

# An Outbreak of *E. coli* O103 Traced to Sprouts; Implications for the FSMA Produce Safety Rule

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## Background

*E. coli* O103 is a strain of STEC not previously reported with sprouts outbreaks. Sprouts are often linked to foodborne outbreaks because of the warm humid conditions necessary to produce them. In this outbreak, Iowans became ill with *E. coli* O103 after eating at a sub-sandwich restaurant chain in central and eastern Iowa. This outbreak was identified through routine surveillance on December 18, 2019. After notification, Iowa's food retail and manufacturing agency, the Iowa Department of Inspection and Appeals (DIA), notified the sub-sandwich franchise owners and sprout grower. Both parties voluntarily suspended the sales of clover sprouts.

A cohort study was conducted. Interviews were performed via phone by IDPH epidemiologists and student interview team, and Local Public Health (LPH) partners using a standard *E. coli* questionnaire and an outbreak-specific supplemental questionnaire.

## Epidemiology Investigation

A total of 23 individuals were identified and interviewed as part of this investigation. Of these individuals, 22 were laboratory confirmed and one probable case was epidemiologically linked to a laboratory confirmed case.

A case was defined as a person with *E. coli* O103 infection, whose clinical isolate was related within 0-2 single-nucleotide polymorphisms (SNPs), and with specimen collection dates between November 26, 2019 and December 21, 2019. A total of 22 (96%) individuals met this case definition from 10 Iowa counties (Figure 1). Of these, 14 (64%) were female. The median age was 29 years (range 18 – 50 years). Onset of symptoms was known for all 22 confirmed cases (Figure 3). One (5%) individual was hospitalized and no deaths were reported.

Of the 22 identified cases, 21 were interviewed using IDPH's standard Shiga toxin-producing *E. coli* questionnaire and an outbreak-specific supplemental questionnaire. One case completed the standard questionnaire but was not responsive to multiple attempts to complete the outbreak-specific supplemental questionnaire. During the standard interview, this case did not report consuming food from a Jimmy John's restaurant in the 10 days prior to onset of illness, though this individual would not have been specifically asked about Jimmy John's during the standard interview.

Of the 21 cases interviewed using both the standard *E. coli* questionnaire and an outbreak-specific supplemental questionnaire:

- One (5%) case denied eating food from a Jimmy John's restaurant in the 10 days prior to onset of illness.
- 20 (95%) cases reported eating food from a Jimmy John's restaurant in the 10 days prior to onset of illness.
- The 20 cases reported consuming food from 15 different Jimmy John's restaurant locations. These 15 restaurants were located in seven different central and eastern Iowa counties.

