

# KILLER CANTALOUPE: IGNORING THE SCIENCE BEHIND FOOD SAFETY

## A Science and Democracy Case Study

### *Science Sidelined*

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#### **TOPIC**

**Dismissing Evidence:** A routine farm audit revealed hazardous conditions and the potential for *Listeria* contamination of fresh produce; ignoring this evidence caused premature and preventable deaths.

During the summer and fall of 2011, cantaloupes contaminated with the bacterium *Listeria monocytogenes* originating at Jensen Farms in Colorado caused one of the deadliest foodborne illness outbreaks in U.S. history. Tainted melons sickened 147 people in 28 states, killed 33, and caused one pregnant woman to miscarry (CDC 2012). Just days before the outbreak began, Jensen Farms received a superior rating from a third-party auditor, despite safety hazards the auditor also identified (U.S. House of Representatives 2012). While we have the scientific know-how to better safeguard our food supply, regulatory gaps, insufficient government resources, and conflicts of interest hinder our ability to adequately protect the public.

#### **RELEVANCE**

**Decision Making Without Evidence:** Consumers and the food industry alike suffer when ineffective or nonexistent policies make it impossible for the best available science to prevent contaminated items from entering the food supply.

Food safety is the business of all Americans, even though most of us do not work in the food industry. We all make decisions every day about what foods to eat and what foods to feed our families. We make these decisions based on evidence. For example, we check foods at the grocery store for expiration dates or visible signs of spoilage before buying them, and we throw away the carton of milk in the refrigerator that has developed a bad smell or the head of lettuce turning brown.

Despite this vigilance over the kind of evidence all of us have access to, every year an estimated 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die as a result of foodborne pathogens we cannot detect (CDC 2013b). However, consumer lapses leading to increased growth of disease-causing microbes, such as improperly cooking meat or allowing leftovers to stand at room temperature for too long, only account partially for the prevalence of foodborne illness. Many common pathogens like *Listeria*, *Salmonella*, and *E. coli* that can contaminate foods before they reach our homes cannot be detected by sight, smell, or taste (University of Nebraska-Lincoln 2012). The cantaloupes harboring *Listeria* that caused the 2011 outbreak did not display any evidence to the people who bought them or ate them that anything was wrong.

The evidence necessary to detect the presence of these pathogens or the potential for food to become contaminated with them is not accessible to ordinary consumers because it involves a different kind of data from that which we have access to ourselves, including on-site observations and samples tested in labs. Such data can only be obtained from the locations where the food is produced, processed, packaged, and stored. For this reason, it is important for science-based rules to govern how industry harvests, handles, and inspects food so that those responsible for food at its sources can better determine its safety before it makes its way to markets and kitchens.

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## PREVAILING WINDS/CONTEXT

**Delaying Science-Based Public Policies:** Before the outbreak, the American people, Congress, and the president had demanded better protections to ensure food safety, but implementation of new legislation did not come quickly enough to prevent the 2011 Listeria outbreak.

### *The Food Safety Modernization Act*

On January 4, 2011, President Obama signed into law the Food Safety Modernization Act (FSMA) following a series of serious multistate foodborne illness outbreaks. These outbreaks included a 2009 Salmonella outbreak linked to peanut butter that caused nine deaths and a 2010 Salmonella outbreak linked to eggs that sickened nearly 2000 people (CDC 2012). The new law mandates significant, science-based improvements to existing food safety regulations, including stronger criteria for designating certain produce harvesting and processing facilities as “high risk,” necessitating better inspection and handling procedures (FDA 2012).

Provisions in the FSMA, the first significant revisions to food safety law in 70 years, are aimed at reducing the number of Americans who experience foodborne illness. These provisions emphasize prevention of contamination rather than merely response to it, as was the norm in the past. Among numerous regulations developed to implement the new law, two major rules proposed by the U.S. Food and Drug Administration (FDA) address problems found at Jensen Farms. These rules had been under development for a number of years in anticipation of the FSMA. They were not created overnight in response to the Jensen Farms outbreak, but their development underscores that the produce industry, food safety experts, and federal regulators had been aware for a long time of the need for an overhaul of food safety law.

One rule, referred to as the produce rule, establishes standards for minimizing microbial contamination of produce through better management of water, soil, animals, worker health and hygiene, and facilities and tools, including requiring that “all agricultural water be safe and of adequate sanitary quality for its intended use” (FDA 2013c). One of the problems at Jensen Farms the auditors identified but for which they did not deduct points on the score was nonuse of an antimicrobial solution in the water used to rinse the melons before putting them into cold storage. Since this practice was not mandated by regulations at the time and only encouraged by guidelines, accepted practices for such audits allowed auditors to note the deficiency but not deduct points from the score.

The other proposed FDA rule requires produce facilities to have written hazard-reduction plans in place that identify potential food contamination hazards and actions necessary to prevent them, specify monitoring procedures, and establish corrective steps for problems when they do arise (FDA 2013b). Another problem found at Jensen Farms was that the owners demonstrated a lack of understanding of contamination hazards, actions necessary to prevent them, and the appropriate authority to consult that could best provide advice on improvements (U.S. House of Representatives 2012).

Although the FSMA had passed months before the 2011 listeriosis outbreak began, lengthy and complex federal rulemaking procedures stalled implementation. The proposed FDA rules were not made available for public comment until January 4, 2013, a full two years after the law was passed and nearly four years after the FDA had first issued draft guidelines; it will be many more months before these rules are finalized and several years before the industry is held fully accountable to them (FDA 2013c). Since guidelines are not the same as regulations, Jensen Farms and its third-party auditors were able to continue to compromise food safety following the original 2009 issuance of the FDA’s draft guidelines on best practices for melon growing because—as the auditors testified at their briefing to House Energy and Commerce Committee staff—neither they nor Jensen Farms had violated any existing regulations (U.S. House of Representatives 2012).

