

Research Article

Food-Contact-Surface and Product-Test *Listeria monocytogenes* Positivity in U.S. Ready-to-Eat Meat and Poultry Establishments: Concurrent, Cumulative, and Temporally Separated Associations in USDA-FSIS Sampling Data, 2015-2025

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Background. *Listeria monocytogenes* (Lm) is a major hazard in ready-to-eat (RTE) meat and poultry, but the relationship between food-contact-surface (FCS) and product-test positivity has not been quantified nationally. **Methods.** We analyzed USDA-FSIS Laboratory Sampling Data for FY2015-2025. Because no event identifier was available, coordinated risk-based Lm events were defined by establishment-date. We assessed concurrent FCS-product positivity, establishment-level cumulative product-positive rates, a four-level FCS/non-food-contact-surface (NFCS) comparison, and exploratory temporally separated associations. **Results.** Among 2,945 coordinated events, product positivity was 20.3% at FCS-positive events versus 0.21% at FCS-negative events (13/64 vs. 6/2,881), an absolute risk difference of 20.1 percentage points (cluster-bootstrap 95% CI: 10.6-30.4). Ever-FCS-positive establishments had higher product-positive rates (rate ratio 4.6, 95% CI: 3.2-6.8), remaining elevated after removal of same-event co-detection (3.2, 95% CI: 2.0-5.0). FCS-positive-only establishments had the highest adjusted product-positive rate, although the FCS/NFCS relationship was non-additive and sensitive to testing structure. Temporally separated estimates were directionally positive but based on only four to five exposed positives. **Conclusions.** FCS positivity was strongly associated with concurrent product positivity and higher cumulative product-positive rates. Findings are associational, informative sampling cannot be excluded, and prospective predictive utility could not be established.

1. Introduction

Listeria monocytogenes is among the most lethal foodborne pathogens and a leading cause of foodborne death in the United States [1]. Ready-to-eat (RTE) meat and poultry are recognized vehicles because contamination introduced after the lethality step—during slicing, peeling, or packaging—reaches consumers without a further listericidal treatment [2], and deli and RTE meats feature among the food vehicles of U.S. listeriosis outbreaks [3]. A central tenet of modern control is that the processing environment is an important proximate source: *Lm* establishes harborage sites and can persist on equipment and premises despite sanitation [4][5][6][7], and whole-genome sequencing has recovered related strains from a facility over time [8]. Systems-based control frameworks emphasize environmental monitoring of food-contact surfaces as a cornerstone of prevention [9][10][11]. This motivates environmental testing and, in particular, the distinction between **food-contact surfaces (FCS)**—which touch product—and **non-food-contact surfaces (NFCS)**, one step removed from product.

USDA-FSIS operationalizes these concepts through defined sampling programs: random and risk-based product sampling (RTEPROD_RAND, RTEPROD_RISK) verify finished product, while the risk-based *Lm* program (RLm) collects coordinated product (RLMPRODC), food-contact (RLMCONT), and non-food-contact (RLMENVC) samples during an establishment visit, under the regulatory framework for *Lm* control in post-lethality RTE products [12][13][14]. Prior national work characterized the occurrence and temporal distribution of *Lm* in FSIS RTE product-verification samples over 2005-2017 [15], and premises-to-product links, including food-contact surfaces as a dissemination route, have been described in smaller and facility-level settings [16][17][18]. What has not been quantified with U.S. national regulatory data is the **strength and structure of the FCS-product relationship**: how strongly an FCS test-positive coincides with a product test-positive within the same coordinated event, whether that signal is stronger for food-contact than for any environmental surface, whether it persists after removing same-event co-detection, and whether it carries to temporally separated product tests.

These are distinct questions—**concurrent**, **establishment-level cumulative**, and **temporally separated** associations—that are frequently conflated. An FCS positive could strongly coincide with a current product positive (useful for detection) and mark higher-risk establishments (useful for scheduling) yet not anticipate later product positivity. Distinguishing them is decision-relevant. We therefore analyze all

three, use NFCS as a comparator with a formal contrast, and frame every estimand as **associational under the observed regulatory-and-corrective-action system**, not causal. We emphasize that the data measure **regulatory test positivity**, not the prevalence of contamination across all product an establishment makes, and that a positive environmental sample is not proof of transfer to product. Concurrent positivity is compatible with several explanations—direct surface-to-product transfer, product-to-surface transfer, a common upstream source, shared harborage, or targeted sampling of a visit already suspected to be high-risk—and our design cannot distinguish among them (Figure 1). Because the originally prespecified prospective analysis proved statistically sparse, we present this work as a rigorous **exploratory** characterization of national regulatory data, with the concurrent-event analysis designated the principal analysis (Section 2.4).

