OUTLOOK

Hasty responses to foodborne illness outbreaks impact California growers

Four major foodborne illness outbreaks in 3 years have led to stricter requirements for leafy greens growers that may satisfy corporate buyers and reassure the public, but also highlight a serious need for more food safety research.

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> n the last 3 years the United States has seen four major foodborne illness outbreaks related to leafy greens, which resulted in 399 cases of foodborne illness. Altogether, 180 people were hospitalized and six people died. These outbreaks were well beyond the severity of foodborne illness we had typically seen prior to 2017. Romaine lettuce, the identified source of all four outbreaks, was recalled, thousands of consumers were told to throw out what they had in their refrigerator and a nationwide questioning of U.S. food safety has ensued.

The U.S. food system is extremely complex and livestock operations, produce growers and retail produce buyers have made significant efforts to address and mitigate food safety risks in this complex system. However, there are hundreds of possible contamination points during production and preparation before food reaches the consumer. The contamination point

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of fresh produce is particularly difficult to trace, since each produce handler is aware only of the previous handler and not the entire system. The agency involved in the traceback process, often the Food and Drug Administration (FDA) or Centers for Disease Control and Prevention (CDC), depending on the size and severity of the outbreak, must trace from consumer to grocery store to distributor to shipper to processor to the multiple farms the processor procures produce from. Identifying the point of contamination is therefore very difficult, and sometimes impossible. For example, investigators of the 2017 leafy green *Escherichia coli* (*E. coli*) O157:H7 outbreak were never able to identify the source of the contaminated produce.

Even if the investigating agency can trace the pathogen source to a contamination site, the process may take several months. Soil, water, vegetation, rodents,



Romaine lettuce in Imperial Valley. UC ANR could test new food safety practices with local farms, translating well-vetted science into appropriate management practices. wild animals and nearby animal facilities — all potential vectors of pathogens — are then tested for the outbreak pathogen strain. However, studies have shown that pathogens present at one time may no longer be found within as little as a month, which is why the exact sources of many outbreaks remain uncertain, such as in the spring of 2018.

Spring 2018 outbreak

In spring 2018, a total of 210 people got sick and five died of hemolytic uremic syndrome, an extreme illness caused by *E. coli* O157:H7 bacteria that produce Shiga toxin (CDC 2018; FDA 2018a). The outbreak lasted several weeks and impacted people in 36 states. A major difference between this outbreak and the 2017 outbreak was the number of illness incidents — in the 2017 outbreak, only 25 people got sick, which meant that there were 185 more epidemiological points in the 2018 outbreak to help track the pathogen source to a food, distributor and farm.

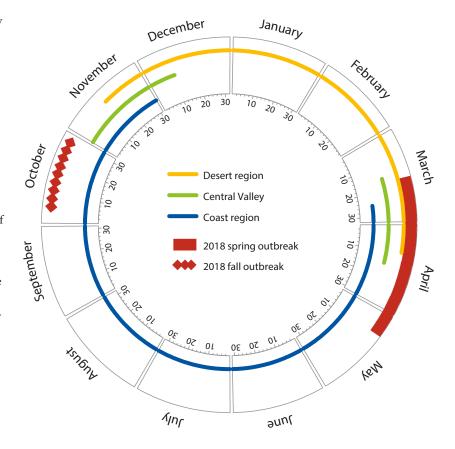
Through the traceback process in 2018, FDA and CDC narrowed down the possible causes to chopped romaine lettuce by day 10 of the outbreak investigation. Because the outbreak started in spring, when the California Central Valley and coastal regions were only just beginning to harvest lettuce, the contaminated romaine lettuce was most likely grown in the desert region. The desert region includes the Imperial Valley and southwest Arizona and harvests lettuce all winter and for several weeks in spring (fig. 1).