### *Responses and Consequences*

A twenty-first century food system demands science-based rules that both protect food throughout its journey from farm to table and ensure the stability of an increasingly centralized industry. Comments on the FDA's 2009 draft guidance anticipating FSMA from "a majority of stakeholders," including farmers, producers, consumers, and industry "supported a food safety system grounded in science" and stated that "regulations developed should be science-based" (FDA 2013e). The FSMA also received largely bipartisan support in Congress because it is aimed at meeting stakeholders' needs. Senator Kay Hagen (D-NC) stated she supported FSMA because it "strikes the right balance between preventing food-borne illnesses and ensuring our nation's farmers can stay in business." Senator Richard Burr (R-NC) stated, "I voted in support of S. 510 ... because I believe it is important that we modernize and update our approach to food safety to address issues that stem from our increasingly global food supply" (Make Our Food Safe 2011).

Indeed, with the increasing centralization of food production, businesses need a regulatory apparatus in place that protects their profits by protecting the safety of their products. Food recalls resulting from foodborne illness outbreaks cost the industry millions of dollars, and industry trade groups, therefore, have also largely supported FSMA (Make Our Food Safe 2011). Ideally, corporate culture should reinforce the importance of good laws. According to Bob Whitaker, chief science and technology officer at the Produce Marketing Association, "the best science in the world won't stop consumers from being sickened and could result in our businesses being ruined until we create a culture within our operations that serves as a guidepost to everyday decisions" (Whitaker 2011).

However, while such a culture was clearly absent from Jensen Farms and the third-party auditing companies it employed, better regulations, in this case, potentially could have prevented sickness, death, and ruined businesses by strengthening the decision-making process. Following its investigation, the FDA concluded that had Jensen Farms simply followed the agency's existing 2009 guidelines, the contamination would not have occurred in the first place (U.S. House of Representatives 2012). But at the congressional briefings following the FDA investigation, neither the owners of Jensen Farms nor the auditors conceded any wrongdoing. The auditors stated they "did not deduct from the score if FDA guidance was not being followed" because "guidelines are opinions ... regulations are law" (U.S. House of Representatives 2012). Since FDA guidelines did not bear the legal authority of regulations, the Jensens, their auditors, and the buyers and retailers they supplied were able to replace advice from a government agency tasked with protecting American food safety with their own short-term, self-interested, and, misguided objectives.

Consequently, the industry as a whole—not just the owners of Jensen Farms or the victims of their killer cantaloupes—suffered because appropriate regulations had not served to guide the series of poor decisions made by multiple parties that led up to the outbreak. While FDA investigators traced the source of the outbreak quickly to one farm in one state, consumption of cantaloupes dropped nationwide by 53 percent in response to consumers' concerns about where the cantaloupes in their local grocery stores had come from (Marcum 2012). Jensen Farms voluntarily recalled their cantaloupes immediately following release of the FDA's audit results conclusively tying the outbreak to Jensen Farms in mid-September (FDA 2011b), but California's Central Valley—known as the Cantaloupe Center of the World because it produces 90 percent of summer-harvested cantaloupes in the U.S.—was especially hard hit by the drop in demand. Since consumers who had trusted the U.S. food safety system to protect them had gotten sick and died, public uncertainty about food safety increased, which resulted directly in cantaloupe industry losses. Although the source of the outbreak was more than a thousand miles away, Central Valley growers lost revenue, laid off workers, and had to leave perfectly good melons to rot in their fields (Marcum 2012). Eric and Ryan Jensen, the owners of Jensen Farms, were themselves defendants in numerous personal injury and wrongful death lawsuits following the outbreak and were compelled to file for bankruptcy in May 2012 (Booth 2012).

## TIMELINE

**The Growing Problem of Foodborne Illness Outbreaks:** Multistate foodborne illness outbreaks have been increasing in recent years; legislative progress to prevent them has been slow to catch up.

Local and state health authorities are the primary investigators of foodborne illness occurring exclusively within their jurisdictions. Such cases account for the majority of foodborne illness in the U.S. (CDC 2013a). However, every year, the U.S. Centers for Disease Control and Prevention (CDC) collect data about multistate outbreaks. While *Listeria* is less common than *Salmonella* or *E. coli*, it has caused some of the deadliest foodborne illness outbreaks on record. Two of these were multistate outbreaks, including the 2011 one traced to Jensen Farms, which was also the second deadliest foodborne illness outbreak of any kind to occur since 1924 (Silk 2012). The table to the right shows a timeline of outbreaks occurring in recent years.

## ACTORS AND LEVERS

**Unclear rules, unclear roles:** Industry, third-party auditors, and the absence of government oversight all contributed to the outbreak, but no one admitted responsibility.

In this story of science-and-democracy-gone-wrong, a lack of readily available information about the latest methods of handling cantaloupes, lack of clarity about who to turn to as an authority on food safety improvements, lack of effective regulatory structures, conflicts of interest at varying points along the chain of quality control, and just plain ignorance about common sense health and hygiene practices all contributed to the multiple lapses in judgment and poor decision making that produced killer cantaloupes.

While it is easy to view the Jensen brothers as the obvious villains in this case, doing so would be an oversimplification. Whether they were cutting corners to save costs, knowingly taking negligent actions, or were merely bad managers with a poor understanding of their business and best food safety practices remains unclear. Due to ongoing lawsuits, they have not spoken out much, but their briefing to House Energy and Commerce Committee staff, as well as local media reports about the outbreak's effect on the community, suggests their role was more complex. Scapegoating them creates the illusion that the conditions at Jensen Farms were an industry anomaly and prevents the closer scrutiny of industry-wide problems that merely came to a head at Jensen Farms.