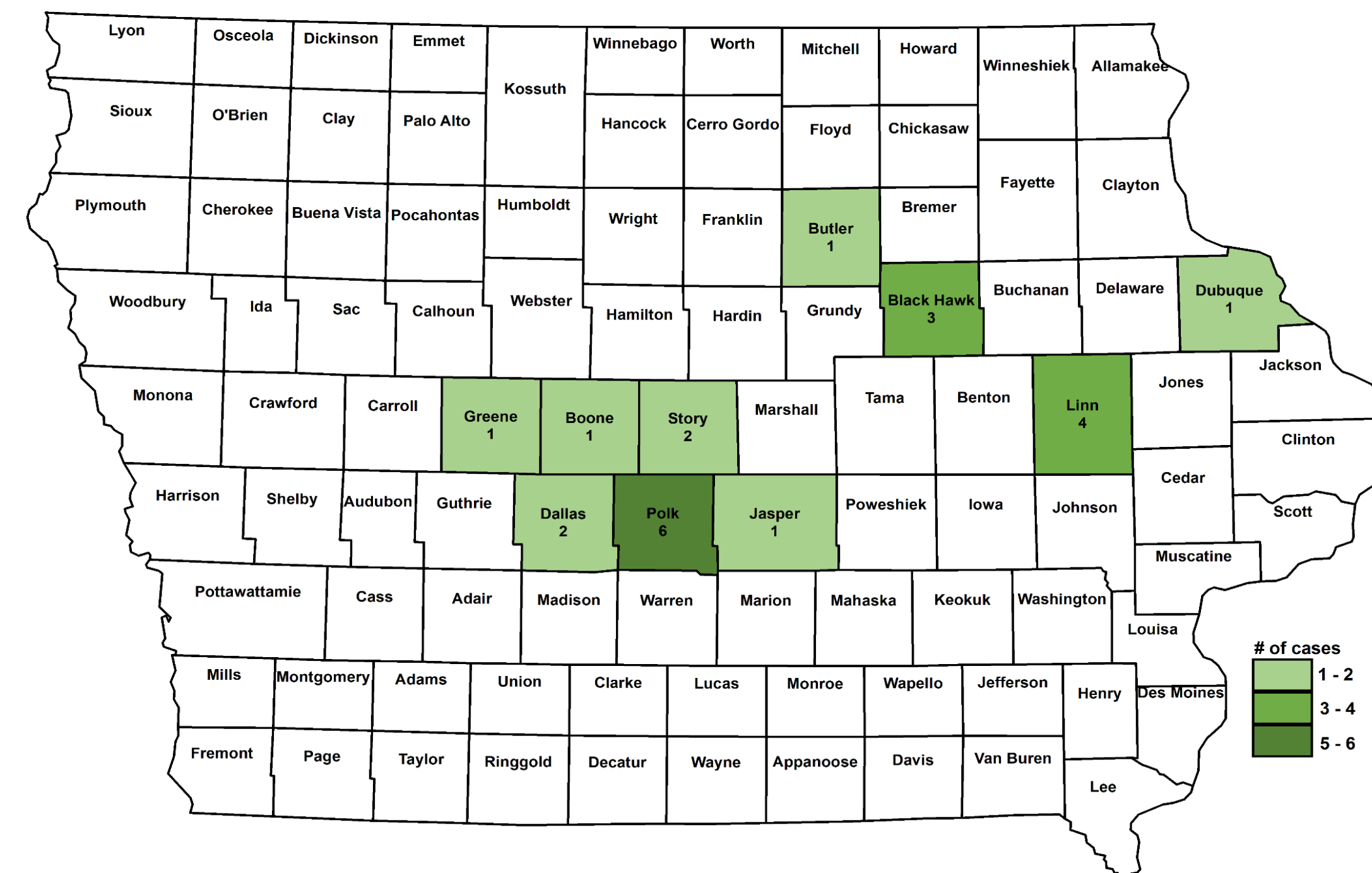


Figure 1. Map of confirmed cases, by county of residence (N=22)



Figure 2: Clover sprouts submitted for testing (photo by C. Lord, SHL)

