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NATIONAL CENTER FOR
FOOD PROTECTION AND DEFENSE
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Castleberry's: 2007 Botulism Recall A Case Study by The Food Industry Center

August 2008



This case summarizes the available information on the 2007 Castleberry's recall and food recalls in general, and raises questions prompted by a recall of this magnitude. A massive, nationwide recall of Castleberry's canned food due to botulism in the summer of 2007 illustrates the complexity of the food industry. Product from a single production line at a single plant, packed under 90 labels (the company's own store brands and foodservice), spurred a recall of tens of millions of cans of food. While every recall is important and unique, the breadth of the Castleberry's Food Company recall and the severe consequences from botulism lend themselves to this exemplary case study.

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Castleberry's: 2007 Botulism Recall

Introduction

In the first weeks of July 2007, state health officials in Texas and Indiana reported suspected cases of botulism, a dangerous foodborne illness, to national health officials. On July 18, Castleberry's announced that some of its products were possibly contaminated. On July 21, Castleberry's expanded the list of suspected products and recalled tens of millions of cans of food. Between July 18 and July 21, and through three subsequent updates, distributors, grocers large and small, government officials and consumers struggled to keep up with what exactly was being recalled and how to dispose of the potentially very dangerous product. Eight people were sickened as a result, according to federal officials. Another died, and though federal officials have not linked the man's death to the Castleberry's recall, his estate claims Castleberry's Austex chili was to blame.

Castleberry's History



Castleberry's Food Company was founded in Augusta, GA on the popularity of barbecued pork and beef recipes of Clement Lamar Castleberry.¹ By 1922, he was preparing barbecue for crowds as large as 12,000. In 1926, his son, Clement Stewart Castleberry, decided to can his father's barbecue hash and Brunswick stew. Castleberry's Product Company was founded. Today, two sites sit next to each other in Augusta: a 230,000-square-foot facility on 22 acres that processes canned and frozen products and a 25,000-square-foot facility that processes fresh vegetables.

Castleberry's was acquired in January 2005 by Connors Bros. Income Fund, a Toronto-based fund intended to generate stable monthly income for its unit-holders. Connors is majority owner of Clover Leaf Seafoods and Bumble Bee Foods. Castleberry's is a subsidiary of Bumble Bee Foods, with corporate headquarters in San Diego. Bumble Bee said Castleberry's generated revenues of \$135.4 million and earnings of \$12.1 million before interest, income taxes, debt and amortization for the 12 months ending on Oct. 17, 2004.²

	Year established	2008 employee count	2008 estimated sales
Castleberry's	1926	420	\$91.7 million
Bumble Bee	1899	4,000	\$444.6 million

Source: 2008 Dun & Bradstreet Million Dollar Database and Bumble Bee Foods Company

¹ Castleberry's Food Company <http://www.castleberrys.com/corp_history.asp>

² Bumble Bee Foods Company press release, Dec. 22, 2004
<<http://www.bumblebee.com/PressRoom/Article9.aspx>>

Connors Bros. and Bumble Bee

Connors, one of Canada's oldest food producers, began as a small canner in Blacks Harbour, New Brunswick, in 1893, and grew to become North America's largest producer of canned sardines by the time it was acquired by George Weston Limited (one of North America's largest food processing and distribution groups) in 1967.³ George Weston Limited, often referred to as "Weston," is a Canadian public company founded in 1882. Sales in 2007 were Canadian \$32.8 billion. Weston has two reportable operating segments: Weston Foods and Loblaw Companies Limited ("Loblaw"). Weston Foods is primarily engaged in the baking and dairy industries within North America. Loblaw is Canada's largest food distributor and a leading provider of general merchandise, drugstore and financial products and services.

Connors Bros. Income Fund (CBF.UN)⁴ was formed in late 2001 to facilitate the sale of Weston's seafood business. Subsequently, when Connors acquired Bumble Bee Foods (itself in existence since 1899) in 2004, Connors became North America's largest branded seafood business. In 2005, Connors bought Castleberry's. Problems started then, plant general manager James Watts told FDA investigators after the botulism outbreak. The company "lost its identity and so did the employees."⁵ While the goal of all business is making money, any change in ownership raises questions about changes in procedures, about how an individual company is making profits and whether it might be making those profits at the expense of quality. Significant changes in corporate ownership and operations preceded the recall:

What is a Canadian income fund?

An income fund is intended to generate stable income rather than capital appreciation; it is an individual equity investment. Most trusts generate cash by producing a product or service, selling it and using the proceeds to cover all expenses. What's left after expenses goes to the unit-holders. A trust's success depends on plenty of cash remaining after expenses to generate monthly or quarterly distributions to unit-holders.

Absent the tax breaks, there would be no point to income trusts; the corporate setup could be retained to pass dividends on common shares to the investors. But Canada's double taxation rules — taxing first the corporation's profits, then taxing the dividends in the hands of investors — make the income-trust setup appealing. An income trust maximizes the value to the investor by eliminating, or significantly reducing, the corporate tax hit and boosting the payout to the unitholder. After-tax yield in these trusts can be double to quadruple the yields provided by preferred shares (though unlike preferred shares, income trusts do not guarantee a fixed payout).

Source: Sheldon Gordon,
"Canadian Income Funds"

March 2000: Connors acquires Stinson Seafood of Prospect Harbor, Maine. Stinson's 25 percent share of the U.S. branded canned sardine market almost doubles Connors' U.S. market share.

³ Connors Bros. Income Fund <<http://www.connors.ca/>> and Bumble Bee Foods <<http://www.bumblebee.com/>>

⁴ http://www.weston.ca/en/abt_corprof.html

⁵ USA Today, "Management Problems Cited in Botulism Case," June 30, 2008

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April 2004: Connors combines with Bumble Bee Foods (formerly Bumble Bee Seafoods) and Clover Leaf Seafoods and their respective subsidiary entities. Bumble Bee originated in 1899 and had expanded over the past 100 years to become the leading branded full-line canned seafood company in North America.

December 2004: Connors announces that the sardine plant in Grand Manan, New Brunswick, will not reopen and production will be absorbed by the sardine plant in Blacks Harbour, New Brunswick.

January 2005: Connors subsidiary Bumble Bee Foods acquires Castleberry's/Snow's and assets of Sara Lee Shelf-Stable Meats business.

May 2005: Connors closes sardine plant in Bath, Maine.

May 2005: Connors subsidiary Clover Leaf Seafoods sells substantially all of the assets of the Brunswick brand in Australia and New Zealand to So Natural Foods of Australia for \$8.6 million.

Later in May 2005: Connors subsidiary Clover Leaf Seafoods sells its can-making facility in Blacks Harbour, New Brunswick, for \$9.9 million.

June 2005: Connors closes a plant in Athens, AL, integrating the canned chicken broth, chunked chicken, chicken and dumplings and pouched products produced at the facility into Castleberry's production facility in Augusta, GA.

October 2005: Connors sells the Athens, AL plant for \$1.2 million.

July 2007: Castleberry's recall.

**Connors Bros. Income Fund
closing unit price by date:**

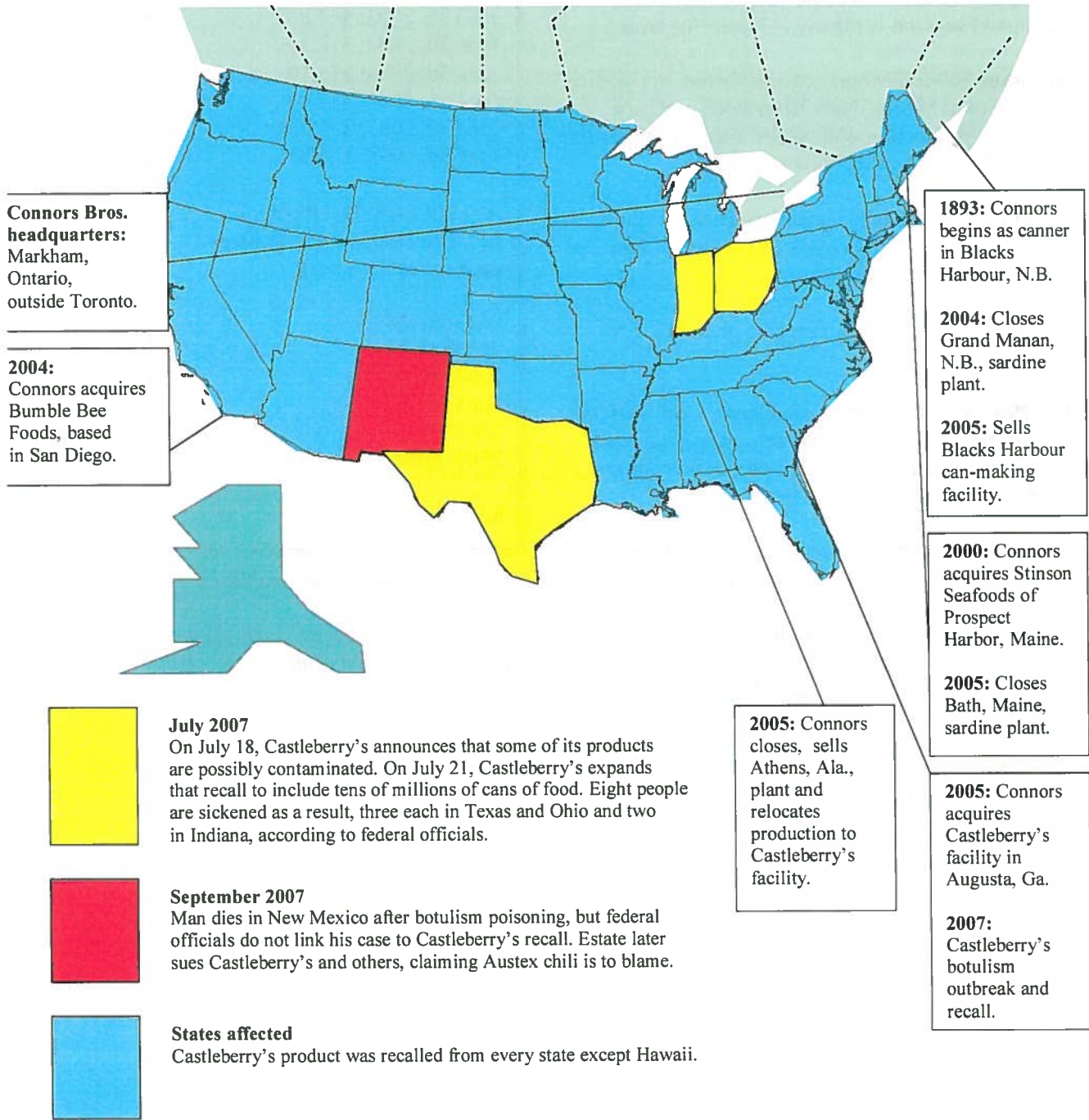
June 30, 2002: \$12.00
June 30, 2003: \$14.80
June 30, 2004: \$16.50
June 30, 2005: \$15.10
June 30, 2006: \$11.60
June 30, 2007: \$11.30
June 30, 2008: \$ 6.85

**Annual cash distributions
per unit (paid to unitholders
on a monthly basis):**

2002: \$1.20
2003: \$1.20
2004: \$1.40
2005: \$1.49
2006: \$1.35
2007: \$0.90

Source: Connors

Connors Bros.' Operations and Castleberry's 2007 Recall



Castleberry's Place in the Food Supply Chain

Castleberry's, like many companies, manufactures and distributes under its own brand, such as: Castleberry's Hot Dog Chili Sauce, Castleberry's Onion Hot Dog Chili Sauce, Castleberry's Brunswick Stew Chicken & Beef, Castleberry's Barbecue Pork, etc. The company also "packs" for other companies, a practice called co-packing.

Co-packing covers a wide range of services, from packaging finished product shipped in bulk, to all of the product development, processing and marketing associated with any consumer food product. The label on food products tells who is distributing the product, not who has produced the product and where. The distributor may operate the production facility or may not. Many producers of branded products produce for other companies, (co-pack) in all distribution channels (retail food brands, foodservice and commercial foods), or sometimes only in channels in which they do not compete with their own brand.

In addition to branded lines and private label, or house brands, there is another category: packer labels. Packer labels are products that are manufactured and minimally marketed; they are made available to retailers looking for a product they can market in their stores and usually is not available at stores with whom they compete, yet is not a store-brand exclusive private label. Castleberry's product was distributed in all of these categories.