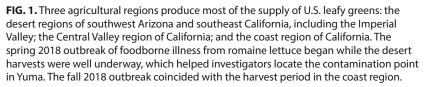
The timing and food product associated with the outbreak can hinder or help an investigation. For example, the fall 2018 lettuce outbreak was very likely to have originated in coastal California farms, and was traced to a farm there. Conversely, during periods of the year when many geographic areas may be producing the product associated with an outbreak, much more time must be spent finding the common source of the contaminated product.

In spring 2018, investigators initially had no way to trace the contaminated chopped romaine lettuce precisely, because many farms produce romaine lettuce in the desert region and chopped and bagged romaine lettuce usually contains lettuce from a variety of farms. Also, the lettuce could have been contaminated during packaging at a processing facility rather than at any of the farms. The traceback process could have stalled, but a week after romaine was identified as the contaminated food source eight inmates in an Alaska correctional facility became ill from whole-head romaine with the same strain of E. coli. Because each head of lettuce can be connected to a specific distributor or processor, this information accelerated the investigation. As a result, the FDA was able to confirm that the romaine had come from the Yuma, Arizona, region.

Investigators with FDA and CDC collected environmental samples in June, July and August to test possible reservoirs of contamination. They found the outbreak strain of *E. coli* in three samples in the sediment of an irrigation canal near Yuma. In the desert region, the only source of water for crops is the Colorado River, via open irrigation canals, so it could be assumed water from that canal was used to irrigate romaine fields. If *E. coli* was in the canal at the time of the last irrigation before harvest, then the irrigation water could have been the vector that contaminated the romaine. However, *E. coli* doesn't spontaneously grow in canals. It had to come from somewhere else — specifically, humans or animals.

A tenuous link to a nearby feedlot resulted in media reports that the feedlot was to blame, although there was no evidence to implicate any particular source of the *E. coli*. FDA and CDC never detected the outbreak strain of *E. coli* on the feedlot premises. They released a final environmental assessment about this outbreak that lacked a clear cause of contamination (FDA 2018b). The feedlot may have been the source, but any cattle or manure that had carried the pathogen were long gone by the time FDA and CDC collected samples, so investigators had no way to test them.





There are many possible sources of *E. coli* in the canal in spring 2018:

- Wildlife carrying *E. coli* may have drunk, swum or walked in the canals.
- Dustborne *E. coli* may have reached the canal from cattle in the Yuma feedlot.
- People withdrawing water upstream may have contributed *E. coli* to the canal water by using improperly cleaned equipment or putting their hands into the water.
- People occasionally use the canals to wash themselves, and someone may have shed *E. coli* while bathing.
- The *E. coli* may have come from a source upstream and settled out of the water over time, living in the sediments for weeks (Jamieson et al. 2005).

Legislation, stricter industry policies

Food safety practices are not new to the U.S. food supply. Various agencies created and continue to revise regulations mandating training and management practices to reduce the risk of pathogens entering the food system. The United States codified requirements for food production and handling as long ago as 1938 (Federal Food, Drug, and Cosmetic Act), with some key updates such as the Hazard Analysis and Critical Control Point (HACCP) procedures in 1996 and the Food Safety Modernization Act (FSMA) in 2011.

What is a pathogen?

A pathogen is an organism (bacterium, virus, parasite, fungus) that causes disease. More than 250 pathogens cause foodborne illness, but eight of them are responsible for 96% of foodborne illness cases in the United States.

What is a foodborne pathogen outbreak?

When two or more people develop a foodborne illness from the same pathogen, usually in a common food source, it is considered an outbreak. In the United States, there are certain levels of illness that are expected and viewed as "normal." A sudden increase in the number of cases of a specific disease compared to what is normally expected helps agencies identify potential outbreaks.

Which agencies are involved in outbreak response?

City, county and state agencies are typically involved in foodborne pathogen outbreaks. The agencies responding depend on the number and location of the affected consumers. When foodborne illness affects consumers in multiple states, the CDC and FDA become involved in the traceback process. Since there are many agencies responsible for responding to foodborne pathogen outbreaks, databases such as PulseNet have been launched to allow multiple agencies to quickly connect illness cases in their area to existing outbreaks and use the data to more rapidly identify the source of contamination. All farms are federally mandated to comply with a basic level of good agricultural practices (GAPs), and, in 2016, the FSMA Final Rule on Produce Safety implemented new inspection responsibilities for the FDA and new standards of practice for farms and processors. Agricultural commodity groups and buyer groups have also formalized food safety interventions as best practices.