## Jensen Farms

Jensen Farms is located near the small town of Holly, population 800, in southeastern Colorado. While a large-scale, 6,000 acre operation that was growing around 40 percent of the cantaloupes from this region at the time, Jensen Farms was also a family business the brothers appeared to take pride in (DenverChannel.com 2011). When Ryan and Eric Jensen inherited the business from their father, they continued as the third generation of Jensens to run it (FDA 2011b). Like their predecessors, they grew alfalfa, wheat, pumpkins, onions, corn, and other crops, along with cantaloupes (Mora 2011).

Having grown up on the farm, the brothers were hardly strangers to producing melons, which Jensen Farms had done for 20 years (U.S. House of Representatives 2012). They labeled their cantaloupes "Rocky Ford" after the eponymous town some 70 miles away. The label "Rocky Ford" is associated with the sweetness of the region's melons (Banda 2011). In September 2011 when FDA

	Multistate Outbreaks	Legislation
2007	6 outbreaks. 884 victims. Worst sickened 654 in 20 states.	
2008	4 outbreaks. 1570 victims. 2 deaths. Worst sickened 1442 in 43 states	
2009	5 outbreaks. 1070 victims. 10 deaths. Worst sickened 714 in 46 states, killing 9.	FDA issues draft guidance on safety standards for "high risk" foods, including fresh produce.
2010	10 outbreaks. 2615 victims. Worst sickened 1939 in 11 states.	
2011	12 outbreaks. 701 victims. 34 deaths. Worst sickened 147 in 28 states, killing 33.	President Obama signs Food Safety Modernization Act into law January 4.
2012	11 outbreaks. 1120 victims. 8 deaths. Worst sickened 425 in 8 states.	Microbiological Data Program eliminated.
2013	3 outbreaks as of April 1. 150 victims. Worst sickened 128 in 13 states.	FDA releases proposed rules for public comment on January 4.

investigators pinpointed Jensen Farms as the source of the contamination, the brothers were cultivating 480 acres of the crop and expecting a seasonal yield of some 300,000 crates, each of which would have contained between five and 15 melons (Mora 2011). By local accounts, Jensen Farms was a respected community fixture; before the outbreak, Holly's residents would regularly stop by to pick up cantaloupes and other produce fresh from the fields. Juanita Ortiz, who had lived in the area her entire life, reported she and her husband "would eat a cantaloupe every day from Jensen Farms" (Flener 2012). As the outbreak unfolded, Holly locals were stunned to find it had originated with their neighbors (Banda 2011).

Jensen Farms had no prior record of food safety problems, but while no reports of problems with the produce itself existed, a year before the outbreak, third-party auditors had identified the potential for such problems to occur. In 2010, Jensen Farms received a score of 95 percent on its audit by Jerry Walzel, president of the third-party auditing company Bio Food Safety, "despite finding several major and minor deficiencies" (U.S. House of Representatives 2012). Following this audit, the brothers expressed an interest in fixing the problems Walzel had identified and improving the safety of their business. Walzel had done consulting work for them in the past, and they turned to him again following the 2010 audit. Upon Walzel's advice, the Jensens replaced an old and inefficient hydro cooler they had been using to wash and prepare the cantaloupes for cold storage with a different though even less viable type of produce-processing machine they bought from a local secondhand farm equipment dealer. The replacement equipment, a spray/bar roller system, was not intended for processing melons at all. It had been designed and previously used for potatoes, which have different decontamination needs (U.S. House of Representatives 2012).

### *Conflict of interest*

Third-party auditors like Walzel operate under an inherent conflict of interest. Growers like the Jensens must pay third-party auditors to produce a report verifying the quality of their produce for distributors and retailers. In this case, Frontera Produce, which distributed the Jensens' melons to Wal-Mart and other major retailers, required audits as a condition of doing business with growers. But Frontera also required the growers to foot the bill for the audits, which creates a conflict of interest between the growers, who need a good audit score, and the auditors, whose business depends on payment for performing audits.

Bill Marler, a leading food-safety attorney who represented victims of the Jensens' cantaloupes, explains the problem this way: "A private auditor is not going to list a farm's flaws, tell it to shut down, then say, 'I finished my audit — can I have my \$2,000?'" (Booth and Brown 2011). When growers pay, the value of the audit as a measure of quality control diminishes, along with the creation of the conflict of interest. Caroline Smith DeWaal, food-safety director at the Center for Science in the Public Interest argues, "For an audit to be truly meaningful, the auditor should be paid by the company that is the potential purchaser [of the produce]" (Weise 2010).

At Jensen Farms—and perhaps in many cases in which growers receive high scores despite deficiencies—there was another twist. Bio Food Safety's audits in both 2010 and 2011 did note vulnerabilities at Jensen Farms, even though these did not cause point deductions. And the Jensens did take some action to correct problems, although it was the wrong action. Having better regulations in place could have made a difference, and the good news about the FDA's proposed produce rule is that once finalized, the argument Jerry Walzel and the Jensens made about having violated only guidelines and not regulations would not hold up because the FDA's Guide to Minimize Microbial Food Safety Hazards of Melons (FDA 2009) and other draft guidance will have become law.