Food processing is similar to other manufacturing processes. Efficiency and profitability is achieved from operating facilities at minimum average cost and purchasing inputs, both food stocks and packaging, in the largest and most advantageous quantities. Therefore, there is a tendency for packers to want to pack as much product as they can and for retailers and others to seek out a packer, rather than operate their own facilities. Price is a factor in this decision process. Lower prices are usually associated with lower-quality product; however, food safety and adherence to good manufacturing processes are expected in any case.

Supply channel maps for retail food stores, foodservice/restaurants and Castleberry's product are found in Figures 1 and 2 (pages 20 & 21 at the end of this document).

Function/Label Matrix			
	National brand	Packer label (and/or regional brand)	Private label (or house brand)
Produces the product/oversees production	Usually	Yes	Possibly
Markets the product	Yes	Minimal	Yes
Investment in product comes from	Brand image	Minimal	Retail/store image

Botulism: "Foodborne Illness with an Extra Kick"

On July 7 and July 11, 2007, public health officials in Texas and Indiana reported to the Centers for Disease Control and Prevention (CDC) four suspected cases of foodborne botulism, two in each state⁶. On July 17, federal and state food safety inspectors arrived at Castleberry's Food Company's canning facility in Augusta, GA, and found swollen cans, which can indicate *C. botulinum* toxin.⁷ (See page 22 for a glossary.) On July 18, the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) issued a news release that announced Castleberry's voluntary recall of chili and certain meat products, a total of 10 products, from the Augusta facility. Records requested by investigators were slow in coming, and were finally produced July 20, when Castleberry's faced an FDA deadline or a potential citation (Castleberry's said it supplied records as quickly as possible, given requests by several agencies).⁸ The recall was expanded to 90 products on July 21. Castleberry's recalled tens of millions of cans of meat and pet food,⁹ every product manufactured on a specific production line, and hired Carolina Supply Chain Services to help remove products from thousands of retail outlets across North America.¹⁰ The Food and Drug Administration (FDA) revised the July 21 recall on July 23 to update "best by" dates and then again on July 26 to update disposal instructions.¹¹ It was a "creeping recall" whose details kept expanding, proving confusing to organizations and consumers and making it difficult for them to take action. Castleberry's issued another news release on August 1 "urging retailers, food service operations, food banks, charitable organizations and consumers to be diligent in identifying and discarding canned products subject to Castleberry's national recall."¹²

At least eight people became severely ill after eating Castleberry's canned hot dog chili. One of the two Lubbock, Texas area children whose illness first alerted investigators to the contamination remained hospitalized and on a breathing machine more than a month after eating Castleberry's Austex Hot Dog Chili Sauce Original for lunch June 28.¹³ Their mother was also among the eight who became ill. An Indiana couple hospitalized July 9 were still hospitalized and on breathing machines nearly a month later.¹⁴ Three unrelated Ohio residents also became ill.¹⁵ In June 2008, a settlement was reached in a lawsuit brought on behalf of the Lubbock family. The amount paid was confidential, and Castleberry's denied liability under the settlement agreement.¹⁶ Another suit was filed in summer 2008 by the estate of a Bernalillo, New Mexico man who died in September 2007, after having suffered from botulism since

⁶ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Aug. 3, 2007: 767-769 <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5630a4.htm>>

⁷ USA Today, "Management Problems Cited in Botulism Case," June 30, 2008

⁸ Ibid

⁹ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Aug. 3, 2007: 767-769 <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5630a4.htm>>

¹⁰ Food and Drug Administration, "Castleberry's Updates Status of National Canned Food Recall," Aug. 1, 2007 <http://www.fda.gov/oc/po/firmrecalls/castleberry08_07.html>

¹¹ Food and Drug Administration, "FDA Expands Its Nationwide Warning About the Risk of Botulism Poisoning from Certain Castleberry's Food Products and Dog Food," July 21, 2007 (updated July 23 and July 26) <<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01670.html>>

¹² Castleberry's Food Company press release, Aug. 1, 2007 <http://www.castleberrys.com/news_pressRelease0801.asp>.

¹³ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Aug. 3, 2007: 767-769 <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5630a4.htm>>

¹⁴ Augusta Chronicle, "Augusta Facility to Drop Products," Aug. 28, 2007

¹⁵ Lubbock Avalanche-Journal, "Lubbock-Area Mother of Children Who Ate Tainted Chili Added to List," Aug. 28, 2007

¹⁶ NewsInferno.com, "Settlement Reached in Castleberry's Botulism Lawsuit," June 19, 2008 <<http://www.newsinferno.com/archives/3305>>

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July 26, 2007. Though the FDA did not connect his illness to the Castleberry's outbreak, the suit (which names Castleberry's and a local retailer) alleges the man died after eating Castleberry's Austex brand chili, which may have been on the grocery shelf after the recall.¹⁷

"We're not talking here about a bug that lands you in the bathroom for a few days with diarrhea," said Dr. David Acheson, the U.S. Food and Drug Administration's lead food safety expert. "We're talking about a toxin that puts you in the intensive care unit. This is foodborne illness with an extra kick in it, big time."¹⁸

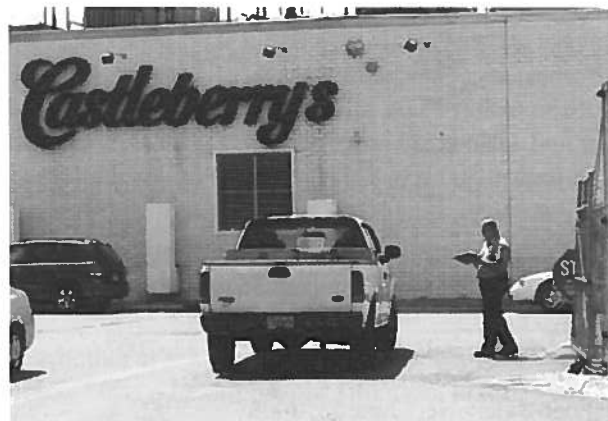
Rare and Particularly Dangerous, a Potentially Fatal Paralytic Illness

An average of 110 cases of botulism are reported each year in the United States, according to the Centers for Disease Control and Prevention. Of these, about 25 percent are foodborne, and most are associated with home-canned foods.

Symptoms, which can strike from six hours to two weeks after eating tainted food, include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth and muscle weakness. Infants with botulism appear lethargic, feed poorly, are constipated, and have a weak cry and poor muscle tone. These are all symptoms of the muscle paralysis caused by the botulinum toxin. If untreated, these symptoms may progress to cause paralysis of the arms, legs, trunk and respiratory muscles.

The respiratory failure and paralysis that occur with severe botulism may require a patient to be on a breathing machine (ventilator) for weeks, plus intensive medical and nursing care. After several weeks, the paralysis slowly improves. If diagnosed early, botulism can be treated with an antitoxin that blocks the action of toxin circulating in the blood. This can prevent patients from worsening, but recovery still takes many weeks.

Botulism can result in death due to respiratory failure. However, in the past 50 years the proportion of patients with botulism who die has fallen from about 50 percent to 8 percent. Patients who survive an episode of botulism poisoning may have fatigue and shortness of breath for years.¹⁹



¹⁷ Albuquerque Journal, "Botulism Death Leads to Lawsuit," July 4, 2008

¹⁸ CNN, "Bursting Cans Give New Urgency to Botulism Warnings," July 27, 2007
<<http://www.cnn.com/2007/HEALTH/07/26/fda.botulism.ap/index.html>>

¹⁹ Centers for Disease Control and Prevention
<http://www.cdc.gov/nczved/dfbmd/disease_listing/botulism_gi.html>

Castleberry's: 2007 Botulism Recall

Grocery industry executives cited the importance of the almost universally used and standardized UPC product codes on individual products (as opposed to UPC case codes or manufacturer production codes, which are not easily communicated between organizations) as the gateway to information because the product codes provide an accurate list of the items affected by the recall, where those items went, which distribution centers they landed at, and which shelves they landed on. Without that information, the executives said, it is difficult to track items in a food chain that is much more a web than it is a straight line.³³

Retailers indicated that they do not heed manufacturers' production lot code information when pulling recalled products. Rather, "if it is recalled, we pull it all."³⁴ Retailers work with UPC codes and case codes in their scanning/point-of-sale and ordering systems, respectively. The production code would need to be checked for every unit of a recalled item on the shelf, making for a more disruptive process at retail than simply pulling all of the recalled products. Retailers expect manufacturers to stand behind their products. Retailers will pull the product, possibly wait for the manufacturer to tell them what to do with the product and make an appropriate deduction to what they owe the manufacturer. While no supplier wants accounts receivable reduced by customers, in the case of a recall, most manufacturers look to work as quickly as possible to "return things to normal."

Tracking down the products was difficult enough. Disposing of them presented its own set of problems. Once a product has been recalled, one of the first questions is, "How do we make sure that it does not get back into the marketplace, and how do we dispose of it safely and efficiently?" For canned, long-life and shelf-stable products like the ones produced by Castleberry's, a can may look OK, yet not be. "We just don't throw it away, because it's a safety risk, and someone may eat out of a dumpster," said spokeswoman Stacie Behler of Meijer, a chain based in Grand Rapids, Mich.³⁵ A typical practice is to mix charcoal into a contaminated product so that the product doesn't make its way back into commerce.

In the Castleberry's case, armed agents escorted some of the contaminated products to an incinerator. The armed escorts were provided to keep people away from trucks full of potentially explosive cans. "If there'd been an accident, (Georgia's agriculture commissioner) was concerned that Joe Blow first-responder would have just opened up the back of the truck," said Oscar Garrison, Georgia's Assistant Agriculture Commissioner. He went on to point out that whereas other foodborne illnesses caused by *Salmonella* or *Listeria* might make people sick, botulism can result in death.³⁶

Despite such vigilance, public health officials continued to find recalled products lingering on store shelves. A 2008 follow-up report by the North Carolina Department of Agriculture and Consumer Services said that the state conducted 250 site visits for recall effectiveness and found that 38 percent of all stores that handled the product still had the product on the shelf. More than 5,000 cans were embargoed or retained and removed. "These initial actions and the results were alarming to the Castleberry recall command staff, due to the serious nature of the consequences of contact or ingestion of the recalled products," the North Carolina report said.³⁷

None of the eight cases of botulism reported to the CDC came from North Carolina, which estimated its cost for the recall effort to be \$418,000. The state's follow-up report made a number of recommendations

³³ Ibid

³⁴ Ibid

³⁵ Grand Rapids Press, "Meijer Brand Chili Part of Recall," July 29, 2007

³⁶ Augusta Chronicle, "Augusta Facility to Drop Products," Aug. 28, 2007

³⁷ North Carolina Department of Agriculture and Consumer Services, "Castleberry Foods Recall After Action Report," Jan. 10, 2008

for how to deal with future incidents, many involving communication and training of responders. The report encouraged “federal partners to better coordinate the information they disseminate to the public, to reduce confusion.”³⁸

“It has been a problem getting the message out,” Lynae Granzow, an epidemiologist with the Indiana Department of Health, said soon after the recall. “We’re having a problem reaching the smaller stores.”³⁹ Two of the eight cases of botulism reported to the CDC came from Indiana.

Canned foods are often purchased on “sale or promotion.” This means that consumers are not purchasing these products for immediate consumption; rather, they are “stocking up” and will hold them for some period of time at home. Recalling products from consumers’ homes involves several forms of incentives for consumers to destroy (or return) suspect product. For canned foods, the expected shelf life is very long and contaminated cans of food could stay in homes far past the commercial recall. In the case of botulism this is a serious health hazard. There is no information about special attempts to recall canned food from homes in this case.

Castleberry’s executives declined to speak about the incident for the purposes of this case study, citing ongoing legal and other reasons.

Supply Chains for Retail Food Stores and Foodservice

Figure 1 (page 20) outlines two separate food supply chains between food manufacturers and the consumer. There are different distribution companies for each retail channel with parallel types of companies in each channel. For example, broadliners are wholesale distributors in the foodservice channel who carry a wide range of products from napkins to fresh fruit and meat. The parallel type of company in the retail food channel is the third-party wholesaler who sells a variety of products to a variety of independent and chain stores. Self-distribution retail food companies are those who belong to a retail chain such as Wal-Mart or Kroger; system distributors in the foodservice channel deliver food and service to particular foodservice chains such as McDonald’s. Specialty distributors deliver special products like fresh produce or bakery products to restaurants, usually in a local territory, and direct store delivery is used by most beverage and salty snack manufacturers in the retail food channel.