Whether federally mandated, buyer-required, or led by agricultural commodity groups, food safety practices include activities and infrastructure to address four vectors of pathogens: humans, other animals, water and soil. Examples are hand-washing stations for on-farm employees, no harvest in areas where wildlife have entered a field, thresholds for microbe concentrations in irrigation water, and a minimum temperature regime for composted manure.

Among the most detailed and transparent industry-led food safety programs are the California and Arizona leafy greens marketing agreements (LGMAs), which include strict metrics for growers: https://lgma. org/food-safety-practices/ (California) and www. arizonaleafygreens.org/guidelines (Arizona). Leafy greens growers, processors and others in the industry created the LGMAs in 2007. LGMA-certified farms now represent about 90% of the U.S. leafy greens supply. The metrics are updated as new scientific information becomes available, as laws change or in response to major outbreaks.

The FSMA was lauded by grocery stores, consumer protection groups and others for its regulatory impact on large agricultural operations (Strauss 2011). However, many large buyers and third-party audit programs have stricter standards than FSMA. For example, growers must undergo more frequent audits under the LGMA certification requirements than under FSMA (Doering 2018).

Much less transparent and more stringent are buyer-led food safety programs. Large buyers can demand specific practices are implemented before they will purchase produce, and they control enough of the market that growers must comply or risk having no sales (Havinga 2006).

Growers have told researchers (e.g., Hardesty and Kusunose 2009; Stuart 2008) about some of the requirements they must follow, but most buyer requirements are not publicized. We discovered a 2007 version of the "On-Farm Produce Standards" required by the Food Safety Leadership Council, which then included buyers such as Disney, McDonald's, Walmart, and Darden restaurants (Olive Garden and other chains), representing significant market power. Requirements included soil analyses if a field had ever been used for anything other than growing produce; destruction of potentially contaminated crops if animals access a field; a ¼-mile buffer from animal grazing and a 1-mile buffer from any concentrated animal feeding operation (CAFO); and microbiological testing of "high risk products (leafy greens,

tomatoes, green onions, herbs, berries sprouts, etc.)" (FSLC 2007).

Recent impacts on growers

After the spring 2018 Yuma outbreak, various organizations and corporate produce buyers wanted to quickly rebuild consumer trust. Despite the lack of a clear cause of the outbreak, these groups immediately and strongly responded to the possibility that the feedlot contributed to it. The California LGMA metrics now state that leafy greens cannot be grown within 1 mile of CAFOs (e.g., feedlots and dairies) with more than 80,000 animals, and no leafy greens can be grown within 1,200 feet of CAFOs with 1,000 or more animals (Ward 2018). The previous restriction was a buffer of 400 feet between leafy greens fields and CAFOs of any size.

The biggest buyers influence the entire producebuying sector (Fister Gale 2006; Havinga 2006; Ribera et al. 2012). Other buyers may decide, in order to remain competitive and entice customers, to adopt similar or even more stringent food safety policies. Various groups have noted this potential "arms race" of food safety requirements (Palma et al. 2010), in which growers are subject to ever-tightening requirements. While large-scale leafy greens growers may be able to accommodate the new FSMA and LGMA requirements without losing significant production acreage, small lettuce growers with fields within 1,200 feet of a CAFO will struggle to stay in the leafy greens industry, because there are no guarantees for higher prices to growers adopting these practices. Produce from fields within the new buffers will be unmarketable — a potentially major loss of income simply due to location. Our conversations with growers indicate buyers may be demanding even stricter buffers than those required by LGMA, including minimum distances to grazing animals.