But regulatory effectiveness depends on enforcement and compliance, and the bad news about the proposed produce rule is that the unofficial role of third-party auditors as the primary overseers of the industry will remain largely unchanged. And since growers—rather than distributors and retailers—will likely still be paying for annual or seasonal audits themselves, the conflict of interest between growers and auditors remains unchanged, as do the related gaps in accountability created when buyers and retailers do not demand that their growers meet regulatory standards. Although FDA inspection will play a role, the FDA states in the text of the proposed rule, "We anticipate that compliance will be achieved primarily through the conscientious efforts of farmers, complemented by the efforts of State and local governments, extension services, private audits and certifications, and other private sector supply chain management efforts" (FDA

2013e). The Jensen Farms case illustrates how poorly these other means of achieving compliance hold up under the limitations inherent in the third-party auditing system.

Conflicts of interest and their related problems of accountability persist despite widespread awareness of their existence within the industry and among its critics because, as the FDA itself acknowledges, its “inspection resources are very limited ... in relation to the number of produce farms and the many other food production, processing and storage settings for which FDA has regulatory responsibility” FDA 2013e). Simply put, the agency lacks the funds and the personnel to adequately oversee all the facilities under its jurisdiction. Despite the inspection mandate, it is unclear how well the agency will be able to fulfill inspection obligations. The number of available inspectors relative to the number of facilities they must inspect paints a bleak picture: Approximately 1,000 FDA inspectors must cover approximately 421,000 produce facilities. By contrast, the USDA employs around 7,000 inspectors for some 7,000 slaughterhouses and poultry facilities (Estabrook 2012).

Third-party auditors like Primus Labs and Bio Food Safety, no matter how rigorous their audits nor how good their intentions, have no power to do anything about the problems they find besides point them out. Without effective regulations that can be routinely enforced, it is ultimately up to growers, buyers, and retailers to take steps independently to mitigate food safety risks based on the information they get from auditors. And although FSMA does give the FDA the authority now to issue mandatory recalls, the agency can only do so if it has accurate and timely information. Even though the FDA will, in theory, be conducting inspections every three years itself, there is no guarantee the third-party audit system will work any better than it has thus far.

Critics of the third-party auditing system contend that retailers are effectively misusing audits as a buffer between themselves and their growers, relying on them as a mechanism for deflecting responsibility rather than ensuring quality. Retailers have their own sets of standards that inform what conditions have to be met before they will stop buying from any given grower, and “It is not clear that if the FDA report [on conditions at Jensen Farms] had been transcribed word for word by the auditor and added as an addendum to his audit, this would have caused Wal-Mart to stop buying” (Prevor 2011). Put another way, without appropriate regulations in place that can be effectively enforced, retailers, buyers, and growers may choose not to take the necessary but perhaps more costly steps to mitigate food safety risks.

The conflicts of interest and accountability built into the system as the result of growers bearing the burden of cost persist because too many retailers see little incentive to reform the current system; it generally works in their favor even when it permits unsafe foods to reach their customers. If retailers took responsibility for the cost of audits, they could also be held accountable for the results, but market forces alone have not exerted enough pressure on companies to change. Many simply find it more cost effective to shift responsibility to growers, despite the risks. Wal-Mart, for example, had to recall a few shipments of bad melons, but in the fiscal year ending January 31, 2012, the company’s total net sales had increased over the previous year by 5.9 percent—hardly a fruitless return (Wal-Mart 2012); the Jensen brothers, by contrast, went bankrupt and lost their family’s business.

Some major retailers have had a longstanding reputation for being responsible about how they handle food safety oversight through third-party delegation. For example, Kraft Foods and Costco, “use detailed plans to prevent food safety hazards” and “supplement third-party audits with their own inspections and testing of ingredients and plant surfaces for microbes” (Prevor 2011). But these are the exceptions, not the norm. For the foreseeable future, compliance with the FDA’s new rules will continue to depend significantly on the flawed oversight capacity of third-party audits.

### ***Bad decisions, poor guidance, lethal and costly results***

In the Jensens’ case, the existing conflict of interest was amplified by the brothers’ request for additional advice. While Walzel had noted “deficiencies” at Jensen Farms in his audit, it may have served his firm’s interests better to suggest to the brothers quick, easy, relatively inexpensive, and ultimately inadequate actions when they asked for his advice rather than more difficult and costly solutions that actually would have improved the safety of their business. In contrast to Walzel’s recommendations, the name “Rocky Ford” has, since the outbreak, been trademarked in an effort by area cantaloupe growers adversely affected but not involved in it to rebrand their product and rebuild their businesses. These other growers banded together and

invested some \$800,000 in safety upgrades to their equipment and hired a full-time food safety manager (Wyatt 2012). The Jensens may not have been willing or able to invest in similar upgrades, and Walzel may have feared the cost to his own business if he suggested more expensive fixes. Or perhaps he was simply uninformed.

Either way, the upshot was that Walzel gave the Jensens bad advice. The old hydro cooler he cited as problematic had relied on recirculated water, which created the possibility of bringing contaminants from the field or initial processing area into the storage area, despite the use of an antimicrobial solution being added to the water in 2010 (Prevor 2011). This was certainly something that needed to be changed. However, the used potato-processing equipment the Jensens replaced it with—already dirty and corroded when they bought it—was impossible to clean adequately for the safe processing of melons (U.S. House of Representatives 2012). To compound the problem, the Jensens dropped their use of a chlorine solution with the implementation of the potato-processing machine because this equipment used one-pass, fresh water rather than re-circulated water like the hydro cooler. While the use of a chlorine rinse had been cited positively by Walzel in the 2010 audit, the 2011 audit, performed in July by a different employee of Bio Food Safety just days before the outbreak began, noted that the antimicrobial wash was no longer used.