Figure 2 (page 21) adopts the general outline of food distribution to show the channels through which the Castleberry’s products were distributed. From a single production facility, the majority of distribution channels were affected.

Recalls are Common

One of Several Large Food Recalls in 2007-08

Castleberry’s recall was just one of several large recalls that made national news during May, June and July of 2007. Because of the possible presence of *E. coli* O157:H7, Davis Creek Meats and Seafood of Kalamazoo, MI, recalled more than 129,000 pounds of meat, PM Beef Holdings of Windom, MN,

³⁸ North Carolina Department of Agriculture and Consumer Services, “Castleberry Foods Recall After Action Report,” Jan. 10, 2008

³⁹ CNN, “Bursting Cans Give New Urgency to Botulism Warnings,” July 27, 2007
<<http://www.cnn.com/2007/HEALTH/07/26/fda.botulism.ap/index.html>>

recalled 117,500 pounds of beef trim products, and United Food Group of Vernon, CA, recalled more than 75,000 pounds of ground beef.

As 2007 ended, Minneapolis-based General Mills subsidiaries Totino's and Jeni's recalled thousands of cases of pizza products because pepperoni topping was suspected of being contaminated with *E. coli* O157:H7 even though no contamination was ever identified by testing the food itself. As 2008 began, Westland/Hallmark Meat Company, based in Chino, CA, recalled millions of pounds of ground beef after a video showing workers' poor treatment of sick animals raised concerns about the safety of the meat. Stores in the United States pulled cantaloupes raised in Honduras because of *Salmonella* contamination. Midway through 2008, stores pulled tomatoes because of suspected *Salmonella* Saintpaul contamination. It later turned out that tomatoes were not the vector for this foodborne outbreak that sickened at least 1,330 people in 43 states. Rather it was jalapeno and Serrano peppers grown in Mexico and served in restaurants and sold in supermarkets throughout the United States. Meanwhile the tomato industry claims it lost \$100 million during the tomato "scare."

During the past five years, there has been an average of 188 Class I food recall events each year, according to the FDA.⁴⁰ A food industry executive estimated that each recall costs a retailer about \$25 per store in labor time spent tracking down recalled product on the shelf and disposing of recalled product.⁴¹

What Exactly is a Recall? Who Issues It?

What is a Company's Role? What is the Government's Role?

A recall is a company's removal of distributed product from commerce when there is reason to believe the product is adulterated or misbranded. Two federal agencies, the FDA and the USDA, are involved in recall administration **but do not have the legal power to order a recall**, except in the case of baby formula, biological products, or devices that may present a serious hazard to health. **Recalls are almost always voluntary.**

Recalls may originate in two ways. Sometimes a company discovers on its own that there is a problem with a product and institutes its own corrective recall. Other times, a routine test by the FDA or the USDA will discover a problem and they inform the company. At that point, if the company does not start a recall process, the product may be seized via court action and the media notified. In the case of USDA-inspected companies, inspectors are withdrawn from the plant, effectively banning the product from interstate commerce. Both the FDA and the USDA can order a factory to close or refer it for criminal prosecution.

The FDA handles recalls of all food and food-related products except meat, poultry and eggs, which are handled by the USDA. If a food company institutes its own recall, it is generally under no obligation to notify the FDA, but it is strongly encouraged to do so and take advantage of the FDA's assistance. The FDA can request (but not mandate) a recall, but this is done, generally, only when public health is in danger.

In the case of the USDA, reports of an unsafe product can come from the manufacturer, routine testing performed by the USDA's Food Safety and Inspection Service (FSIS), or consumer complaints.

Additionally, FSIS field inspectors may come across a situation in a facility that flags a potentially unsafe

⁴⁰ Food and Drug Administration <<http://www.fda.gov/oc/po/firmrecalls/pilot.html>>

⁴¹ Confidential interview

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food. A company-initiated recall is handled similarly to the FDA method. An FSIS-initiated recall usually occurs only in instances of serious health threat.

The FDA and the USDA guidelines categorize all recalls into one of three classes according to the level of hazard involved: Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death. Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate federal labeling or manufacturing regulations.

With all food recall situations, the overseeing government agency expects a company to have a recall plan, with such elements as:

- Identification of recall personnel
- Evaluation of health hazards
- Depth of recall
- Public notification
- Returned product control and disposition
- Recall procedures
- Scope of recall
- Recall communication
- Effectiveness checks
- Recall simulations

Even in a best-case scenario, however, when a company has planned well and communicates the recall well, there are difficult hurdles because of the complexity of the food supply system. Food takes many routes to get from producers to consumers. A consumer might buy food at a retail food store, a membership club or a foodservice establishment such as a sit-down restaurant, a fast-food restaurant or a hot-dog stand. In between the producer and the grocery store, club or foodservice establishment might be distributors of many different types (self-distribution centers, system distributors and specialty distributors), third-party wholesalers, even other clubs and grocery stores. As organizations in the middle of the supply system find themselves with too much of one product in one place, they may divert it to other parts of their operation (perhaps in a different part of the country) or sell it to other organizations. Some product may be donated to foodshelves (as was the case in the Castleberry's recall). Obviously, the more twists and turns a product takes within the food supply system, the more difficult it becomes to track, and the more vital the UPC product codes become. For the purposes of a recall, citing information such as brand names, use-by dates and manufacturer production codes often causes confusion.

Castleberry's Actions after the Recall

After the initial recall announcement and the subsequent updates, Castleberry's eventually:

- Issued public warnings through the news media.
- Established a toll-free hotline for consumers that handled tens of thousands of calls.
- Posted recall information on the company's website.
- Instituted a refund program available online or by mail (requiring no return of product to retailers).
- Deployed recall audit teams to conduct on-site inspections at retail outlets across the country (as of July 31, 2007, more than 17,500 stores had been audited).
- Placed recall advertising in consumer publications.
- Began an effort to reach Spanish-speaking consumers and retailers.⁴²

⁴² Castleberry Food Company press release, Aug. 1, 2007
<http://www.castleberrys.com/news_pressRelease0801.asp>



Going Forward

When Castleberry's reopened the Augusta plant in September 2007, it issued a statement saying that it had "made modifications to operating procedures in order to strengthen them," but did not say what changes were made.⁴³

It introduced a new brand, American Originals, basically replacing many of its previous brands item for item. A spokesperson for Connors Bros. Income Fund said the Castleberry's plant would no longer process private-label products for chains such as Food Lion, Kroger and Piggly Wiggly.⁴⁴ Food industry executives interviewed for this case study said such a move is typical, an effort to distance companies from a damaging incident. They said whether their company would continue to do business with a company that issued a recall would depend greatly on the uniqueness of the company's product, the relationship with the company before the recall and the quality of that company's communication. One of those executives rated Castleberry's recall as a 7 on a 1 to 10 scale, with 10 being the best recall.⁴⁵ Castleberry's seemed to recover fairly successfully from the recall, reporting in May 2008 that it had resumed distribution to 85 percent of stores that previously carried its products. It did not specify whether this was under its own labels or under retail house brands.⁴⁶

In a separate but related incident early in 2008, the FDA on March 11 notified Castleberry's that it was suspending the Temporary Emergency Operating Permit that the company had operated under since September 2007. This halted production at the Augusta factory for three weeks. The USDA also notified Castleberry's that it was withholding inspection at the Augusta factory until the company made certain process modifications and answered FDA questions regarding factory operations.⁴⁷ A FDA and USDA inspection on Feb. 27, 2008, had raised questions about operations on a processing line that was not related to the recall, but that could have resulted in the undercooking of meat.⁴⁸ The factory resumed

⁴³ Augusta Chronicle, "Castleberry's Restarts Today," Sept. 18, 2007

⁴⁴ Augusta Chronicle, "Augusta Facility to Drop Products," Aug. 28, 2007

⁴⁵ Confidential interviews

⁴⁶ Connors Bros. Income Fund, "Management's Discussion and Analysis," May 12, 2008

⁴⁷ Connors Bros. Income Fund press release, March 11, 2008 <<http://phx.corporate-ir.net/phoenix.zhtml?c=144315&p=irol-newsArticle&ID=1117311&highlight=>>

⁴⁸ NewsInferno.com, "Settlement Reached in Castleberry's Botulism Lawsuit," June 19, 2008 <<http://www.newsinferno.com/archives/3305>>

production on March 31, 2008. The three-week shutdown cost Connors Bros. Income Fund another \$700,000.⁴⁹

Why is Botulism in Commercial Applications so Infrequent?

The answer to the question, “Why is botulism in commercial applications so infrequent?” can be addressed by looking at the underlying principle of food law in the United States, specifically the doctrine of “strict liability.” Under strict liability, a person or corporation is responsible for the damage and loss caused by his or her acts and omissions. Manufacturers of all products bear and accept this responsibility for producing safe products, meaning products that will not cause harm. External regulatory agencies, such as the FDA, specify standards to follow, as is done for canned food production. It is required that each canning establishment file its thermal processes with the FDA each year as part of their good manufacturing practices (GMP). Manufacturers of thermally processed, low acid, canned foods must follow a HACCP plan that is monitored during operations.

HACCP stands for Hazard Analysis and Critical Control Points, a systematic preventive approach to food safety and pharmaceutical safety that addresses physical, chemical, and biological hazards by means of prevention rather than finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key process steps, known as Critical Control Points (CCPs), can be managed to reduce or eliminate food safety risks. The system is used at all stages of food production and preparation processes, including packaging, distribution, etc. The FDA requires mandatory HACCP programs for juice and seafood production. In addition, the mandatory requirements in the Pasteurized Milk Ordinance and canned food regulations follow the principles of HACCP. Mandatory meat and poultry HACCP systems are regulated by the USDA and include canned meat products. The use of HACCP is currently voluntary in other industry segments.⁵⁰

Nonetheless, cases of botulism sometimes occur. In the event of under-processing, *Clostridium botulinum* could grow and produce sufficient botulinum toxin to cause illness. Often such food is spoiled by putrefaction to such an extent that a consumer would not eat it. Thermal processing, a process of heating canned foods at high temperatures (under pressure) in retorts, kills the *Clostridium botulinum* spores and prevents botulinum toxin production as well as spoilage. Or, if the consumer fully heats the product by bringing it to a boil for several minutes, the toxin can be completely inactivated. However, too many times, public health workers have heard, “It just did not taste or smell right, but I ate it anyway.” Since, regulatory/legal standards cannot be minimized; it is also necessary to consider potential adverse health impacts on the consumer when GMPs are not followed.

What if Botulinum Toxin Contamination or a Similar Event were Intentional?

By all accounts, the Castleberry's 2007 recall was accidental, but preventable. Machinery was installed improperly and worked improperly, Castleberry's failed to detect and correct the problems, and FDA inspectors failed to detect the problems. Furthermore, it would be virtually impossible to contaminate properly canned food products with *C. botulinum* spores or neurotoxin because the thermal processing would inactivate both the spores and the botulinum toxin. However, it may be possible for something equally dangerous to be purposely put into the commercial food system. If this were to happen, what

⁴⁹ Augusta Chronicle, “March Shutdown Cost Investment Fund \$700,000,” May 14, 2008

⁵⁰ U.S. Department of Agriculture, “HACCP: A Focus on Hazard Analysis and Critical Control Points”
<http://fsrio.nal.usda.gov/document_fsheet.php?product_id=155>

would the consequences be? A seemingly random intentional insertion into the system, even on a small scale, could have huge and lasting effects. The food industry and food safety regulators, including the Department of Homeland Security, have developed sophisticated measures to minimize the probability of deliberate (terrorist) attacks on the food supply.

The immediate impact of a deliberate attack would depend in large part by the dose of the contamination inserted into the food supply, whether only a single batch or case or package was affected vs. whether several batches, cases, packages, and brands were affected randomly, and whether a threat was made and/or responsibility was taken for the insertion. In addition, the impact would also be determined by the amount of consumption or use of the product and the "vulnerability" of the consumers who ate the product. For instance, a product that is used many times a day by a specific age segment could have more of an impact than a product that is used only occasionally. The magnitude of the economic impact of an intentional contamination on the targeted industry and all of food processing cannot be overestimated and is beyond the scope of this case.

