Salmonella I 4,[5],12:i:-/Romaine Lettuce/Aug 2026 - CARA ID 1402

On 8/4/2026, CDC notified FDA/CORE of a new Salmonella I 4,[5], 12:i- cluster reported by (b)(5) state partners, with a possible signal for romaine lettuce. As part of their investigation, state partners in (b)(5) identified two subclusters where romaine lettuce was identified as a common exposure among cases. Furthermore, from an ingredient level analysis conducted by (b)(5), romaine lettuce was statistically significant. On 8/7/2026, CDC named romaine lettuce as the leading vehicle of interest for the outbreak. FDA/CORE initiated a traceback investigation consisting of four traceback legs ((b)(4) (2-separate locations), (b)(4) and (b)(4)) representing 12 cases who reported exposures to romaine lettuce in meals purchased/consumed from four different Points-of-Sale (POS) in (b)(5), and (b)(5) during the time period from 7/7/2026 thru 7/20/2026. The four traceback legs converged on a single supplier and processor of prepackaged, shredded romaine lettuce, (b)(4)). On 8/18/2026, FDA Office of Inspections and Investigations (OII) Office of Human Food Inspectorate (OHFI) C3 and (b)(5) state partners initiated a Full Scope Preventive Control (PC) Inspection at the(b)(4) During the inspection, the inspectional team collected one sample consisting of 110 environmental swabs throughout the receiving, processing, washing and packaging environment for Salmonella analysis. The sample screened negative for Salmonella spp. No finished product samples were collected as the romaine lettuce of interest was out of shelf life and not available for sampling. On 9/1/2026, investigators closed the PC inspection with issuance of an FDA Form 483 noting issues related to the firm's sanitation preventive control, corrective action, and verification procedures. There were no product actions taken related to this incident as the product of interest was out of shelf-life. Due to the strong epidemiological and traceback evidence (convergence), romaine lettuce processed and distributed by (b)(4) was confirmed as the outbreak vehicle. On 9/14/2026, CDC closed the epidemiologic investigation. As of 10/30/2026, this outbreak involved a total of 43 cases in (b)(5) states: (b)(5). There were 6 hospitalizations, and 0 deaths reported.