In 2009, the FDA’s draft guidance anticipating FSMA had included recommendations to the produce industry on how “to minimize the risk of foodborne illness from melon production and distribution” (U.S. House of Representatives 2012). While the Jensens’ nonuse of an antimicrobial wash was universally denounced in general media coverage of the outbreak as a violation of common sense and an egregious failing on their part, the FDA’s guidance, in fact, made “no mention of any requirement for antimicrobial usage in single-pass or non-recirculating systems” (Prevor 2011). The guidance does mention “dump tank water” needing to be “of sufficient microbial quality for its intended use” and “Validating and verifying that melon wetting and brushing operations are not a potential source of melon contamination or cross-contamination” (FDA 2009). But it does not indicate how exactly this is to be done or what specific equipment to use or avoid. Water disinfectant added to dump tanks is also discussed, but the purpose of the disinfectant “is not to clean the melons but rather to prevent the water from becoming contaminated should pathogens be introduced into the water from melons” (FDA 2009).

Since the spray/bar roller system the Jensens were using did not involve dump tanks or water that had previously come into contact with other melons, they may well have thought they were within FDA guidelines when they discontinued use of the chlorine solution, without being aware that their equipment itself was not appropriate for handling cantaloupes. And Bio Food Safety later pushed back against the authority of FDA guidance, which “represent[s] the FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public” (FDA 2009). Walzel defended the score of 96 percent Jensen Farms received in 2011 as being in line with standard—if not best—practices (U.S. House of Representatives 2012).

Many questions about what happened at Jensen Farms remain unanswered: Did the Jensens understand the inherent conflict of interest in the auditor-client relationship? Why were these third-generation farmers apparently unaware of the proper equipment and facility needs for processing the melons their family had been growing for two decades? Why did they stop using the antimicrobial wash? And why—in the absence of stricter regulations—did the FDA not at least provide stronger, more explicit guidance on how to keep contaminants off of cantaloupes? Answers to these and other questions are a matter of speculation, but what is clear is that while the Jensens—as the growers—were the primary party responsible for the quality of their produce, there is plenty of blame to go around.

### *Third-party audits vs. FDA inspections*

While not required by the FDA, third-party audits of growers are commonly requested by retailers or by distributors themselves and are conducted according to standardized sets of scoring parameters that determine pass/fail status and note any deviations from industry norms—or, in some cases, best practices—as a means of assuring quality along the supply chain. Frontera Produce—the company Jensen Farms engaged to coordinate placement of their melons at major retailers—employed Primus Labs as its primary auditing company at the request of the retailers it supplied. Primus Labs is a major, California-based food

safety auditing company that conducts, in collaboration with subcontractors like Walzel's Bio Food Safety, approximately 15,000 audits a year worldwide (U.S. House of Representatives 2012).

Although audits and inspections were frequently referred to interchangeably in much of the general press coverage of the Jensen Farms outbreak, the distinction between audits and inspections is an important one. An inspection is "an assessment at a 'moment in time' which identifies positive and negative conditions" and is "structured to initiate immediate corrective action, when it is required" (AIB 2013). The key point to note about inspections is that they emphasize action. An inspector identifies problems. The business under inspection is supposed to—and sometimes required to—fix them promptly. For example, U.S. Department of Agriculture (USDA) inspections assessing regulatory compliance in the meat industry carry significant authority and can lead to facility shutdowns.

At the time of the Jensen Farms outbreak, the FDA did not require or conduct routine inspections of the produce industry, and the industry did not routinely engage third-party entities to conduct them (in contrast to the audits discussed below). Nor did the FDA require regular sampling and recordkeeping to track potentially problematic patterns. A positive step resulting from passage of the FSMA is that the FDA now has an inspection mandate: the FSMA "calls for all high-risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that" (FDA 2013d).

Additionally, the FDA's 2013 proposed rule on produce standards includes provisions for additional inspection and testing of water that produce could be exposed to, a major problem at Jensen Farms. This proposed rule, which governs standards for the growing, harvesting, packing, and holding of produce for human consumption would "require that, at the beginning of the growing season, the agricultural water system components under a farm's control be inspected to identify conditions that are reasonably likely to introduce pathogens to produce or food-contact surfaces." Further, the FDA is proposing that "specific criteria for the quality of agricultural water be established for water that is used for certain purposes, with proposed requirements for periodic analytical testing" (FDA 2013e). The [full text of the proposed rule](#) lays out these criteria and requirements.

In theory, the results of these future inspections would prompt immediate corrective action to prevent contamination, such as that which occurred at Jensen Farms, before it causes an outbreak. Newly required recordkeeping would document the evidence of good or bad practices. But the water quality inspections themselves would still be carried out routinely by the produce growers or by third-party entities. Overshadowed by its budget constraints, the FDA expects to "facilitate compliance through education, technical assistance and regulatory guidance," rather than seasonal or even annual FDA inspections (FDA 2013c).

An audit, by contrast, is "A systematic evaluation to determine if programs and related activities achieve planned expectations." If such expectations are not achieved, an audit provides "potential assistance in identifying root cause[s], which can lead to long term corrective action" (AIB 2013). According to experts familiar with the process, "The rigor of audits varies widely and many companies choose the cheapest ones, which cost as little as \$1,000, in contrast to the \$8,000 the Food and Drug Administration spends" (Moss and Martin 2009). The key point to note about audits is that, no matter how rigorous, they emphasize assessment rather than action with the goal of long-term, gradual improvement rather than immediate remediation.

As appalling as the Jensen Farms' high audit scores may appear to those unfamiliar with the food industry relative to the numerous deficiencies the auditors noted, Bio Food Safety had not strayed from standard practices for audits at all. These were simply "to assess whether the client's operations are in compliance with current baseline industry standards—not to improve those standards or push a client towards best practices" (U.S. House of Representatives 2012). Growers can choose to make improvements based on what the auditors find, but they are under no pressure or obligation to do so unless a distributor or retailer requests changes as a requirement of continuing to do business. And no matter what conditions third-party auditors find, they have no authority to close a business or issue a recall.