However, looking at what happened in the Castleberry's case as well as other recall situations, the following scenarios can be assumed:

i) If a large dose of a lethal contaminant, that was not killed in thermal processing, were present in each can, one can only hope that when consumers opened individual cans, a strong odor or visual change would be a significant deterrent to eating the product. This would increase the "awareness of the problem" and serve to reduce consumption. However, there is no guarantee that deliberate contamination would be detected prior to consumption, depending on the agent used for contamination.

ii) The Castleberry's 2007 recall covered more than 90 different items distributed across the country. If deliberate contamination were confined to a single brand, the immediate health impact would probably be lower and identifying the correct products to recall would be easier. However, if the product were used more intensively, more frequently, by more people and consumed in larger quantities, it is quite possible that many people would be sickened or killed before a complete recall could be conducted.

iii) In a disclosed intentional incident, the long-term impact would be more significant, as discussed below. In terms of the immediate health impact and agency response, this would depend on when a claim of responsibility was made and/or the actions of public health agencies, law enforcement and the media.

Because of the nature of the canning process, Donald W. Schaffner, an Extension Specialist in Food Science and Professor at Rutgers, considers canned products a low-probability vehicle for an intentional attack: "As a terrorist, I would choose an easier target." Nevertheless, if the explicit defenses in the canning process are overcome, the overall safety and public confidence in canned foods must be considered. He summarizes the vulnerability of canned foods as follows:

Canned Foods Vulnerability to Intentional Contamination for Terrorism

Source: Donald W. Schaffner, Ph.D., Extension Specialist in Food Science
and Professor at Rutgers University

Reasons to use canned food:

- 1) Long shelf life.
- 2) Perception as a safe food, so using it for terror will have a greater impact.
- 3) An "American food," this increases its impact.

Reason not to use canned foods:

- 1) If the food is targeted before the thermal process, the agent will need to be very heat-resistant.
- 2) If the food is targeted after the process, the nature of the canned food means opening the can, which limits ease of attack.
- 3) Canned food plants are generally complex, so the target point may be difficult to locate.

Timothy Sellnow, a Professor of Communication at the University of Kentucky and a researcher for the National Center for Food Protection and Defense, explained the impact of an intentional insertion as follows:

First and foremost, penetrating the commercial food system and intentionally contaminating a widely consumed product with a pathogen as lethal as botulism would create a considerable drop in consumer confidence. Based on research we did for the CDC during the anthrax attacks of 2001, you could expect three reactions on a macro scale. First, there would be an immediate drop in consumer confidence. Second, there would be an influx of hoaxes from a variety of disturbed individuals and dissident groups. Third, the story would dominate the media, including expanded stories evaluating the overall safety of nearly every aspect of the food and water supply.

One distinction between this case and the 9/11 attacks is that people must eat. After 9/11, many people avoided unnecessary air travel. Some people found ways to avoid the mail during the anthrax crisis. What makes foodborne terrorism unique is that people cannot simply stop eating. They can, however, avoid major segments of the market. Restoring confidence in canned food would require a consistent message as well as highly visible and unprecedented corrective actions in the canning industry. Such was the case in the packaging industry following the Tylenol episode.⁵¹ The sweeping changes made in response to the Tylenol crisis are now taken for granted. A botulism crisis would likely call for change on the same scale.

Hoaxes are an unfortunate, but common occurrence when public alarm is high about a threatening issue. Communicating in a hoax environment produces a paradox: officials often know the threat is false; yet they must respond publicly, out of an abundance of caution, as if the threat is real.

⁵¹ USA Today, "Tylenol tampering case remains unsolved, in 25 years," Sept. 29, 2007

Assuming a threat is a hoax, only to realize later that the threat is real, can result in death or injury and a precipitous drop in public confidence. Thus, government agencies and the canned food industry would likely be inundated with hoaxes that would certainly be a distraction in the recovery process.

The risk-communication demands from government agencies and the canned food industry would be intense and unrelenting. This event would foster stories that would stay in the lead story or front page story categories for months. Agency and industry leaders would be asked to participate in live interviews at an exhausting rate. Maintaining message consistency and avoiding unnecessarily alarming coverage would be challenging in this environment. The best strategy to accommodate this demand would be the use of consistent press conferences held by government agencies and collaborative industry groups. Addressing each media outlet individually, as opposed to this press conference format, would be overwhelming.

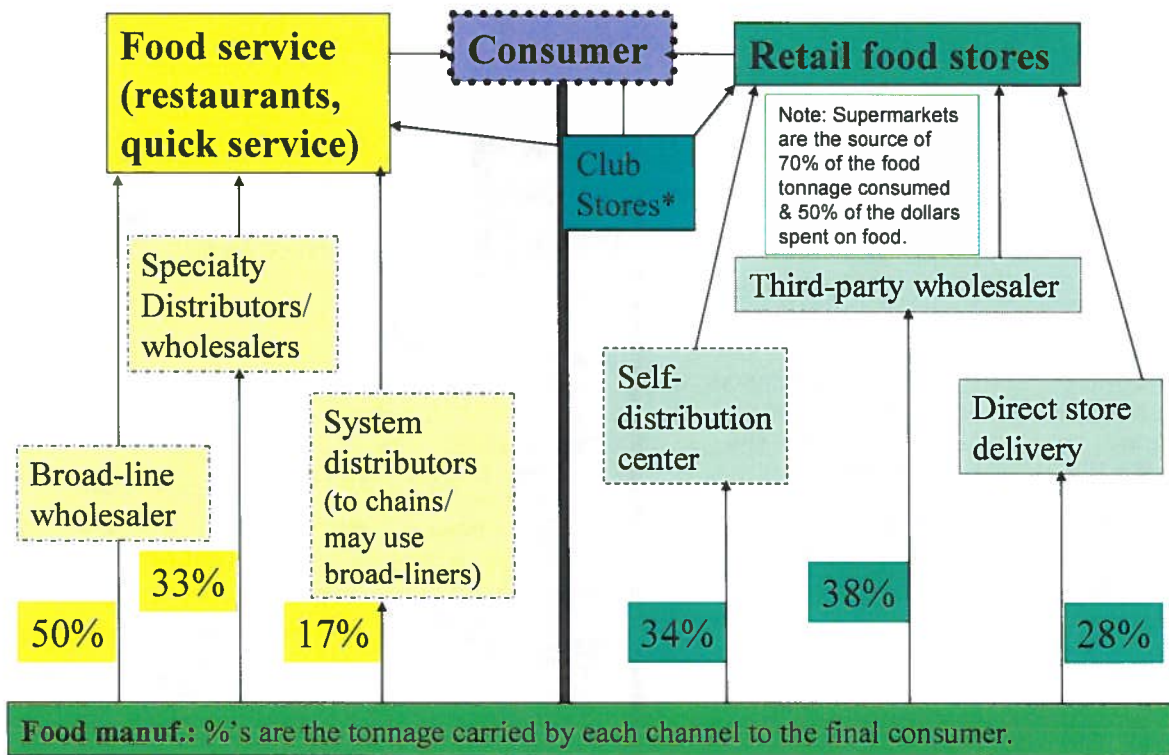
Conclusions and Questions

The Castleberry's recall illustrates the complexity of the food supply system. When health authorities sounded the alarm, they appeared to have a food equivalent of a multi-alarm fire. In the case of an actual fire, residents or workers hear an alarm when it is pulled, and fire officials respond immediately. In the case of manufactured food, it is not so easy. Food travels many paths to get to consumers, and those paths are not always tracked very closely. Identifying the source of the problem is difficult enough; determining how to address the problem and then communicating that solution to government and business officials and consumers compounds the difficulty.

The Castleberry's incident can be used to illustrate the strengths and weaknesses of the U.S. food supply chain including the regulatory process. Individual companies, policy makers and classes in food science, marketing and law may want to explore the following issues.

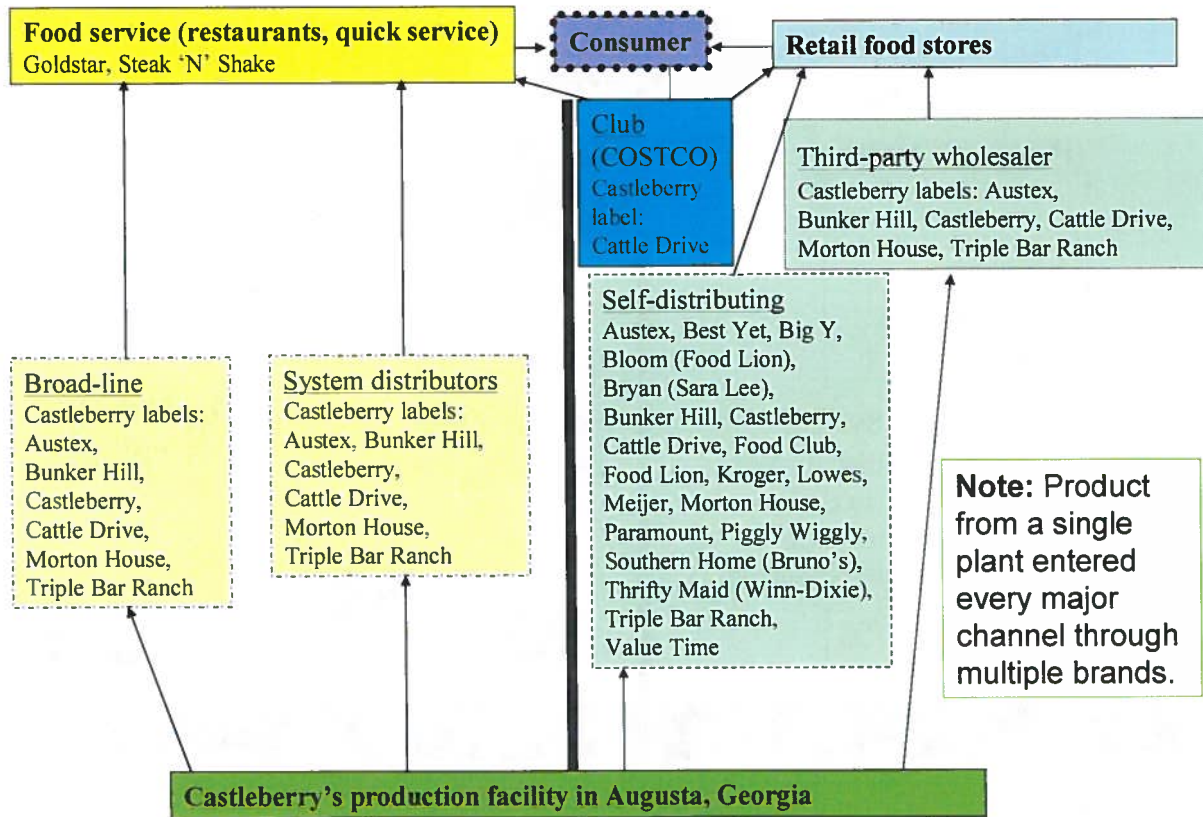
- 1) The flexible, almost fluid nature, of the food supply system provides manufacturers, wholesalers, retailers, restaurants and consumers with the widest possible variety of outlets to meet their needs. At the same time, this variety continually compounds the difficulty of determining where the affected product is and how to recall it. Product can be sold and re-sold with limited traceability. How can complete and final recall of product be assured?
- 2) What were the products subject to recall? Ultimately Castleberry's recalled 90 different items with multiple recall notices over several days. The inability to maintain and identify individual production lots compounded the company's problems. What industry practices need to be changed in order to identify products more precisely? How can products be better recalled from consumers?
- 3) At the same time, because there was no single dominant brand that the company had built, once production problems were isolated and corrected, the company was able to re-launch its products under new names with apparent success. Brands may not be as important in this category as in some others. What problems does this type of food production present to retailers with private label brands? To consumers?
- 4) Looking at the history of Castleberry's and Connors Bros., what factors contribute to product safety, quality and innovation? What factors compromise product safety, quality and innovation?
- 5) How do we safely dispose of potentially dangerous products?

Figure 1: Generic Supply Chain Chart



* Club stores are included in retail. They sell to consumers, small stores and food service. Product usually come direct from the manufacturer.

Figure 2: Supply Chain Applied to Castleberry Products Recalled



Glossary

Botulism is a rare but serious paralytic illness. Foodborne botulism is the name of the disease (actually a foodborne intoxication) caused by the consumption of foods containing the neurotoxin produced by *C. botulinum*.