While there are small farm exemptions and exceptions in FSMA, small growers still have to comply with new monitoring, recordkeeping and reporting requirements as of January 2020. These requirements are difficult to understand, even to determine one's eligibility for an exemption. Altogether, compliance is more expensive for smaller farms than for large farms (Hardesty and Kusunose 2009; Karp, Baur et al. 2015). Although small growers are rarely implicated in foodborne illness outbreaks, they are subject to the regulatory consequences of a large outbreak and are confronted with barriers that may make small-scale production financially nonviable (DeLind and Howard 2008; Karp, Baur et al. 2015).

Converting to an alternative crop is not necessarily a viable option to help these growers stay afloat. Many economic and experiential barriers make crop conversion a significant challenge, such as the lack of expertise in growing alternative crops; the different equipment and labor needed; and the realities that alternate crops may not suit the local climate or soils, or the grower may be a land lessee with crop options limited by the landowner (Pollans 2017; Rodriguez et al. 2008). In addition, some buyer food safety policies have expanded buffer restrictions to crops that are not typically consumed fresh, such as grains, nuts and dried beans (Gennet et al. 2013).

Decisions made without science

Popular press coverage of the 2017 and 2018 outbreaks called for "safer" leafy greens, criticized the U.S. food safety system and outright accused feedlots for the spring 2018 outbreak. The complex traceback process frustrated everyone as it trudged forward and ended without certainty about the outbreak origin. Unfortunately, the need for quick action led to costly changes in management systems that weren't backed by scientific evidence or evaluated for their impact on agriculture. The changes increased costs for growers, increased hostility in the agriculture community and allowed the intervention of retail corporations, who are largely uninvolved in agriculture in these specific growing conditions. Impacted growers in Imperial County and the San Joaquin Valley will need to make tough decisions about staying in business, and our supply of leafy greens may look different over time - more expensive, more seasonal and more imports.

Many requirements imposed by corporate buyers are based on science that may not be appropriate for the system where they are applied. For example, to reduce the risk of pathogen contamination in leafy greens production during sprinkler irrigation, growers with type B water (i.e., untreated canal water — the most common type of agricultural water in the Imperial Valley) are now required to treat the water with approved antimicrobials, such as chlorine, within 21 days of harvest. They must also test the irrigation water for indicator bacteria monthly, and if they are irrigating within 21 days of harvest, they must test the water twice during that period. However, there are gaps in data and information regarding the efficacy of the water testing protocol (FDA 1998); and using chemicals to clean irrigation water has not been thoroughly researched to understand the potential negative impacts to the soil and productivity.

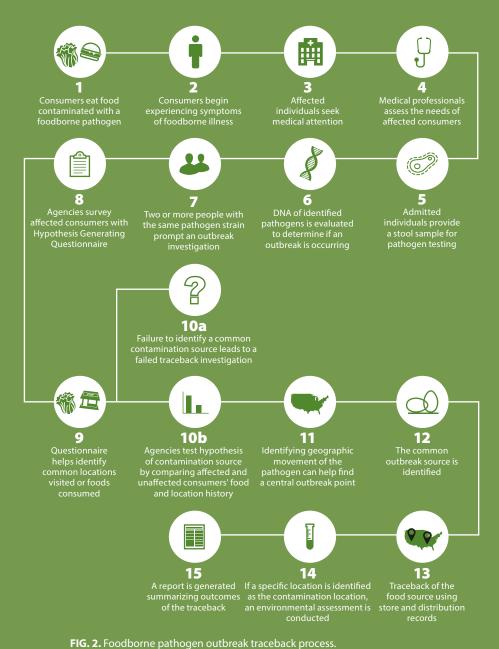
There is also little evidence, and even less of a scientific consensus, that the buffer distances will reduce the risk of pathogen movement or that the animal capacity thresholds indicate a critical level of risk. The previous setback distances were based on a study by Berry et al. (2015) in Nebraska near a 6,000-head feedlot. Although this study provided excellent data, it didn't represent the significantly larger livestock operations found in California or their arid, low-desert environment. The principle is seemingly valid — the risk of contamination should decrease as distance from a contamination source increases — but the recently implemented distances from CAFOs (see Ward 2018) are less so. Moreover, CAFOs are not the only



possible source of pathogens. Increased buffer distances do nothing to protect against other contamination sources.

