent. As a result, Maple Leaf implemented this intervention for all NRTE stuffed chicken production.

During the meeting with the district FSIS, Scott and his team presented a detailed action plan to support his case for lifting the Suspension in Abeyance order. It included details on improvements in raw material risk assessment and environmental controls. He also advised FSIS that it is premature

to identify *Salmonella* as a hazard in the company's HACCP plan as it continues to be infeasible to produce this product free from *Salmonella*. Future changes in the company's HACCP plan would be driven by results from its ongoing intervention research and the review of upcoming FSIS policy.

On March 9, the district FSIS responded to the company's request to eliminate the Suspension in Abeyance status. FSIS identified three areas it would require to grant the company normal inspection status. Each was required to support the company's conclusions that *Salmonella* was not a hazard in the company's food system.

- Non-chicken ingredients Certification of Analysis (COA) needed to be supported with vendor sampling protocol.
- Chicken purchasing specifications (Category 1) needed to be supported with a letter of guarantee from producers.
- The company needed to implement a validated intervention (acidifier) into the process.

Meanwhile, the industry was continuing to deal with the FSIS at the national level. On March 12, industry representatives of the four major processors, along with representatives of industry associations and their attorneys met with FSIS policy heads in Washington, DC. Their goal was to express concern and objections to the agency's potential proposal to treat *Salmonella* as an adulterant in raw poultry products. The ramifications of such a policy change would be that any poultry containing *Salmonella* would be subject to recall.

Key among the industry's arguments was that labeling options had not been exhausted—that the problem was essentially a labeling and consumer education issue. Standardized labeling changes had been proposed to FSIS in December 2008. The industry group presented labeling ideas and alternatives for the next generation of labels developed by the industry.

Further, the industry group argued that such an abrupt policy change would have major ramifications for both the industry and FSIS. Since achieving non-detectable levels of *Salmonella* within the category was unattainable short-term, this policy change likely would trigger recalls. Consumers would develop a false sense of security with the category, potentially leading to even greater product-handling issues. Such a drastic policy change should involve careful consideration of alternatives and opportunities for meaningful public comment. And, FSIS should follow the rule-making procedures outlined in the Administrative Procedure Act.

Conclusions reached during that meeting and in subsequent discussions included:

- FSIS appeared to have softened from its hard-line, non-detectable stance, indicating they understood some of the industry's concerns.
- FSIS still felt the need to issue written guidance, but nothing was "imminent."
- FSIS considered not listing *Salmonella* as an adulterant, but this position could change with either another outbreak or a new boss.

On March 28, 2009, Minnesota reported two more cases of *Salmonellosis* traceable to improperly cooked NRTE chicken products (Exhibit 5).

On May 11-12, 2009, the district FSIS performed an onsite review of Maple Leaf's corrective actions outlined in the March 9 response to the Notice of Intended Enforcement. As of June 1, the company had not received any results from the review.

Finally, on May 21, 2009, the four major processors, along with the National Chicken Council, again met with the FSIS in Washington, DC, at which the industry presented updates on packaging, labeling, and intervention activities. At the conclusion of the meeting, the head of the FSIS policy branch addressed the group to announce that FSIS had decided to begin drafting a policy notice that would address *Salmonella* in NRTE stuffed chicken that appears ready to eat as an adulterant. This decision was influenced heavily by the March 28 outbreaks in Minnesota.

Supplemental Reading

Breaking News on Food and Beverage Development—North America Senator Feinstein introduces food safety bill with food maker focus

By *Caroline Scott-Thomas, 02-Dec-2009*

Related topics: Food safety and labeling, Meat, fish and savory ingredients

Senator Dianne Feinstein (D-Calif.) has introduced food safety legislation that would require all food producers to take responsibility for certifying that finished products are pathogen-free.

The legislation would amend the Poultry Products Inspection Act, the Federal Meat Inspection Act and the Federal Food, Drug and Cosmetic Act to prohibit the sale of any food that has not been certified as safe. It would also require manufacturers to list every cut of meat included in ground meat products, and ensure that food makers tell the consumer about all added colorings, synthetic flavorings and spices, according to a bill summary released on Monday.

Sen. Feinstein said in a statement: “Food producers must be obligated to produce food that is free of pathogens. It is the responsibility of the food producer, not the consumer, to make sure our food is safe to eat.”

The bill comes in the midst of a flurry of food safety legislation that has been introduced this year, in the wake of a multi-state *Salmonella* outbreak linked to peanut products in January. The Food Safety Enhancement Act passed a House vote in July, while a Senate variant, the Food Safety Modernization Act, has been stalled as the Senate concentrates on the debate over health care reform. The Health, Education, Labor and Pensions (HELP) Committee signed off on the bill last month, but it is unlikely to gain a hearing by the full Senate until next year.

Pathogen reduction

Nevertheless, Feinstein believes that this bill does not go far enough to plug the holes in the US food safety system, which is why she has introduced the Processed Food Safety Act. It would “*prohibit the sale of any processed poultry, meat and FDA-regulated food that has not either undergone a pathogen reduction treatment, or been certified to contain no verifiable traces of pathogens.*”

Feinstein said: “Serious reform is needed. This bill would require companies that process any kind of food, from ground beef to frozen pot pies, to test their finished products and their ingredients to make sure that they are safe to eat and pathogen free.”

She claims that this will reduce the presence of food pathogens and enable consumers to make better-informed decisions about which foods they choose to eat.

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