

The Romaine Outbreak: Where Do We Go From Here?

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On November 1, FDA issued its assessment of factors contributing to this year's deadly outbreak of illness caused by contaminated romaine lettuce produced in the Yuma, Arizona growing region. This was the largest outbreak of *E. coli* O157:H7 infections in the United States since the spinach outbreak of 2006. Ninety-six people were hospitalized and five died.

In an accompanying letter to the leafy greens industry and state officials in Arizona and California, FDA also issued a strong call to action, saying: "Bold action is needed to prevent future outbreaks, especially ones of this magnitude, and to restore consumer confidence in the safety of leafy greens available on the market."

We emphatically agree. The question is what action and by whom. The key players are FDA, the states, the leafy green industry and food retailers – the businesses that directly link food producers with consumers. They all have roles to play. The cattle feeding industry must also be part of the conversation. Typically, multiple factors contribute to major outbreaks, but just as run-off from cattle grazing was implicated in the 2006 spinach outbreak, a concentrated animal feeding operation (CAFO) is implicated in the romaine outbreak due to the CAFO's close proximity to irrigation canals and growing fields.

Our organization, Stop Foodborne Illness, has represented individuals and families directly affected by serious foodborne illness for the last 25 years. We've been at the table helping drive change. While we can't make leafy greens safe, we do have three roles to play: (1) ensuring all those responsible for producing food remember the human stakes by hearing the voices of impacted families, (2) pushing for continuous improvement and implementation of best practices in food safety, and (3) supporting those in government and industry who are committed to effective action on food safety.

And for Lauren, the issue is intensely personal. As a college student, she was seriously injured in the 2006 spinach outbreak caused by the same pathogen implicated in this year's romaine outbreak. This makes the current outbreak feel all too familiar. Yet, we are as committed as ever to collaborating with industry and government to prevent more consumers from getting sick.

As we write, the good news is that the need for action in response to the romaine outbreak is widely recognized, and important steps have been taken. FDA and the states investigated. FDA issued its environmental assessment. The Arizona and California leafy green industries recently issued new "metrics" and guidance on steps that Leafy Green Marketing Agreement (LGMA) members should take to address problems highlighted by the romaine outbreak. We understand some retailers are sharpening their purchase specifications to address the potential for water contamination due to the presence in leafy green growing areas of large cattle feeding operations.

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And the Center for Produce Safety is considering research to address key questions. All of this is positive.

There are other positive signs that the romaine outbreak will be a catalyst for effective action. One of the key issues on which FDA called for action is modernizing traceability systems to enable rapid traceback and more effective recall communications. On October 29, The Pew Charitable Trusts brought together industry leaders, consumer groups, and government representatives to discuss strategy and next steps for harnessing modern information technology to bring traceback practices into the 21st Century.

This is a matter of life and death for consumers when outbreaks happen. In an industry that relies too often on paper and handwritten records and on disconnected datasets, consumers cannot wait any longer for producers to take advantage of the abundance of available technology. It's now a matter of industry will, leadership, and collaborative problem solving, with encouragement and support from FDA. The commitment to action we heard expressed at the Pew meeting makes us optimistic that modernization of traceability can happen.

It is less clear where we are headed on the hazard posed by CAFOs operating in the vicinity of leafy green production. And we are concerned that FDA's call for action did not include the cattle feeding industry. Through LGMA, many leafy green producers continue working to improve their food safety practices, but cattle feeders are part of the problem and have to be part of the solution, too.

The McElhaney Feedyard has a capacity of over 100,000 head of cattle and sits on a rise of land immediately adjacent to the irrigation canal that FDA found contaminated with the outbreak strain of *E. coli* O157:H7. FDA was cautious in characterizing the possible role of this CAFO in causing the outbreak, but noted that there is no alternative explanation for how the pathogen got into the water. However, for anyone with food safety knowledge who observes that CAFO and the conditions surrounding it, there is no reasonable doubt that it presents a significant hazard and was the source of the *E. coli* that made people sick. And it would be hard for any consumer viewing that CAFO and its proximity to irrigation canals and growing fields to be confident that greens produced there are safe to eat.

The question is what to do about it. We appreciate that FDA and the leafy green industry take this issue seriously. They agree there needs to be a larger buffer between the CAFO and growing fields, but also that such buffers alone don't solve the problem. Their actions so far include calling for growers in the vicinity of CAFOs to conduct rigorous assessments of the risk of water contamination posed by the CAFO and take steps to mitigate the risk. FDA specifically calls for industry to develop best practices for assuring that the water they are using meets the "safe and adequate" safety standard in the FSMA produce safety rule.

This is where more aggressive and collaborative problem solving is needed, and consumers cannot afford to wait.

The problem is that both FDA and the leafy green industry are leaving it to individual growers to both assess the risks posed by a particular CAFO and figure out the right risk-mitigation best

practices to deal with the risk once they have assessed it. We recognize and agree that the wide diversity of production systems and conditions requires a degree of flexibility for growers to assess local risks and devise practices that work to produce safe food. But, when it comes to CAFOs located next to leafy greens, flexibility cannot take precedence over ensuring an acceptable standard of care is widely observed. In the case of a hazard as specific and glaring as the one posed by the CAFO in Yuma, and by similar CAFOs in proximity to irrigation canals and growing fields in other locations, leaving it to individual growers is not enough.

Fortunately, some retailers are already setting conditions under which they will require targeted risk-reduction interventions, such as water treatment and pathogen testing of both water and finished product. This is a positive step, but consumers expect more than that. Given the evident significance of the CAFO hazard and the tragic scale of the romaine outbreak of 2018 (and spinach in 2006), consumers rightly expect clarity and transparency now about the standard of care all producers will meet, including appropriate pathogen testing and water treatment, to prevent such tragedies from happening again (and again).

Looking ahead, we urge growers, CAFO operators, and federal and state agencies to improve assessments of risk through proactive collaboration. This should start with pooling all possible data (including new environmental testing as needed) to generate a detailed microbial profile of the environment in and around the Yuma CAFO. This is essential to determine possible pathways of contamination and science-based interventions.

This critical issue won't be solved in the near-term by regulation alone, but it can be solved by stakeholders coming together to improve risk assessment and expeditiously resolve what happens after a risk is identified and assessed. CAFOs must also be at the table, implement effective preventive measures, and be held responsible for the impact of their operations on the environment and other producers.

Consumers' lives depend on it.

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