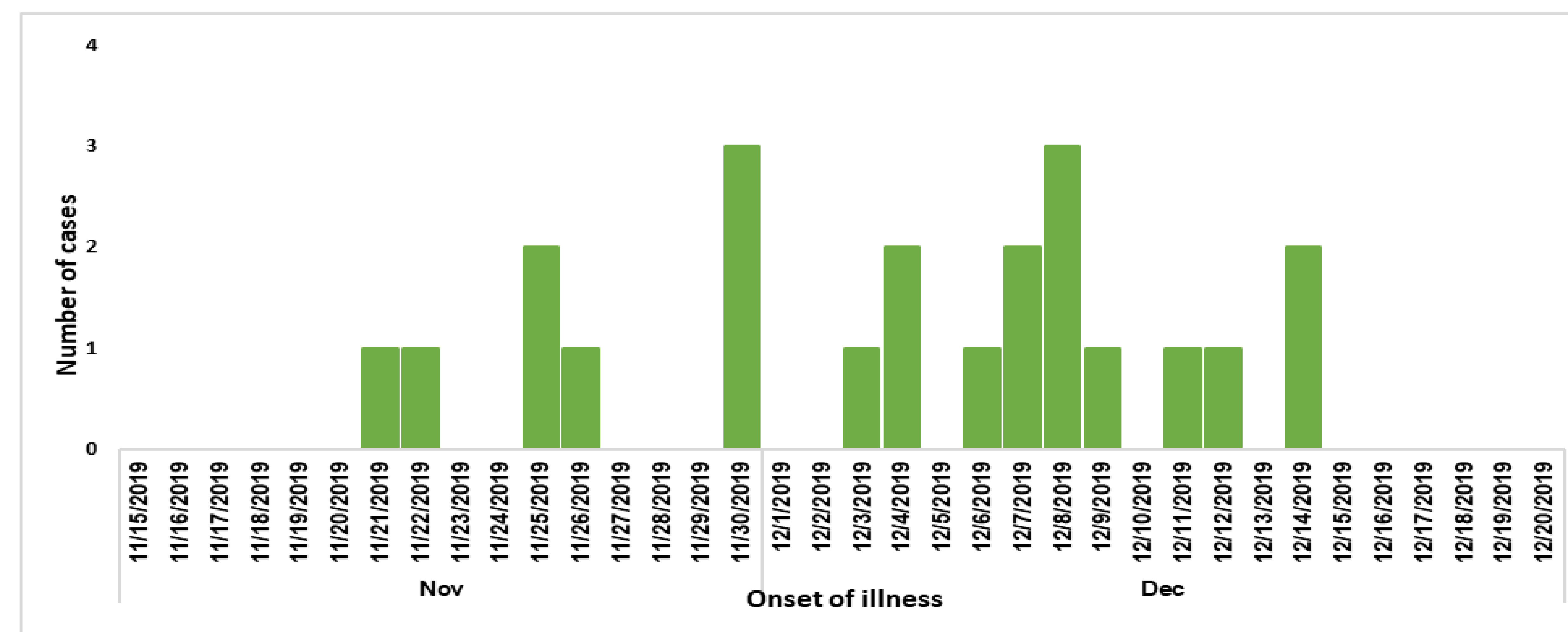


Figure 3. Epidemiologic curve of confirmed cases, by date of illness onset

## Environmental Investigation

After notification on December 19, 2019, DIA notified the sub-sandwich franchise owners on December 20, 2019 and conducted a traceback investigation that identified a single Iowa based sprout producer. DIA worked with the franchise owners and corporate headquarters to have the product removed from sale at all of the restaurant locations. Based on epidemiological information, all locations voluntarily suspended the sales of clover sprouts immediately.

On December 22, 2019, DIA worked with the sprout grower and requested clover sprout distribution records, clover seed supplier records, spent irrigation water testing results, and clover sprout production records. The sprout grower stated approximately 98% of their clover sprouts were distributed to the Iowa based restaurant locations. The remaining were distributed to retail grocery stores and none of their sprouts were distributed outside of Iowa. Based on the epidemiological information, the grower voluntarily ceased distribution, recalled clover sprouts, and decided not to distribute any additional clover sprouts or other sprout varieties grown on the same line as the clover sprouts.

On December 31, 2019, DIA and the Food and Drug Administration (FDA) performed a week-long inspection at the sprout grower. Violations observed during this inspection lead FDA to issue a warning letter to the sub-sandwich franchise on February 21, 2020 and the sprout grower on February 25, 2020.

## Laboratory Investigation

Spent irrigation water (SIW) and 16 packages of clover sprout samples were collected and sent to SHL for testing. Enrichment procedures recommended and used for *E. coli* O157 testing in this complex matrix were used (Figure 2).

All clinical and environmental samples submitted to SHL were identified as carrying the *stx1a* toxin gene using real-time PCR, serotyped by conventional agglutination, and sequenced using PulseNet procedures. SHL identified *E. coli* O103 from 12/16 clover sprouts packages and corresponding SIW. Both environmental isolates (one clover sprout package and the SIW) were highly related to the 22 human clinical isolates by whole genome sequencing (0-2 SNP's).