New corporate food safety policies that dictate stricter farming practices provide the perception of enhanced food safety. That perception, regardless of whether it is supported by data, may rebuild consumer trust and provide the corporation with an edge against competitors. But this enforcement of stricter requirements is especially troubling given that the requirements are typically not publicized, and therefore not subject to industry scrutiny, scientific rebuttal or affirmation, or any accountability on the part of the buyer to uphold their own standards (Stuart 2008). In summary, buyers have carte blanche to demand that growers shoulder the burdens of reassuring the public without regard to whether the demands are supported by science.

Without scientific analysis, new required agricultural practices in the name of food safety may backfire. For example, a decade ago many growers on the Central Coast removed noncrop vegetation, including trees and vegetative buffer strips, to comply with processor and retailer food safety requirements (Stuart 2008). However, increased bare soil correlates to increased erosion, water contamination and *E. coli* prevalence (Karp, Gennet et al. 2015), which could result in food contamination downstream — exactly



The traceback process

A noutbreak begins with consumers eating food contaminated with a foodborne pathogen (fig. 2). In terms of traceback, what makes the process more difficult is the fact that not all people who consume the food and develop the illness seek medical attention. For serious illnesses such as those caused by *E. coli* O157:H7, people are likely to seek medical attention, but for less severe illnesses such as salmonellosis, otherwise healthy individuals may experience only mild symptoms not requiring medical attention (table 1). Low rates of reporting these illnesses decreases the data points epidemiologists can use to trace back the pathogen to a source.

Epidemiologists rely heavily on those affected by the pathogen remembering the food they have consumed within an appropriate time period. However, if a patient shows symptoms a week after food was consumed, remembering what they ate can be extremely difficult. The patient may know that they had a salad last week but may not know what leafy greens were in that salad or where they obtained the greens. Retailer receipts and loyalty cards can help, but they don't always have the information needed, such as the brand name or item description.

Food recollection also helps investigators identify foods that the affected population consumed more frequently than the average population consumed them. For example, if within an outbreak week 46% of nonaffected people had eaten lettuce and 98% of affected people ate

the opposite of the stated goal. This is just one reason why we want to ensure that future changes in practice are thoroughly evaluated and have a positive impact on food safety.

Risk management

Though we have seen an increase in the number of foodborne illness outbreaks over the last 30 years, the trend may not be related to unsafe production practices. Increases in leafy greens consumption and healthy eating influences have increased the quantity of uncooked foods being consumed, which increases the likelihood of foodborne illness. For example, leafy lettuce availability increased 1,856% from 1970 to 2005 (Wells and Buzby 2008).

Since our food is grown in a dynamic system and not a closed, sterile environment, no matter the lengths we go to to reduce the risk of outbreaks, we will never achieve 0% risk. We must acknowledge that a problem as complex as the risk of foodborne illness outbreaks is not ever solved, even with the best science. We may in fact reveal more questions with more science. As Powell et al. (2013) note, management decisions are judgment calls informed by science and other evaluations of risk amidst uncertainty.

However, there are clear ways to reduce the impacts of outbreaks. For example, recent widespread use of

lettuce, the large difference is evidence that consumption of lettuce could be associated with the illness. More detailed statistical analyses help to determine to what extent the product is associated with the illness.

If the pathogen is traced to a site, an environmental assessment is carried out. However, as in the spring 2018 Yuma outbreak, the potential sources are varied, and technologies to rapidly, reliably and effectively identify pathogens on-site are lacking. On-site sampling cannot yet specify distinct strains of pathogens. In-depth laboratory analysis such as whole-genome sequencing helps in true identification but is costly. Given the costs and availability of current pathogen detection technologies, investigators must unfortunately choose between evaluating a few samples with high specificity (expensive test) or evaluating many samples with a more generic (and inexpensive) test. The either-or choice can hinder detection and identification of the pathogen.