Both the 2010 and 2011 audits Bio Food Safety performed at Jensen Farms were not comprehensive ones, and Frontera Produce has since worked with NSF International, a leading provider of more rigorous audits, to improve the way it interacts with auditors and responds to their evaluation of growers (U.S. House of Representatives 2012). It remains unclear why Frontera was not already requiring more comprehensive audits since it supplied produce to Wal-Mart. In December 2007, Wal-Mart had become the first major U.S.

retailer to make a commitment to [Global Food Safety Initiative \(GFSI\) certified audits](#) for its produce, the gold standard for third-party audits (Wal-Mart 2008). However, as this case illustrates, the type of audit growers get ultimately matters if, in the absence of regulations or FDA enforcement capability, retailers, distributors, and growers can choose to ignore the results rather than take appropriate actions.

### **BREAKTHROUGH/TIPPING POINT**

**The Right to Timely, Accurate Scientific Information about Food Safety:** News stories about Listeria victims dying agonizing deaths temporarily raised public awareness about food safety but did little to generate actionable concern about underlying problems.

Relative to other foodborne illnesses, such as Salmonella and E. coli, Listeria is both an uncommon and particularly nasty infection to get. Only a few thousand cases are estimated to occur in the U.S. each year, yet Listeria is one of the leading causes of death from foodborne illness (FDA 2013a). Healthy people may experience only mild to moderate gastrointestinal symptoms. Some people may even fight off the bacteria before it manifests any symptoms at all. But for adults over 50, young children, pregnant women, individuals with compromised immune systems, and other high risk groups, a Listeria infection can become invasive, spreading beyond the gastrointestinal system to attack the blood, nervous system, lungs and other organs.

Compared to a less than one percent death rate for Salmonella and three to five percent for E. coli, Listeria kills an estimated 15 to 30 percent of all its victims, with fatality rates skyrocketing to between 50 and 70 percent for those cases in which septicemia or meningitis develops (FDA 2013a). Given these statistics, it is not surprising so many news stories throughout the fall of 2011 highlighted the outbreak's rising death toll, the pain and suffering victims experienced as they died in shock and organ failure, and the terror of their families as they helplessly watched loved ones become so sick so quickly from something so ordinarily sweet, delicious, and healthy as fresh cantaloupe.

Many such stories did bring up third-party audits and problems with regulatory oversight in passing, but a general lack of investigative depth in mainstream (as opposed to trade and public health) coverage hints at confounding factors journalists face when reporting on food safety. The shock value of a high death toll coupled with a food safety "first"—Listeria had never been linked to cantaloupes before—had the potential to generate public outrage over a flawed oversight system. Instead, people got angry at the Jensens and their auditors, stopped buying cantaloupes, even when they had obviously not come from Jensen Farms, and became more concerned than they otherwise would have been over a mild stomachache not even preceded by the eating of cantaloupe.

Many less deadly, less dramatic multistate foodborne illness outbreaks go relatively unnoticed by the media and the public. Reporting more on the increase in the occurrence of these outbreaks could have helped contextualize the Jensen Farms outbreak as part of a trend rather than an anomaly, but the public often hears little more than a passing recall announcement about these events. Helena Bottemiller, an experienced food safety writer, explains that a lack of transparency at federal agencies may be one reason why the public knows less about the pattern of outbreaks than journalists may want to report: "It [...] can be challenging to get access to the scientists and policymakers who have the most knowledge about newsworthy events, like major recalls, multistate outbreaks, or policy change" (Bottemiller 2013a).

Journalists could play a key role in driving a public call for action on better food safety policies, but they need timely access to scientists and scientific information at the FDA, CDC, and other agencies involved in the tracking and investigation of outbreaks so that they can help inform public opinion and decision making. If the public doesn't see a problem with food safety—or if they only see one unusual incident rather than a pattern of incidents that suggests a much larger problem—they will ignore the issue after short-term concern during a major outbreak has subsided, and their elected officials will ignore it, too. The following chart summarizes statistics about recent multistate foodborne illness outbreaks. Some of them may be familiar, like the 2009 Salmonella outbreak linked to peanut butter and the Peanut Corporation of America, but it is the overall trend that is most disturbing and which should more effectively and prominently contextualize reporting on major outbreaks.

*FIGURE: Summary of Multistate Foodborne Illness Outbreaks 2007-2012 (CDC 2013a)*

	<i>Salmonella</i>			<i>E. coli</i>			<i>Listeria and other</i>		
	Cases	Deaths	Sources	Cases	Deaths	Sources	Cases	Deaths	Sources
<b>2007</b>	824	0	Peanut butter, frozen pot pies, Veggie Booty (snack food), dog food	61	0	Frozen beef patties, frozen pizza	0	0	n/a
<b>2008</b>	1,521	2	Peppers and tomatoes, cantaloupe, Malt-O-Meal	49	0	Ground beef	0	0	n/a
<b>2009</b>	949	9	Peanut butter, alfalfa sprouts	121	2	Prepackaged cookie dough, ground beef	0	0	n/a
<b>2010</b>	2,642	0	Eggs, black and red pepper, deli meats, alfalfa sprouts, frozen chicken and rice entrée, frozen fruit pulp, Restaurant Chain A	92	0	Cheese, ground beef, shredded lettuce	0	0	n/a
<b>2011</b>	970	1	Chicken livers, ground turkey, frozen turkey burgers, papayas, pine nuts, alfalfa and spicy sprouts, ground beef, cantaloupe, frogs, chicks and ducklings, microbiology labs	82	0	Lettuce, bologna, hazelnuts,	<b>153</b>	<b>34</b>	<b>Cantaloupe, sprouts</b>
<b>2012</b>	1,719	3	Peanut butter, beef, dog food, mangoes, cantaloupe, raw tuna, Restaurant Chain A, live poultry, small turtles, hedgehogs	80	1	Spinach, sprouts, unidentified source	<b>22</b>	<b>4</b>	<b>Ricotta cheese</b>

### WEIGHT OF THE EVIDENCE

**The Science Was Clear:** Once FDA, CDC and state and local investigators had collected and considered the science-based information about the conditions on Jensen Farms and, they quickly determined how the contamination had occurred.