Clostridium botulinum*, or *C. botulinum, organisms are commonly found in soils and marine sediments throughout the world. *C. botulinum* may be found in any region of the world. Because it is found in the soil, it may contaminate vegetables cultivated in or on the soil. It also colonizes the gastro-intestinal tract of fishes, birds and mammals.

Botulinum toxin is a neurotoxin protein produced by the bacterium *Clostridium botulinum*. Botulinum toxin is one of the most powerful known toxins. Botulinum toxin is a neurotoxin (a poisonous complex that acts on the nervous system). Though it is highly toxic, botulinum toxin is used in minute doses both to treat painful muscle spasms, and as a cosmetic treatment.

(sources: FDA, "Foodborne Pathogenic Microorganisms and Natural Toxins Handbook"
<<http://www.cfsan.fda.gov/~mow/chap2.html>> and "Botulinum Toxin: A Poison That Can Heal"
<http://www.fda.gov/fdac/features/095_bot.html>)

Responders are those people whose job is to respond quickly when the public or even individuals are in danger of injury or death. Firemen and police are the most familiar "first responders." But, in the case of foodborne illness, responders may be teams of food company personnel who communicate with the public and media and/or ensure a rapid action to retrieve contaminated product from retail shelves.

Reverse Logistics moves product from homes, retail stores and supply warehouses back up the supply chain.

Addendum

September 2008

On September 16, 2008, Connors Bros. Income Fund announced that within 60 days the Castleberry's foods products made in Augusta would be made at the New Jersey plant of Aunt Kitty's Foods Inc., a subsidiary of privately owned Hanover Foods Corp.

The Augusta facility was not part of the transaction, the Augusta Chronicle reported on September 17. Hanover acquired the rights to the brand, inventory and some of the equipment in the plant. According to county records, the Castleberry's site was worth \$7.5 million. Terms of the sale were not disclosed. Proceeds were to be used to pay down debt. Chris Lischewski, the fund's president and chief executive officer, said the products were not a good fit with the rest of the company's holdings.

Appendices

I: 2007 Castleberry's Recall Timeline

April 30-May 22 — Cans manufactured during this time period are later tested and found to contain botulinum toxin.

July 7 — Public health officials in Texas report two suspected cases of foodborne botulism to CDC.

July 11 — Public health officials in Indiana report two suspected cases of foodborne botulism to the CDC.

July 18 — USDA Food Safety and Inspection Service (FSIS) issues a news release that announces a voluntary recall of chili and certain meat products from a Castleberry's canning facility in Augusta, GA.

July 21 — Canning facility closed and recall expanded. Castleberry's voluntarily recalls tens of millions of cans of meat and pet food, every product manufactured on a specific production line, and hires a firm to help remove the recalled products from thousands of retail outlets across North America.

August 18 — Connors Bros. President Chris Lischewski tells investors the recall is costing the company \$35 million. The company later reports \$78 million in recall-related costs.

August 24 — CDC raises to eight, the number reported to be suffering from botulism poisoning.

September 18 — Castleberry's canning facility reopens.

II. Complete List of Recalled Castleberry's Products (processed at Augusta, GA.)

(source: FDA, "Chili Products (Botulism) Recall"

<<http://www.fda.gov/oc/opacom/hottopics/castleberry.html>>

Brand, product, size, label, UPC barcode

- * Austex Onion Hot Dog Chili Sauce, 10 oz can (UPC 3030097101)
- * Austex Hot Dog Chili Sauce, 10 oz can (UPC 3030099533)
- * Austex Beef Stew, 15 oz can (UPC 3030090815)
- * Austex Chili With Beans, 15 oz can (UPC 3030091015)
- * Austex Chili With Beans, 19 oz can (UPC 3030092519)
- * Austex Chili No Beans, 15 oz can (UPC 3030097715)
- * Austex Chili No Beans, 19 oz can (UPC 3030097719)
- * Best Yet Corned Beef Hash, 15 oz can (UPC 4218741082)
- * Best Yet Chili With Beans, 15 oz can (UPC 4218740842)
- * Big Y Chili No Beans, 15 oz can (UPC 1889480424)
- * Big Y Corned Beef Hash, 15 oz can (UPC 1889480225)
- * Big Y Chili With Beans, 15 oz can (UPC 1889480425)
- * Black Rock Chili With Beans, 15 oz can (UPC 3030001715)
- * Bloom Hot Dog Chili Sauce, 10 oz can (UPC 2543992448)
- * Bryan Hot Dog Chili Sauce With Beef, 10 oz can (UPC 5340030010)
- * Bryan Corned Beef Hash, 15 oz can (UPC 5340030110)
- * Bryan Chili No Beans, 15 oz can (UPC 5340030200)
- * Bryan Chili With Beans, 15 oz can (UPC 5340030205)
- * Bryan Chili No Beans, 10 oz can (UPC 5340035264)
- * Bunker Hill Hot Dog Chili Sauce, 10 oz can (UPC 7526604152)
- * Bunker Hill Chili No Beans, 10 oz can (UPC 7526604112)
- * Bunker Hill Spicier Chili No Beans, 10 oz can (UPC 7526604224)
- * Castleberry's Hot Dog Chili Sauce, 10 oz can (UPC 3030000101)
- * Castleberry's Onion Hot Dog Chili Sauce, 10 oz can (UPC 3030007101)
- * Castleberry's Brunswick Stew Chicken & Beef, 15 oz can (UPC 3030000315)
- * Castleberry's Barbecue Pork, 10 oz can (UPC 3030000402)
- * Castleberry's Barbecue Pork, 14.5 oz can (UPC 3030000415)
- * Castleberry's Barbecue Beef, 10 oz can (UPC 3030000602)
- * Castleberry's Beef Stew, 15 oz can (UPC 3030000815)
- * Castleberry's Corned Beef Hash, 15 oz can (UPC 3030000915)
- * Castleberry's Chili With Beans, 15 oz can (UPC 3030001015)
- * Castleberry's Sausage Gravy, 10 oz can (UPC 3030005130)
- * Castleberry's Creamed Chip Beef Gravy, 10 oz can (UPC 3030005150)
- * Castleberry's Hot Chili With Beans, 15 oz can (UPC 3030007217)
- * Castleberry's Chili No Beans, 10 oz can (UPC 3030007701)
- * Castleberry's Chili No Beans, 15 oz can (UPC 3030007715)
- * Castleberry's Georgia Hash, 15 oz can (UPC 3030000215)
- * Cattle Drive Beef Stew (Steak), 15 oz can (UPC 3030001531)
- * Cattle Drive Chili No Beans, 15 oz can (UPC 3030001520)
- * Cattle Drive Chicken Chili With Beans, 15 oz can (UPC 3030001525)
- * Cattle Drive Chili With Beans, 15 oz can (UPC 3030001515)
- * Firefighters Chicken Chili With Beans, 15 oz can (UPC 7372500413)
- * Firefighters Chili With Beans, 15 oz can (UPC 7372500411)
- * Firefighters Chili No Beans, 15 oz can (UPC 7372500412)

Castleberry's: 2007 Botulism Recall

- * Food Club Corned Beef Hash, 15 oz can (UPC 3680080204)
- * Food Club Chili No Beans, 15 oz can (UPC 3680080404)
- * Food Club Chili With Beans, 15 oz can (UPC 3680080504)
- * Food Lion Hot Dog Chili Sauce, 10 oz can (UPC 3582606911)
- * Goldstar Original Chili, 10 oz can (UPC 2457500001)
- * Goldstar Chili, 15 oz can (UPC 2457500005)
- * Goldstar Tex-Mex Chili With Beans, 15 oz can (UPC 2457500008)
- * Great Value Chili With Beans, 15 oz can (UPC 8113179994) – CANADA ONLY
- * Great Value Hot Chili With Beans, 15 oz can (UPC 8113179995) – CANADA ONLY
- * Kroger Hot Dog Chili Sauce, 10 oz can (UPC 1111083942)
- * Kroger Beef Stew, 15 oz can (UPC 1111083928)
- * Kroger Chili With Beans, 15 oz can (UPC 1111083930)
- * Kroger Chili No Beans, 15 oz can (UPC 1111083908)
- * Lowes Foods Chili No Beans, 15 oz can (UPC 4164301092)
- * Lowes Foods Corned Beef Hash, 15 oz can (UPC 4164301094)
- * Lowes Foods Chili With Beans, 15 oz can (UPC 4164301097)
- * Meijer Hot Dog Chili Sauce, 10 oz can (UPC 4125085862)
- * Meijer Chili No Beans, 15 oz can (UPC 4125095220)
- * Meijer Chili With Beans, 15 oz can (UPC 4125095221)
- * Meijer Corned Beef Hash, 15 oz can (UPC 4125095229)
- * Morton House Chili With Beans, 15 oz can (UPC 7526665851)
- * Morton House Corned Beef Hash, 15 oz can (UPC 7526665830)
- * Paramount Hot Dog Chili Sauce, 10 oz can (UPC 7526600510)
- * Paramount Chili for Hot Dogs, 15 oz can (UPC 7526600526)
- * Paramount Chili No Beans, 15 oz can (UPC 7526600501)
- * Paramount Chili With Beans, 15 oz can (UPC 7526600502)
- * Piggly Wiggly Chili With Beans, 15 oz can (UPC 4129037252)
- * Piggly Wiggly Chili No Beans, 15 oz can (UPC 4129037354)
- * Piggly Wiggly Chili No Beans, 10 oz can (UPC 4129037355)
- * Piggly Wiggly Corned Beef Hash, 15 oz can (UPC 4129037357)
- * Prudence Corned Beef Hash, 15 oz can (UPC 4114100020)
- * Southern Home Chili No Beans, 10 oz can (UPC 3825948713)
- * Southern Home Chili No Beans, 15 oz can (UPC 0788015340)
- * Southern Home Chili With Beans, 15 oz can (UPC 0788015341)
- * Southern Home Corned Beef Hash, 15 oz can (UPC 0788015360)
- * Steak n Shake Chili With Beans, 10 oz can (UPC 5184400120)
- * Thrifty Maid Hot Dog Chili Sauce, 10 oz can (UPC 2114021367)
- * Thrifty Maid Chili With Beans, 15 oz can (2114021370)
- * Thrifty Maid Corned Beef Hash, 15 oz can (2114021375)
- * Triple Bar Ranch Chili With Beans Slow Cooked, 15 oz can (UPC 3030005801)
- * Triple Bar Ranch Chili With Beans, 15 oz can (UPC 3030005804)
- * Triple Bar Ranch Chili No Beans, 15 oz can (UPC 3030005805)
- * Value Time Beef and Chicken Chili With Beans, 15 oz can (UPC 1122542159)

In addition, the following canned Natural Balance brand pet food products:

- * Natural Balance Eatables for Dogs Irish Stew With Beef, Potatoes & Carrots, 15 oz can (UPC 2363359860)
- * Natural Balance Eatables for Dogs Chinese Take Out With Sauce With Vegetables and Chicken, 15 oz can (UPC 2363359861)

Castleberry's: 2007 Botulism Recall

* Natural Balance Eatables for Dogs HOBO Chili With Chicken & Pasta, 15 oz can (UPC 2363359863)

* Natural Balance Eatables for Dogs Southern Style Dumplings With Chicken & Vegetables, 15 oz can (UPC 2363359862)

III. Federal Class I Food Recalls and Warnings in 2007-08

(source: FoodSHIELD, sponsored by the National Center for Food Protections and Defense
<<http://www.foodshield.org>>)

January 2007

Pap's Louisiana Cuisine Head Cheese (*L. monocytogenes*)
Gold Star Sausage Co. Sausage (*L. monocytogenes*)
Royal International Trading, Inc. Herring (*C. botulinum*)
Garden Leaf Foods Pasta Salad (*L. monocytogenes*)
Natural State Meat Co. Ground Beef Products (*E. coli O157:H7*)

February 2007

Peter Pan and Great Valu Peanut Butter (*Salmonella*)
Dole Cantaloupes (*Salmonella*)
Earth's Best Baby Food (*C. botulinum*)
America's Kitchen Green Bean Casserole (*L. monocytogenes*)
Castle Produce Cantaloupes (*Salmonella*)
First quality Sausage Ham Steaks (*L. monocytogenes*)
Carolina Culinary Foods Chicken Strips (*L. monocytogenes*)

March 2007

Simply Fresh Fruit Inc. Fruit Trays (*Salmonella*)
Tyson Fresh Meats Ground Beef (*E. coli O157:H7*)
Cibo Specialty Foods Olives (*C. botulinum*)

