Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Three Outbreaks of E. coli O157:H7 During the Fall of 2019

Executive Summary

In November and December 2019 there were three *E. coli* O157:H7 foodborne illness outbreaks A (167 illnesses), B (11 illnesses), and C (10 illnesses) associated with consumption of romaine lettuce or leafy greens from the Salinas Valley area of California. FDA and multiple state and federal partners investigated these three foodborne illness outbreaks to identify any contributing factors that may have led to romaine lettuce contamination with *E. coli* O157:H7 and subsequent illnesses. During the course of these investigations, it was determined that:

1. each of these three outbreaks was caused by distinctly different strains of *E. coli* O157:H7 as determined by whole genome sequencing (WGS) analysis;
2. Outbreak A strain of *E. coli* O157:H7 was found in two different brands of fresh-cut salads containing romaine lettuce in 2019;
3. traceback investigations of multiple illness sub-clusters and supply chain information identified a common grower with multiple ranches/fields, which supplied romaine lettuce during the timeframe of interest to multiple business entities associated with Outbreaks A, B and C; and
4. the Outbreak A strain of *E. coli* O157:H7 was detected in a fecal-soil composite sample taken from a cattle grate on public land less than two miles upslope from a produce farm with multiple fields tied to the outbreaks by the traceback investigations.
5. other STEC strains, while not linked to outbreaks A,B, or C, were found in closer proximity to where romaine lettuce crops were grown, including two samples from a border area of a farm immediately next to cattle grazing land in the hills above leafy greens fields and two samples from on-farm water drainage basins.

FDA considers adjacent or nearby land use for cattle grazing as the most likely contributing factor associated with these three outbreaks. While the agency could not confirm a definitive source or route(s) of contamination of the romaine fields, the Agency considers indirect transmission of fecal material from adjacent and nearby lands from water run-off, wind, animals or vehicles to the romaine fields, or to the agricultural water sources used to grow the romaine, as possible routes of contamination. Working with our state partners, FDA is continuing, through the 2020 growing/harvest season, to conduct mission critical STEC investigations in the Salinas growing region to follow up on our findings from the 2019 outbreaks.

This document provides an overview of the investigation approach and factors that potentially contributed to the contamination of romaine lettuce with *E. coli* O157:H7 in two multistate and one single-state foodborne illness outbreaks in the fall of 2019. Of note, the number of cattle we observed on nearby lands during the 2019 investigations was far lower than the volume of what is considered a large concentrated animal feeding operation, offering a useful reminder that high-density animal operations are not the only factor to consider. These findings reinforce our concern about the possible impacts of nearby and adjacent land use on the safety of leafy green crops and further underscore the importance of implementing appropriate risk mitigation strategies.

For a copy of the final report go to: Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Three Outbreaks of E. coli O157:H7 During the Fall of 2019 | FDA