In late August 2011, officials at the Colorado Department of Public Health and Environment (CDPHE) became concerned when seven cases of *Listeria* were reported within just a few days of each other. To figure out whether the patients all had the same strains of *Listeria* as a first step in determining if their illnesses were coincidental or the start of an outbreak, the CDPHE contacted the CDC on September 2. To answer the CDPHE's questions, the CDC engaged PulseNet, a national network of local, regional, and federal agency laboratories coordinated by the CDC to perform molecular subtyping, also known as "fingerprinting," of the pathogens that cause foodborne illness. Just four days later, data from PulseNet revealed that, indeed, all seven Colorado residents had the same strains of *Listeria* and that, additionally, these were the same strains identified in one *Listeria* case in Nebraska and another in Texas (CDC 2011).

After careful review of what all the victims had eaten in the days and weeks before they got sick, cantaloupe emerged as the one common food item. On September 8 and 9, CDPHE enlisted the assistance of the FDA, and both agencies collected cantaloupe samples from retail locations where victims said they had purchased them. The distribution chain linked all of these locations to Jensen Farms. On September 10, FDA investigators visited Jensen Farms for an initial facility inspection to collect samples of water, surfaces, and equipment with which cantaloupes came into contact in the processing and packing areas, along with more cantaloupe samples. Preliminary testing caused CDC and FDA officials enough concern to issue statements warning high risk individuals nationwide not to consume cantaloupe with Jensen Farms or Frontera Produce labels. On September 14, Jensen Farms voluntarily recalled all its cantaloupes, and on September 19, FDA

scientists confirmed that 13 of the 39 samples taken tested positive for *Listeria*. The *Listeria* strains found in these positive samples all matched the outbreak strains (FDA 2011a).

In order to better understand how *Listeria* had contaminated the cantaloupes, particularly since this was the first known instance of *Listeria* contamination not only of cantaloupes but of a raw fruit or vegetable agricultural commodity of any kind, FDA scientists returned to Jensen Farms for a full environmental assessment on September 22-23. The environmental assessment was conducted by a multi-disciplinary, multi-agency team of scientists with “expertise in produce safety, agriculture, veterinary medicine, epidemiology, microbiology, environmental health, and sanitation from FDA, the Colorado Department of Public Health and Environment, the Colorado Department of Agriculture, and Prowers County Department of Health” (FDA 2011a).

The group of investigators used Good Agricultural Practices (GAPs)—the same ones behind the FDA’s 2009 draft guidance for produce that was dismissed, ignored, or misunderstood by the Jensens and Bio Food Safety—to inform their evaluation of conditions on the farm and their hypotheses of what had happened. They examined water, soil, growing and harvesting practices, animals, land use, employee health and hygiene practices, facility and equipment design, sanitizing practices, and the washing, drying, cooling, storing, and transporting of cantaloupes. They also interviewed the Jensens and their management team (FDA 2011a).

On October 19, scientists announced their findings publicly. Since reservoirs of *Listeria* are typically found in damp areas with a presence of ruminant animals and rotting vegetation, investigators expected they would trace the source strain to the growing fields. However, while they never conclusively ruled out field contamination, no field samples of water, soil, or cantaloupes tested positive. Investigators did discover strong evidence that contamination had occurred in the packing facility. How the *Listeria* got there in the first place remains uncertain, though a truck that routinely travelled between the packing facility and a nearby cattle facility could have introduced it (FDA 2011a).

Once the bacteria had been introduced, three factors contributed to its growth and introduction to the cantaloupes: poor facility design, inappropriate equipment, and flawed postharvest practices (FDA 2011a). Of these factors, equipment design has already been discussed. In essence, the used potato-processing machine the Jensens retrofitted to use with cantaloupes “appeared to be un-cleanable, and dirt and product buildup was visible on some areas of the equipment, even after it had been disassembled, cleaned, and sanitized. Corrosion was also visible” (FDA 2011). Samples confirmed the presence of the outbreak strain of *Listeria* on this equipment.

In addition to inappropriate equipment, poor facility design allowed water to pool on the floor below the processing equipment. Since cool and wet environments can harbor *Listeria*, it is possible this aspect of facility design contributed to the contamination. Investigators also noted that the floor was impossible to clean adequately because a drainage area was inaccessible.

Lastly, the cantaloupes were not pre-cooled before they were placed into cold storage. This is an important postharvest practice. When cantaloupes still warm with heat from the fields are placed directly into cold storage without a pre-cooling stage to remove moisture, condensation occurs. If *Listeria* is present, condensation creates ideal moist and cool conditions for the bacteria to grow. Unlike other foodborne pathogens, *Listeria* thrives under refrigeration. Investigators concluded that “contamination occurred in the packing facility” and “proliferated during storage” (FDA 2011a).

## **OUTCOME**

**Uncertain Future:** Science-based reforms mandated by the FSMA and following from the Jensen Farms outbreak are important and should be implemented as quickly as possible, but it remains to be seen whether these reforms go far enough to prevent future outbreaks.