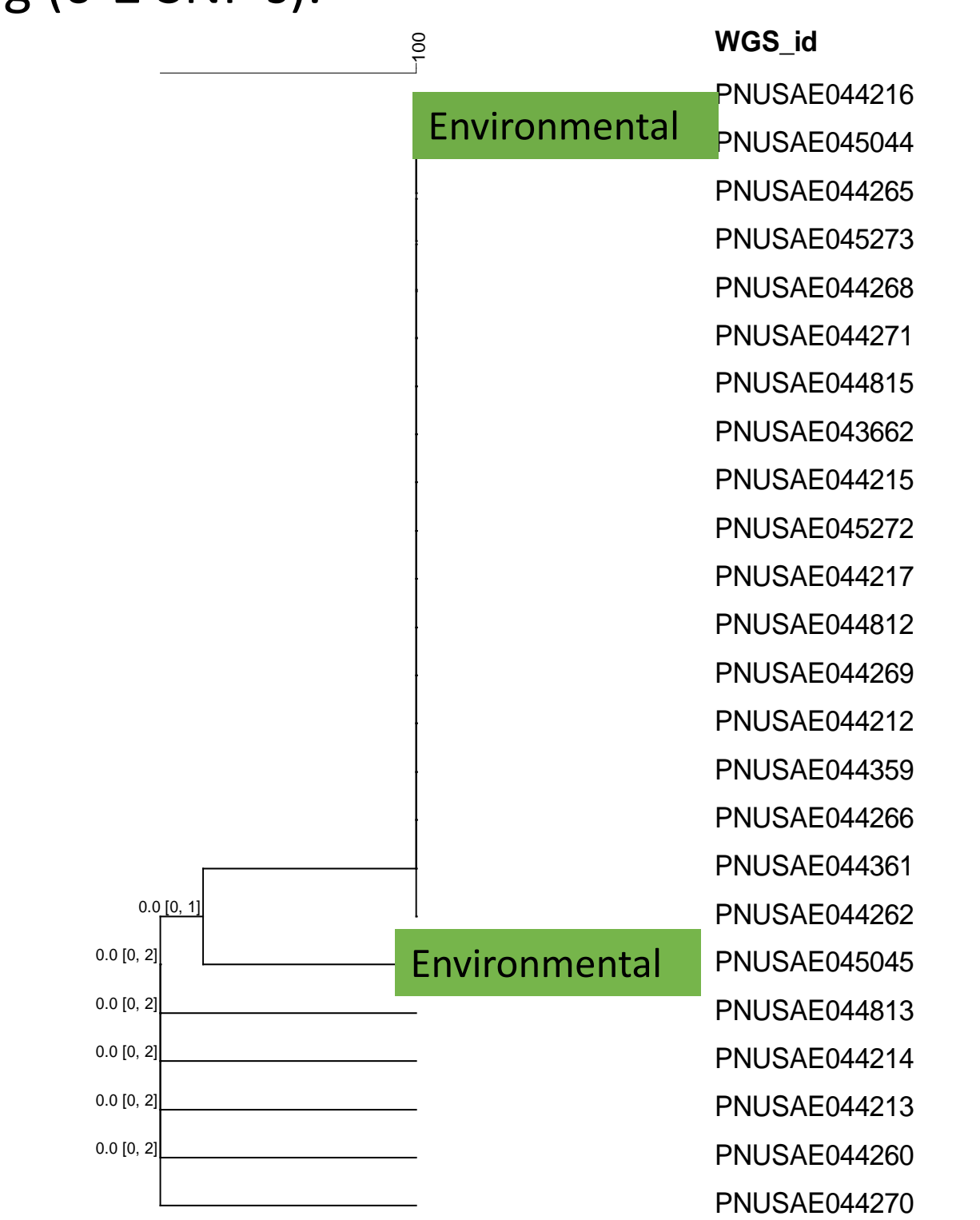


Figure 4. Dendrogram of *E. coli* O103 clinical and environmental isolates

## Discussion

The FSMA Produce Safety rule establishes science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption which includes sprout. Sprout growing operations are subject to sprout-specific requirements which include testing spent irrigation water for *Salmonella* and *E. coli* O157:H7. STEC testing is currently not included in this requirement. Given the fact that there have been other reports of non-O157 STEC outbreaks and the recent occurrence of this *E. coli* O103 outbreak associated with sprouts has major implications to the FSMA Produce Rule.

## Recommendations

STEC testing of SIW should be recommended as best practice for improving sprout safety to prevent future outbreaks of toxigenic *E. coli*. In addition, method validations should be performed on SIW for STEC testing. SHL was able to successfully detect the STEC using the same enrichment procedures recommended and used for *E. coli* O157 testing in this complex matrix.