Traceback is important but, to better protect public health, improved on-site pathogen detection technologies could be adapted to proactively detect pathogens before an outbreak occurs. The cheaper that detection gets, the more widely it can be adopted throughout the food production and processing chain. Commodity groups and agencies have dedicated funds to encourage researchers to develop new technologies to increase the speed and specificity of on-site sampling to identify pathogens more effectively.

TABLE 1. Sources	ABLE 1. Sources of common foodborne pathogens		
Pathogen	Symptom occurrence after ingestion	Potential food sources	
<i>E. coli</i> (STEC) O157	1–8 days	Undercooked beef Unpasteurized milk and juice Raw fruits and vegetables Contaminated water	
Salmonella enteritidis	6–72 hours	Raw meat, poultry and seafood Unpasteurized milk or juice Raw eggs Fresh fruits and vegetables	
Norovirus	12–48 hours	Raw produce Uncooked foods Contaminated water Shellfish from contaminated water	
Clostridium perfringens	8–16 hours	Meats Poultry Gravy Precooked foods	
<i>Campylobacter</i> spp.	2–5 days	Raw and undercooked poultry Unpasteurized milk Contaminated water	
Staphylococcus aureus	1–6 hours	Improperly refrigerated meats, prepared salads, cream sauces, cream-filled pastries	
Toxoplasma gondii	5–23 days (Some healthy individuals exhibit no symptoms.)	Raw or undercooked meat Contaminated water Contact with cat feces Transmission from pregnant woman to fetus	
Listeria monocytogenes	9–48 hours or 2–6 weeks	Unpasteurized milk Soft cheeses made with unpasteurized milk Deli meats	

E. coli (STEC) O157

harvest location labels enabled consumers to avoid potentially contaminated romaine in the 2019 outbreak. The many potential sources of foodborne pathogens and possible early interventions could be more thoroughly studied. New technologies for food traceability and for detecting pathogens; new techniques of assessing and reducing on-farm and processing risks; and new partnerships with agencies to accelerate the traceback process could all help reduce the number of people who get sick from foodborne pathogens. A systematic risk assessment and risk model could move discussions of food safety concerns toward actual risk reduction. For example, practical models of risk assessment could indicate crop harvests that need more sampling for pathogens, additional washes during processing, or a delay in harvesting or repurposing a harvest for animal feed.

UC ANR could bridge science gap

The recent outbreaks and reactions from the public, commodity groups, produce buyers and growers have indicated gaps in research on livestock-produce interactions and traceback through the U.S. food system. UC researchers, such as those with the Western Institute for Food Safety and Security at UC Davis, study a variety of food safety topics and influence food safety practices. They have been awarded recent grants for improving sanitation technologies, identifying movement of pathogens through animal operations and studying the potential of wildlife to move pathogens into fields. However, existing research does not adequately inform the agricultural community on how to adapt practices in the face of changing food safety pressures. This is where UC Agriculture and Natural Resources, and especially UC Cooperative Extension farm advisors, could provide a valuable service. Because of the strong relationships we establish in our communities, we can test new and adaptive food safety practices with local partners in the farming community. Especially important is extension work with small growers to minimize the impact of regulatory changes on their bottom line. With greater collaboration and information sharing among UC food safety researchers and UC Cooperative Extension academics, we could better address gaps in food safety knowledge across the state.

As advisors and specialists, we could be critical points in the reduction of food pathogen risk. We have multiple areas of expertise to help define the direction of food safety research and translate the best available scientific information into management practices that are not only effective in reducing the risk of foodborne illness for consumers but also feasible for growers to implement. We need changes that reduce the risk of pathogen movement in our food system and not changes that simply address perceptions of safety. While the leafy greens industry and retailers must respond quickly with the best available information, it is our responsibility as researchers to provide them with well-vetted, relevant science to ensure that changes they do make don't have unforeseen consequences.

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