April 2007

Earle of Sausage RTE Sausage (*S. aureus*)

May 2007

Diestel Turkey Ranch RTE Turkey Products (*L. monocytogenes*)
Aulcorp Food Marketers Inc. Risotto (*Salmonella*)
Davis Creek Meats and Seafood Ground Beef Products (*E. coli O157:H7*)
Whole Foods Market Sesame Tahini (*Salmonella*)
nSpired Sesame Tahini (*Salmonella*)

June 2007

The Really Cool Food Co. Chicken Products (*L. monocytogenes*)
Toby's Family Foods Dressing (*Salmonella*)
Tyson Fresh Meats Inc. Ground Beef Prodducts (*E. coli O157:H7*)
WA Beef Co. Beef Products (May have been produced with nonpotable water)
Gill's Onions LLC, Diced Yellow Onions (*L. monocytogenes*)
Robert's American Gourmet Veggie Booty (*Salmonella*)
Tennessee Cook Chill RTE Chicken Products (*L. monocytogenes*)

July 2007

Castleberry's Chili (*C. botulinum*)
Custom Pack Inc. Ground Beef and Buffalo Products (*E. coli O157:H7*)

August 2007

Cloud's Food Service Inc. Sandwiches (*Listeria*)
Krasniy Oktyabr Inc. Canned Herring (*C. botulinum*)
Oyster from Growing Area 6 (*V. parahaemolyticus*)
IFS Inc. Sandwiched (*L. monocytogenes*)
Acme Smoked Fish Co. Smoke Salmon (*L. monocytogenes*)
Ocean King Enterprises Inc. Seafood Dip (*L. monocytogenes*)
Metz Fresh LLC. Bagged Spinach (*Salmonella*)
Everlasting Distributors Inc. Sardines (*C. botulinum*)

September 2007

Dole Packaged Salads Recall (*E. coli O157:H7*)
Baby's Bliss Gripe Water (*Cryptosporidium*)
Organic Pastures Raw Cream (*L. monocytogenes*)
Organic Pastures Raw Cream (*L. monocytogenes*)
Quong Hop & Co. Tofu (*L. monocytogenes*)

October 2007

Jensen's Wild Smoked Salmon Spread (*L. monocytogenes*)
Kraft Foods Baker's White Chocolate Baking Squares (*Salmonella*)
Cargill Meat Solutions Co. Frozen Ground Beef Patties (*E. coli O157:H7*)
Aliko Foods Inc. Chicken and Pasta (*L. monocytogenes*)
ConAgra Chicken and Turkey Pot Pies (*Salmonella*)
Arko Veal Co. Ground Beef Products (*E. coli O157:H7*)
Topps Meat Co. Frozen Ground Beef Products (*E. coli O157:H7*)
Blue Ribbon Meats Frozen Ground Beef Products (*E. coli O157:H7*)
Del Mar Provisions Co. Frozen Ground Beef Products (*E. coli O157:H7*)

November 2007

General Mills Operations Frozen Meat Pizza (*E. coli O157:H7*)
Annex Foods Cooked Beef and Chicken Products (Inadequate verification of processing)
Cargill Meat Solutions Corp. Ground Beef Products (*E. coli O157:H7*)
Del Rey Tortilleria, Inc. Flour Tortillas (Undetermined Illness)
Double B Foods, Inc. Sausage Rolls (*L. monocytogenes*)
Le Gourmet Jack Cheese (*L. monocytogenes*)
Sweetwater Valley Farms, Inc. Cheese (*L. monocytogenes*)
American Foods Group, LLC Ground Beef Products (*E. coli O157:H7*)
Sweetwater Valley Farms, Inc. Cheese (*L. monocytogenes*)

December 2007

Soma Beverage Metromint Flavored Water (*B. cereus*)
Peregrina Cheese Corp. Queso Fresco (*L. monocytogenes*)
Snapps Ferry Packing Ground Beef Products (*E. coli O157:H7*)
Top Line Specialty Produce Basil (*Salmonella*)
Royal Seafood Baza Inc. Dried Roach Fish (*C. botulinum*)
New Era Canning Company Green Beans (*C. botulinum*)
Maramont Corp. Beef Patties (*L. monocytogenes*)
Prestige Oyster Co. Raw Oysters (*Norovirus*)

January 2008

Olivier, Dip (*C. botulinum*)
Grassy Meadows, Cheese (*S. aureus*)
Shiloh Farms, Sesame Seeds (*Salmonella*)
Seoul Shik Poom, Inc., Fish (*C. botulinum*)
Inter-American Products, Bean Salad (*C. botulinum*)
New Era, beans (*C. botulinum*)
Rochester Meat Co., Beef (*E. coli O157:H7*)
Mark's Quality Meats, Inc., Beef (*E. coli O157:H7*)

February 2008

Walker's Food Products, Bean Salad (*C. botulinum*)
Hallmark/Westland, Beef (High Impact Class II Recall)
Nutri-Foods, Inc., Sesame Seeds (*Salmonella*)
Choyce Products, Tuna (*Salmonella*)
New Era, Canned Vegetables (*C. botulinum*)

March 2008

Dole Fresh Fruit Co., Cantaloupes (*Salmonella*)
Spokane Produce, Inc., Cantaloupes (*Salmonella*)
Chiquita, Cantaloupes (*Salmonella*)
JARD Marketing, Cantaloupes (*Salmonella*)
Bounty Fresh, Cantaloupes (*Salmonella*)
Fresh Express Foods, Cantaloupes (*Salmonella*)
Simply Fresh Fruit, Cantaloupes (*Salmonella*)
Tropifresh, Inc., Cantaloupes (*Salmonella*)
T.M. Kovacevich, Cantaloupes (*Salmonella*)
Central American Produce, Cantaloupes (*Salmonella*)

April 2008

Chang Farm, Soy Sprouts (*Listeria*)
Piney Ridge Dairy, Raw Milk (*Listeria*)
Malt-O-Meal, Cereal (*Salmonella*)
Taylor Fresh Foods, Cantaloupe (*Salmonella*)
Grand Supercenter, Croaker (*C. botulinum*)

May 2008

Fresca Italia Inc., Burrata (*L. monocytogenes*)
Orval Kent Foods, Macaroni Salad (*E. coli O157:H7*)
Supreme Cuts LLC., Corn (*L. monocytogenes*)
Cecina Los Amigos, Sausages (*Listeria*)
Sofia Chicharones Inc., Pork Crackling (*Salmonella*)
JSM Meat Holdings Co., Beef Products (*E. coli O157:H7*)
Sweetwater Valley Farm, Cheese (*Listeria*)
Palama Holdings, Ground Beef (*E. coli O157:H7*)
Gourmet Boutique, Meat and Poultry (*Listeria*)

June 2008

Nebraska Beef Ltd, Ground Beef (*E. coli O157:H7*)

Kroger Co., Ground Beef (*E. coli O157:H7*)

Fresca Italia, Inc., Cheese (*L. monocytogenes*)

Tipu's Tiger Chai Inc., Chai Tea (*C. botulinum*)

Gourmet Foods Inc., Chicken Products (*Listeria*)

Dutch's Meat Inc, Meat Products (*E. coli O157:H7*)

Tomatoes/Peppers (*Salmonella*)

IV: Links for the 2007 Castleberry's Recall

June 2008 USA Today article

www.usatoday.com/money/industries/food/2008-06-29-botulism-FDA-canned-food_N.htm

Centers for Disease Control report

www.cdc.gov/mmwr/preview/mmwrhtml/mm5630a4.htm

U.S. Food and Drug Administration

www.fda.gov/oc/opacom/hottopics/castleberry.html

www.fda.gov/opacom/7alerts.html

U.S. Department of Agriculture FSIS

www.fsis.usda.gov/

U.S. Government Accountability Office report on food safety

www.gao.gov/new.items/d0551.pdf

2007 Gallup Poll on Americans reacting to food scares

www.gallup.com/poll/28264/Seven-Ten-Americans-Reacted-Food-Scare-Past-Year.aspx

Castleberry's Food Company

www.castleberrys.com

V: Articles on the Recall

http://www.usatoday.com/money/industries/food/2008-06-29-botulism-FDA-canned-food_N.htm

Management problems cited in botulism case

Julie Schmit, USA TODAY, 6/29/2008

Last July, Food and Drug Administration officials issued a rare warning to U.S. consumers: Botulism toxin was suspected in hot dog chili sauce made by Castleberry's Food.

The botulism outbreak, which would eventually sicken eight and lead to a recall of tens of millions of cans of food, was the first in a U.S.-made canned food in 33 years.

The day before the warning, FDA investigators had begun an inspection at a Castleberry's plant that set off alarms within the agency.

Two 10-foot-tall cookers may not have heated cans enough to kill all bacteria, including those leading to botulism toxin.

The cookers had broken alarms, a leaky valve and an inaccurate temperature device, the FDA said in a previously undisclosed report. USA TODAY obtained a copy from a congressional committee.

The cookers in the Augusta, Ga., plant showed "poor maintenance," and management failed to "correct ongoing deficiencies" in the plant, the report said.

"Failure in management was ultimately the reason for the botulinum toxin in the cans," according to the report.

The outbreak drove FDA officials to step up inspections at other canneries. In late November, the FDA began inspecting the New Era Canning plant in Michigan, where it discovered botulism spores, a precursor to the toxin, in cans of green and garbanzo beans. No illnesses were reported. New Era recalled 1.2 million cans of vegetables because of the risk.

The recalls worried FDA and industry officials. Botulism toxin — so deadly that it's feared as a bioterror weapon — had been virtually eradicated in the canning industry for decades through time-tested manufacturing processes. The FDA feared some plants had slipped into lax practices that led to botulism-prevention regulations in 1973. On Dec. 21, the day of New Era's recall, the FDA sent a letter warning canneries to "not become complacent."

Donald Zink, a senior FDA food scientist, says a refocus on good manufacturing practices is needed. "Probably, we've suffered from being too successful," he said in an interview. "Maybe some have gotten a little sloppy."

The FDA's report also underscored the limits of government oversight. The FDA criticized Castleberry's for failing to correct problems, but those problems went undetected by FDA inspectors at the plant five months before the outbreak and by Department of Agriculture inspectors who were in the plant weekly.

Rep. Bart Stupak, D-Mich., who chairs a subcommittee that has held eight hearings on food safety in the past 18 months, says both recalls were "largely a function of careless producers and insufficient regulatory oversight."

"This (canning) process is decades old and well validated. There should be no reason for these hiccups," adds Michael Doyle, director of the Center for Food Safety at the University of Georgia. "It's a matter of properly maintaining equipment and applying proper protocols."

Castleberry's: 2007 Botulism Recall

Zink and industry officials say the recalls and FDA warnings caused other companies to tighten safety procedures. "It may be we've seen the worst of it," Zink says. "It may be that we find a few more firms" with problems.

Castleberry's made fixes at its plant and reopened. New Era also made changes and received FDA clearance Thursday to resume production. Both companies say the problems that led to recalls were hard to detect and not the result of sloppiness.

Food-borne botulism is so rare that only about 30 cases are reported in the U.S. each year — almost all from home-canned foods, says the Centers for Disease Control and Prevention. Commercially canned foods are one of the safest foods because they're cooked long and hot enough to kill bacteria, unlike fresh produce, in which there is no processing "kill" step.

Even so, botulism is a concern because it's so deadly, claiming 8% of victims, often because breathing muscles become paralyzed.

The toxin flourishes in the low-oxygen environment of a sealed can or jar in low-acid foods, such as vegetables, meat, poultry, fish, milk and olives.

Proper canning prevents botulism. But undercooking, and leaky can seams that let in bacteria after cooking, may cause it.

'It was mass chaos'

Food safety inspectors from the FDA and Georgia descended on Castleberry's the night before its July 18 recall, the report said.

Four people in Texas and Indiana had fallen ill, all of whom reported eating Castleberry's hot dog chili sauce, local and state health officials had determined.

The recall began with FDA-regulated meatless hot dog chili sauce and soon grew to 90 products made over two years, including beef stew, corned beef hash, chili sauce and pet food.

Inside Castleberry's warehouse, investigators found swollen cans, which can indicate relatively harmless spoilage or deadly botulism. In one sample of 17 swollen cans, the toxin was in 16 of them, the FDA report says.