The speed and effectiveness demonstrated by scientists in linking the outbreak strains of *Listeria monocytogenes* to Jensen Farms and determining the factors there that contributed to the contamination illustrate that the knowledge to prevent such outbreaks exists. However, in the case of the Jensen Farms killer cantaloupes, this knowledge was deployed responsively rather than proactively. A primary goal of the FSMA is to shift the emphasis of food safety measures from responding to problems to preventing them. By transforming the FDA’s draft guidelines into binding regulations in the form of the proposed produce rule,

the FSMA takes food safety a positive step in the right direction, but, as the Jensen Farms case illustrates, delays in implementing this law have already had deadly consequences. The produce rule is not something the FDA dreamed up overnight upon the 2011 signing of the FSMA but has been nearly a decade in the making (FDA 2013e). How much longer do the American people have to wait before this rule is finalized and the industry is held accountable?

One positive, direct outcome of the Jensen Farms outbreak, above and beyond the new—if still too infrequent—FDA inspections to begin upon finalization of the produce rule, is that the FDA will be conducting a series of additional inspections of cantaloupe facilities during 2013 “to assess the current practices by this segment of the produce industry and to identify insanitary conditions that may affect the safety of cantaloupe destined for distribution to consumers” (FDA 2013f). In a public letter announcing these inspections, the FDA reiterates to the industry the importance of following its existing guidelines on melon growing and consulting additional sources, such as state and local experts and industry educational materials. While the letter assures growers that the FDA wants to collaborate on food safety, it also warns, “in the event of adverse findings, we will take action as needed to protect the public health” (FDA 2013f).

As reassuring as this increased attention to the cantaloupe industry may seem, the public and policymakers should not forget that the Jensen Farms outbreak was the first time *Listeria* had ever been linked to cantaloupes. Although such attention may prevent a future outbreak of killer cantaloupes, we ought to be asking what it will do to prevent the next outbreak linked to some other agricultural commodity. Will provisions in the FDA’s proposed rules be enough to prevent assassin avocados, slayer squashes, or executioner eggplants?

The continuing reliance on third-party audits poses a serious threat to the effectiveness of implementing the FDA’s new produce rule. Language in the text of the rule optimistically discusses FDA initiatives, public/private partnerships, and industry efforts to educate growers about Good Agricultural Practices and the new regulatory standards. But the FDA articulates a role for itself ultimately as more facilitator of good behaviors than enforcer of regulations and “aims to assist farmers in gaining the food safety knowledge they will need to comply with the provisions of a final produce safety rule” (FDA 2013e). No one wants to see more deadly outbreaks occur in the future that everyone knows could have been prevented by reliance on available scientific evidence, but as long as the industry continues to rely on a system of oversight with an inherent conflict of interest, the risk posed to food safety demonstrated by the case of Jensen Farms will persist.

### **CASE IN POINT**

**Ineffective or Absent Structures and Instruments for Providing Science Advice:** Following the Jensen Farms outbreak, effective structures for providing science advice caused the speedy recall of another batch of tainted cantaloupes, but the federal program that detected that contamination has since been eliminated due to a lack of funding.

Ineffective or absent structures and instruments for providing science advice limit the amount of information public officials have access to when making important decisions affecting Americans’ health and safety. The current lack of federal resources to support food safety not only raises concerns about the FDA’s ability to implement its new produce rule but has also led to other important food safety programs being cut.

While the Jensen Farms case was the first time *Listeria* had ever been discovered in cantaloupes, unfortunately, it was not the last. In June of 2012, less than a year after the Jensen Farms outbreak, Burch Equipment LLC of North Carolina, commonly known as Burch Farms, began shipping out its seasonal crop of cantaloupes. On their way to places like Florida, Georgia, Illinois, Pennsylvania, and New York, the melons passed through a packing facility in Faison, NC, where some were contaminated with *Listeria monocytogenes*. Unlike the case of contaminated melons from Jensen Farms, no one died and no one got sick, thanks to the actions of a federal project called the Microbiological Data Program (MDP).

Established in 2001, the MDP was a national program run by the Agricultural Marketing Service (AMS) of the USDA that monitors the prevalence of foodborne pathogens. According to Dr. David Acheson, former Associate Commissioner for Foods at the FDA, the MDP cooperated with a range of state and federal agencies to manage the “collection, analysis, data entry and reporting of foodborne pathogens on selected agricultural commodities at the retail level” (Acheson 2012). In pursuit of this mission, MDP

collected monthly samples of commodities from final markets and distribution centers in 11 states that together represented 50 percent of the US population and all regions (AMS 2013). In this case, it was MDP sampling of a melon in New York that first detected *Listeria*, leading first to a partial recall and ultimately to a recall of more than 100,000 melons (Beach 2012).

The MDP played a crucial role in getting the melons off the market, but initiating recalls is not the only valuable thing the program did. Before the program was eliminated, MDP collected 80 percent of the data about the prevalence of foodborne pathogens in produce (Bottemiller 2012a). That data, which was reported to the CDC's national PulseNet database, helped regulators design and set baselines for food safety regulations and look for patterns to inform future actions, including the FDA's new proposed rules.

Simply put, the basis of efforts by food safety regulators to protect the American public from foodborne pathogens is knowledge about where the pathogens are. For that reason, food safety experts across the country are concerned that the MDP was cut from the 2013 budget. As a result of the cuts, the MDP stopped testing for new cases of foodborne pathogens in November and shut its doors on December 31, 2012 (Bottemiller 2012b). The MDP's operating budget of \$4.5 million seems like a small price to pay for preventing yet another deadly multistate outbreak.

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