Investigators also asked for records, lots of them. None came until the evening of July 20, three days into the probe, which is when the FDA gave Castleberry's 24 hours to produce records or face a potential citation, the report said.

Some key records couldn't be immediately provided because they were stored on the laptop of the plant's maintenance manager, who was on vacation, according to the report.

"It was mass chaos," said Christopher Lischewski, Castleberry's CEO, in an interview.

By following production codes on contaminated cans, the FDA quickly narrowed its focus to cans made May 7 and May 8 on two of the 100 cookers in the plant.

The FDA said new controls on one cooker were improperly installed in February and gave off false temperature readings.

In late May, a technician from the cooker's manufacturer, Malo of Tulsa, noticed the controls were "far out of line," the FDA said in its report, citing the technician's report.

Castleberry's: 2007 Botulism Recall

The FDA also said an employee operating the cooker failed to do required checks on the cooker's thermometer, the "reference instrument" for temperature. That's an "egregious" oversight, said canning expert John Rushing at North Carolina State University. "Everybody knows to do that."

The other cooker that may have produced contaminated sauce had a worn valve that failed to seal properly, the FDA said. That allowed water to back up in the cooker, lowering the temperature inside. Zink calls the worn valve a "maintenance failure."

Alarms or alarm lights, designed to alert operators to problems, on both cookers were malfunctioning. "Leaking valves and burned out alarm lights ... provide a picture of ... poor maintenance and inattention," the FDA report said.

According to the FDA, the Malo technician said in his report that the cookers had been well maintained two years earlier but that they were "maintained poorly now."

Castleberry's was sold in 2005 to Bumble Bee Foods, an operating company of Canada's Connors Bros. Income Fund.

Some of Castleberry's problems started then, as the 400-employee company "lost its identity and so did the employees," plant general manager James Waits told investigators.

An 'almost undetectable' flaw

Castleberry's, which hadn't seen the FDA report until USA TODAY provided it for comment, disputes the report's assessment of poor management and maintenance.

Lischewski, who's also CEO of Connors and Bumble Bee, says testing showed that the leaky-valve cooker was the likely culprit. That problem was "almost undetectable" unless the valve was taken apart, which wasn't part of Castleberry's weekly maintenance check, he said.

Neither the Malo technician nor Waits, the plant manager, were fully informed, he said. The technician wasn't aware of changes Castleberry's had made in its maintenance program since the company's sale and his judgment was inaccurate, according to Lischewski. Waits joined the management team eight days after the recall and made several comments to the FDA "out of emotion," he added.

Castleberry's said it supplied records to investigators as soon as possible, given requests from multiple agencies. Paper copies of records kept by the vacationing manager were at the plant, it said.

"It's a tough-worded report. But I do not believe there was any sloppiness," Lischewski said. "We believe it was more of a technology and design issue than an operating issue."

The FDA's Zink said it's not clear which of the two cookers produced contaminated cans, because the plant's clocks weren't synchronized with equipment that stamped cans.

"When you have a firm that fails so badly that they produce cans with *Clostridium botulinum* ... there are invariably multiple process failures, multiple violations ... and failed management systems," Zink said. Those failures went undetected by two USDA inspectors who were in the plant several days a week to check meat-containing products.

USDA spokeswoman Amanda Eamich said inspectors check food-safety controls, but they may not be trained to spot hard-to-detect equipment problems.

The FDA did a three-day inspection at the plant in February 2007 and found no major issues. That inspection covered a new line of cookers, not the ones that led to the recall, Zink said. To inspect all 100 cookers would have taken a month, he added, unfeasible given the scarcity of FDA inspectors.

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'Out of control'

Alarmed by Castleberry's outbreak, the FDA inspected 15 other canneries that used the same equipment, a step to prevent another outbreak. Only one sent up red flags: New Era.

In its warehouse, investigators found cans with swells, buckles and defective seams, according to the FDA's inspection report. New Era was cited for failing to discover whether its products posed a "potential public health hazard" and to fix problems.

New Era also did something that Zink said he hadn't seen in 25 years. Some cans that had buckled after cooking had been pressed back into shape and sold.

"Debuckling" can mask a "critical defect," Zink said, because buckled cans may have damaged seams. Canneries typically destroy severely buckled cans.

"This was a plant that was out of control for some time and dodged a bullet," said John Cerveny, food microbiologist with NSF-Cook & Thurber, which audits food plants. He reviewed the FDA report.

New Era didn't undercook, Zink said. The FDA suspects that botulism spores entered the plant's water via a broken well line and got into cans through seams while cans were cooled in water.

New Era didn't know how long the water line had been broken, the report said. Nor did it chlorinate its cooling water, which is commonly done to kill bacteria, or adequately maintain seaming equipment or monitor bacteria levels in cooling water, the FDA said.

"When cans buckle and compromise the ... seam and you cool them with unchlorinated water, you really create a disastrous situation," Zink said.

Post-recall reforms

Since their recalls, both companies have made changes.

Castleberry's took suspect cookers out of service. It added backup valves to others, redesigned controls and retrained workers. The recall's costs hit \$38 million, it said in March.

New Era will check bacteria in water more often and chlorinate cooling water, even though President Rick Ray said that wouldn't have prevented contamination in this case. Zink said that's uncertain.

New Era no longer pushes buckled cans back into shape. The company says only a tiny number were, and that buckles don't pose a safety risk if seams aren't affected. New Era never intentionally sold cans with damaged seams, it says, and disputes Zink's opinion that its previous practices posed a "disastrous situation."

A USDA audit of the plant four weeks before the FDA's inspection found the plant in compliance, the company says.

New Era is a peak-season employer of 250 in a village twice that size. The recall was the first for the 98-year-old family-owned company, Ray said.

"We are very concerned about creating safe food, and our track record shows it," he said.

www.cdc.gov/mmwr/preview/mmwrhtml/mm5630a4.htm

Botulism Associated with Commercially Canned Chili Sauce
— Texas and Indiana, July 2007

On July 30, 2007, this report was posted as an MMWR Dispatch on the MMWR website (<http://www.cdc.gov/mmwr>). (MMWR is the Morbidity and Mortality Weekly Report)

On July 7 and July 11, 2007, public health officials in Texas and Indiana, respectively, reported to CDC four suspected cases of foodborne botulism, two in each state. Investigations conducted by state and local health departments revealed that all four patients had eaten brands of Castleberry's hot dog chili sauce before illness began. Botulinum toxin type A was detected in the serum of one Indiana patient and in a leftover chili mixture obtained from his home. CDC informed the Food and Drug Administration (FDA) of the apparent link between illness and consumption of the chili sauce. On July 18, FDA issued a consumer advisory, and the manufacturer, Castleberry's Food Company (Augusta, Georgia), subsequently recalled the implicated brand and several other products produced in the same set of retorts (commercial-scale pressure cookers for processing canned foods) at the same canning facility. Examination of the canning facility in Georgia during the outbreak investigation had identified deficiencies in the canning process. On July 19, the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) issued a press release that announced a recall of chili and certain meat products from the Castleberry canning facility and provided recommendations to consumers. That recall was expanded on July 21 to include additional canned products. A fifth case of botulism potentially linked to one of the recalled products is under investigation in California. This report describes the ongoing investigation by members of OutbreakNet* and others and the measures undertaken to control the outbreak, which is the first outbreak of foodborne botulism in the United States associated with a commercial canning facility in approximately 30 years. Clinicians should be vigilant for symptoms of botulism, including symmetric cranial nerve palsies, especially if accompanied by descending flaccid paralysis. Consumers should not eat any of the recalled chili sauce or other recalled products and should carefully dispose of all recalled products. Information regarding product disposal is available at http://www.cdc.gov/botulism/botulism_faq.htm.

Case Reports

Texas. On July 7, the Texas Department of State Health Services (TDSHS) reported to CDC two suspected cases of foodborne botulism in children who are siblings. On June 29, both patients had onset of illness that progressed to include cranial nerve palsies and symmetric, descending paralysis typical of botulism. The two children initially were evaluated at two different hospitals, where multiple diagnoses were considered. After one child was transferred to the same hospital as the sibling, botulism was identified as the etiology of the shared symptoms. The two children required mechanical ventilation; botulinum antitoxin was requested on the evening of July 7, released by CDC, and administered the next morning. Patient stool and serum specimens, collected 9 days after symptom onset, were negative for botulinum toxin by mouse bioassay. Initial stool cultures did not yield *Clostridium botulinum*.

The children had shared several meals in the days before symptoms began. They had eaten Castleberry's Austex Hot Dog Chili Sauce Original for lunch on June 28. The opened can from this meal had been discarded and could not be located. However, one unopened can of this product, produced on May 7 at the Castleberry's Food Company canning facility in Georgia and purchased at the same time as the discarded can, was found in the children's home. The TDSHS laboratory tested an aliquot from this can using an enzyme-linked immunosorbent assay (ELISA) for botulinum toxin and did not detect toxin. One child remains hospitalized and is on mechanical ventilation. The second child has been removed from mechanical ventilation and begun rehabilitation.

Indiana. On July 11, the Indiana State Department of Health (ISDH) reported to CDC two suspected cases of foodborne botulism in a married couple. The couple had onset of symptoms on July 7. Like the Texas children, the Indiana patients initially were evaluated at two different hospitals, where multiple diagnoses were considered. On July 9, after both were admitted to the same hospital, botulism was identified as the etiology of the shared symptoms. The man and woman were hospitalized with cranial nerve palsies and symmetric, descending paralysis

Castleberry's: 2007 Botulism Recall

typical of botulism and were placed on mechanical ventilation. On July 11, CDC released botulinum antitoxin, and the antitoxin was administered to both patients. Serum samples collected on July 10 were sent to CDC's Botulism Reference Laboratory and received on July 15. On July 16, CDC detected botulinum toxin type A by mouse bioassay in the man's serum sample. Botulinum toxin also was detected by mouse bioassay in the woman's serum sample, but the sample volume was insufficient to determine the toxin type.

During the initial investigation by ISDH, food histories could not be obtained from the patients because of the severity of their illnesses. Local health officials collected several foods from the home of the patients, including an unlabeled, sealed plastic bag of leftover chili mixture from the refrigerator. On July 16, CDC detected botulinum toxin type A by mouse bioassay in the chili mixture. Empty, well-rinsed cans (with no visible signs of food debris) of Castleberry's Hot Dog Chili Sauce Original and chili made by another company were found in the couple's recycling bin. CDC re-rinsed the two cans and tested the rinse water for botulinum toxin by mouse bioassay; both were negative. The label on the Castleberry's Hot Dog Chili Sauce Original can indicated a production date of May 8 and a time of 2:23 a.m., less than 5 hours after the 9:41 p.m., May 7 production time indicated on the can collected from the Texas patients; the Indiana can had been manufactured in the same set of retorts as the Texas can. Both patients remain hospitalized and on mechanical ventilation.

On July 17, CDC OutbreakNet staff members provided information regarding the production dates and times to FDA; the evidence strongly suggested that brands of Castleberry's hot dog chili sauce were the common source of the four cases of botulism. On July 18, FDA issued a consumer advisory. On that same day, after being informed about the outbreak and findings from FDA investigation of the canning facility, Castleberry's Food Company issued a voluntary recall that included limited production dates of Castleberry's Hot Dog Chili Sauce Original, Castleberry's Austex Hot Dog Chili Sauce Original, and Kroger Hot Dog Chili Sauce. That recall was expanded on July 21 to include all production dates for 91 types of canned chili sauce, chili, other meat products, chicken products, and dog food that were manufactured in the same set of retorts as the hot dog chili sauce at the Castleberry's Food Company facility in Georgia. These included Castleberry's brands and products produced by the manufacturer but distributed under 25 other brand names (e.g., Austex, Kroger, and Piggly Wiggly).†

California. On July 25, the California Department of Public Health (CDPH) reported to CDC a case of botulism caused by botulinum toxin type A with a potential link to one of the recalled products. On July 1, several days after reportedly eating a recalled chili product, the patient, a woman, had onset of symptoms that progressed to include cranial nerve palsies and bilateral generalized weakness. She was hospitalized on July 5. On July 7, CDPH released botulinum antitoxin, which was administered to the patient. Botulinum toxin type A was detected by mouse bioassay from a serum sample collected on July 7. The product had been discarded and could not be tested. The patient was hospitalized for 10 days and is now recovering at home. CDPH is continuing to investigate to determine whether the patient's illness was associated with the recalled chili product.

Canning Facility Investigation

The Castleberry's canning facility in Georgia produces both FDA- and FSIS-regulated products. The outbreak investigation by FDA and FSIS identified production deficiencies that might have permitted spores of *C. botulinum* to survive the canning process. *C. botulinum* spores are in the environment and can be present in foods that have not been properly subjected to high temperature and pressure during the canning process. Anaerobic conditions, low acidity (pH>4.6), low salt and sugar concentrations, and temperatures >39.0°F (>3.9°C) allow germination of *C. botulinum* spores and subsequent production of botulinum toxin. FDA officials tested 17 swollen cans of Castleberry's hot dog chili sauce produced on May 8 in the same set of retorts as the cans associated with the Indiana and Texas botulism cases. Sixteen of the 17 cans were positive for botulinum toxin type A by ELISA. Mouse bioassay results were consistent with ELISA findings. Castleberry's Food Company has closed its Georgia canning facility and has hired a firm to help recall products from approximately 8,500 retail outlets.

Reported by: MM Ginsberg, MD, County of San Diego, Health and Human Svcs Agency. L Granzow, MPH, RF Teclaw, DVM, PhD, Indiana State Dept of Health. LK Gaul, PhD, S Bagdure, MD, A Cole, R Drumgoole, Texas Dept of State Health Svcs. Food and Drug Admin. US Dept of Agriculture Food Safety and Inspection Svc. EJ Barzilay, MD, MS Biggerstaff, MPH, MF Lynch, MD, SE Maslanka, PhD, IT Williams, PhD, Div of Foodborne,

Bacterial, and Mycotic Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases; PC Juliao, PhD, C Barton Behravesh, DVM, CK Olson, MD, EIS officers, CDC.

Editorial Note:

In the United States, foodborne botulism usually is associated with home-canned foods. During 1950—2005, local and state health departments reported to CDC 405 events (i.e., single cases or outbreaks) of foodborne botulism in which an implicated food item was identified. Of these 405 events, 371 (92%) were linked to home-processed foods and 34 (8%) to commercially processed foods, including foods prepared in restaurants. Only four of the outbreaks associated with commercially processed foods (i.e., canned tuna, liver paste, vichyssoise, and beef stew) were associated with deficiencies in a commercial canning process. The last such outbreak in the United States occurred in 1974 and was associated with commercially canned beef stew (1). Although rare, any deficiency in the retort canning process is a major public health concern because of the severity of botulism and the widespread distribution of canned products.

Botulism is a nationally notifiable disease. Investigators are actively seeking additional cases that might be linked to the current outbreak by issuing health alerts and examining reported botulism cases dating back to 2005. Clinicians should consider botulism in patients with symmetric cranial nerve palsies, especially if accompanied by descending flaccid paralysis. Suspected cases of botulism should be reported immediately to local or state public health officials, who should then call the 24-hour CDC Emergency Operations Center (770-488-7100); callers will be connected immediately with an on-call CDC botulism specialist. Health-care providers and public health officials are encouraged to inquire specifically about consumption of the recalled canned products as part of the food history of persons with suspected botulism. Additional information regarding this botulism outbreak is available at <http://www.cdc.gov/botulism/botulism.htm>. Consumers should check their homes for any of the 91 recalled products listed by Castleberry's Food Company at http://www.castleberrys.com/news_productrecall.asp. Persons with unopened cans of recalled products should dispose of the cans without opening or puncturing them, as described at http://www.cdc.gov/botulism/botulism_faq.htm.

Reference

- 1 Blake PA, Horwitz MA, Hopkins L, et al. Type A botulism from commercially canned beef stew. *South Med J* 1977;70:5—7.

* A network of public health epidemiologists at the local, state, and federal levels (including employees of CDC, FDA, and FSIS) who investigate foodborne and diarrheal disease outbreaks.

† The recalled products were distributed in 49 of the 50 United States (all states except Alaska). A listing of the 91 products recalled as of July 21 is available at http://www.castleberrys.com/news_productrecall.asp.

Castleberry's: 2007 Botulism Recall

www.fda.gov/oc/po/firmrecalls/castleberry08_07.html

AUG. 1, 2007

Recall — Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Castleberry's Updates Status of National Canned Food Recall

Officials Express Urgent Need for Retailers and Consumers to Identify and Discard Recalled Items

Contact:

Doug McGraw
Fleishman-Hillard
(212) 453-2202

FOR IMMEDIATE RELEASE — AUGUSTA, Ga. – August 1, 2007 – Citing a continuing threat to public health, Castleberry's Food Company is urging retailers, food service operations, food banks, charitable organizations and consumers to be diligent in identifying and discarding canned products subject to Castleberry's national recall.

"Our primary focus is making sure that no potentially contaminated products are on grocery shelves, in peoples' homes or in emergency food supplies," said Steve Mavity, SVP Technical Services/Quality Assurance for Castleberry's. "Surveys by our own audit team, as well as those by inspectors from federal, state and local health agencies, confirm that some retail outlets, especially smaller independent and convenience stores, may still have recalled products available for sale. We are renewing our warning not to sell, open, or consume these products."

Castleberry's voluntarily instituted the recall on July 18 due to the risk of botulinum toxin, a toxin which can cause botulism, a potentially life-threatening illness. The company broadened the scope of its recall on July 21 and has temporarily ceased production in its Augusta, Ga. plant, where it is suspected that there was a processing problem on one of the facility's canning lines. Castleberry's continues to work with the FDA and USDA to identify and correct any production issues.

What Consumers and Retailers Should Do

"Consumers, retailers, restaurants, food pantries and others should reconfirm that all products included in the recall, regardless of best-by date, are immediately disposed of," Mavity said. "Check the product description and can size of products included in the recall and follow disposal instructions communicated by Castleberry's and recommended by governmental agencies. In addition, consumers should notify family members and friends about the recall."

Mavity added, "To strengthen our outreach to smaller independent grocers, gas stations, and convenience stores, we've re-directed all of our direct retailer, distributor and wholesaler customers to contact their respective customers downstream, to ensure they are aware of the recall and follow the proper removal and disposal instructions."

Castleberry's will assist retailers in disposing of the products through Carolina Supply Chain Services (CSCS). The retailer/distributor hotline to arrange for pickup is 1-800- 821-5293. "CSCS will arrange for immediate collection," Mavity said.

In disposing of any cans that remain in homes, or in retail establishments with just a few cans on hand, Castleberry's and health officials are instructing people to double bag the cans in plastic bags that are tightly closed before being placed in a trash receptacle for non-recyclable trash outside of the home. If any of the cans are swollen, bulging or leaking, the consumer should put on gloves and eye protection before double-bagging and disposing of the cans.

Castleberry's: 2007 Botulism Recall

Slowly remove gloves and dispose of them after use. People should then wash their hands with soap and running water for at least two minutes.

Individuals who feel ill after handling or accidentally consuming any of the recalled products should seek immediate medical attention. Symptoms may include general weakness, dizziness, double vision, and trouble speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation are also common symptoms.

There is no need to return cans to stores. For refunds and answers to questions, consumers should contact the consumer hotline at 1-800-203-4412 or visit www.castleberrys.com.

Outreach Efforts Continue

Since the recall was announced July 18, Castleberry's has:

- * Issued public warnings through the news media
- * Established a toll-free hotline for consumers that has handled more than 20,000 calls
- * Posted recall information and guidance on the company's Web site at www.castleberrys.com
- * Instituted a refund program available online or via mail (requiring no return of product to retailers)
- * Deployed recall audit teams to conduct on-site inspections at retail outlets across the country (as of July 31, more than 17,500 stores have been audited)
- * Placed recall advertising in consumer publications
- * Begun an effort to reach Spanish-speaking consumers and retailers (the company's Espanol section of Web site dedicated to Spanish speakers will launch August 1)

www.fda.gov/oc/po/firmrecalls/castleberry207_07.html

JULY 21, 2007

Recall — Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Castleberry's Expands Voluntary Recall of Hot Dog Chili Sauce and Canned Meat Products

Contact:

Doug McGraw, Fleishman-Hillard
(212) 453-2202

FOR IMMEDIATE RELEASE —AUGUSTA, Ga. – July 21, 2007 – Castleberry's Food Company today announced that it is taking extra steps to ensure public safety by voluntarily expanding its recall originally announced on July 18 due to the risk of botulinum toxin, a bacterium which can cause botulism.

Botulism can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

The recall originally announced on July 18 affected only 10 products with 'best by' dates from APR30 2009 through MAY22 2009. ...

Consumers should not use these products even if they do not look or smell spoiled. Consumers with these products should dispose of them by double bagging in plastic bags that are tightly closed before being placed in a trash receptacle for non-recyclable trash outside of the home, according to the Food and Drug Administration. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faqs.htm.

"There is nothing more important to us than the health of those who use our products every day," said Steve Mavity, SVP Technical Services/Quality Assurance for Castleberry's. "We are taking every step necessary, and are working hand in hand with health officials around the clock to ensure the safety of consumers."

Mavity said, "We believe we have isolated the issue to a situation of under-processing on one line of our production facility. As an extra precaution to the recall we announced on Wednesday, we have shut down this line altogether and are recalling all products produced on it."

Castleberry's is working with the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC) to investigate possible contamination of these products.

Castleberry's was notified by the FDA of two confirmed botulism cases and two potential botulism cases involving individuals who ate Hot Dog Chili Sauce products. No new cases have been reported since the recall was announced on July 18.

There have been no reported illnesses linked to Natural Balance canned pet food, but Castleberry's recommends that all these products should be discarded. While botulism can affect some pets, dogs and cats are inherently resistant. The disease has only been seen occasionally in dogs and has not been reported in cats. Ferrets are highly susceptible to botulinum toxin. The incubation period can be two hours to two weeks; in most cases, the symptoms appear after 12 to 24 hours. Botulism is characterized by progressive motor paralysis. Typical clinical signs may include muscle paralysis, difficulty breathing, chewing and swallowing, visual disturbances and generalized weakness may also

Castleberry's: 2007 Botulism Recall

occur. Death usually results from paralysis of the respiratory or cardiac muscles. Pet owners who have used these products and whose pets have these symptoms should contact their veterinarian immediately.

Consumers with any questions should visit Castleberry's Web site (www.castleberrys.com). A toll-free hotline is also available for consumer questions at 1-800-203-4412 or 1-888-203-8446.

www.fda.gov/oc/po/firmrecalls/castleberry07_07.html

JULY 18, 2007

Recall — Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Castleberry's Announces Voluntary Recall of Chili Products

Contact:

Castleberry's Consumer Hotline
1-888-203-8446

FOR IMMEDIATE RELEASE — Augusta, Georgia — July 18, 2007 – Castleberry's Food Company today announced that it is voluntarily recalling the following products: Castleberry's Hot Dog Chili Sauce, 10 oz can (UPC 3030000101), Austex Hot Dog Chili Sauce, 10 oz can (UPC 3030099533), Kroger Hot Dog Chili Sauce, 10 oz can (UPC 1111083942), Morton House Corned Beef Hash, 15 oz can (UPC 7526665830), Cattle Drive Chili with Beans, 15 oz can (UPC 3030001515), Southern Home Corned Beef Hash, 15 oz can (UPC 0788015360), Meijer Corned Beef Hash, 15 oz can (UPC 4125095229), Castleberry's Chili with Beans, 15 oz can (UPC 3030001015), Castleberry's Barbecue Pork, 10 oz can (UPC 3030000402) and Bunker Hill Chili No Beans, 10 oz can (UPC 7526604112).

Castleberry's is working with the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC) to investigate possible contamination of these products with *Clostridium botulinum*, a bacterium which can cause botulism, a life-threatening illness. Botulism can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

This recall only affects the products listed above with a "best by" date of APR30 2009 through MAY22 2009. The "best by" date can be found either on the top or bottom of the can. Consumers who have any of these products should discard them. Consumers should not use these products even if they do not look or smell spoiled. Consumers may return the label to the location where the product was purchased for a full refund.

Castleberry's was notified by the FDA of four potential cases of botulism involving individuals who ate these products. "We are taking this precautionary measure to ensure the safety of our consumers," said Steve Mavity, SVP Technical Services/Quality Assurance for Castleberry's. "We will continue to work closely with the FDA, USDA, and CDC."

Consumers with any questions or concerns about this recall should go to Castleberry's website (<http://www.castleberrys.com>) or call Castleberry's consumer hotline at 1-888-203-8446.