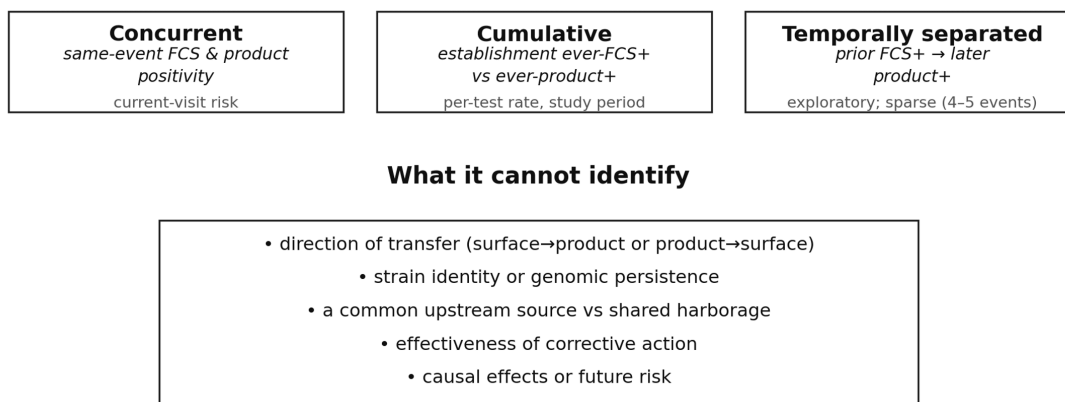


Figure 1. *Estimands estimated by this study (concurrent, cumulative, temporally separated) and what the design cannot identify.*

2. Materials and Methods

2.1. Data and provenance

We analyzed the public FSIS Laboratory Sampling Data ("Ready-to-Eat Product & Risk-based *Listeria monocytogenes* Sampling"), downloaded as fiscal-year JSON files FY2014–FY2026 on 2026-06-23; each file's SHA-256 checksum, size, and provenance are recorded in the repository, and raw files were never modified. Analyses used the 11 complete fiscal years **FY2015–FY2025**; incomplete FY2026 was excluded and FY2014 served only as prior-history context.

2.2. Analytical unit, classification, and analysis-specific cohorts

Every record carries a unique `sample_number` and an effectively unique `form_id` (256,079 distinct values across 256,080 rows; no `form_id` spans two project codes). The public data therefore expose **form-level laboratory results**, not verified physical-sample counts or composite structure; we use "form-level laboratory result" throughout and make no claim about the number of swabs or sub-samples a form represents. Records were classified by `project_code` and `sample_source_name` as **routine product** (RTEPROD/_RAND/_RISK), **RLm-coordinated product** (RLMPRODC), **FCS** (RLMCONT; "Product Contact Surface Sponge"), or **NFCS** (RLMENVC/RLMENVR; "Non/Product Contact Surface Sponge"). Because "Non/Product Contact Surface" contains the substring "Product Contact Surface," the non-food-contact test was applied first. RLMENVR contributed only 29 routine form-level results (all Lm-negative, predominantly water/brine), so non-food-contact results are effectively RLMENVC; an NFCS analysis using RLMENVC only was identical to one including RLMENVR (Section 3.5). Intensified/for-cause programs (codes beginning "INT") were held separate from routine analyses. The Lm result was treated as positive/negative when determinate; non-Lm *Listeria* species were never counted as Lm. The complete project-code × sample-source classification dictionary is provided as Supplementary Table S1.

Establishment-level analyses used **analysis-specific tested cohorts** so that a negative environmental exposure means *tested-negative*, not *untested*: the FCS-cumulative cohort comprised establishments with qualifying product testing **and** at least one FCS test; the NFCS-cumulative cohort, product testing **and** at least one NFCS test; the joint cohort, product, FCS, **and** NFCS testing. Establishments never tested for the relevant surface were excluded, not coded negative (counts in Section 3.1 and Figure 2).

2.3. Coordinated-event definition and aggregation

No official sampling-unit, assignment, lot, or event identifier exists in the public data. A **coordinated RLm event** is therefore defined operationally as an `establishment_id` on a `collection_date`; the primary concurrent analysis uses events at which both RLMPRODC product and RLMCONT FCS were collected. Event positivity is defined as ≥ 1 positive form of the relevant type on the establishment-date (product-positive event: ≥ 1 positive RLMPRODC form; FCS-positive event: ≥ 1 positive RLMCONT form; NFCS-positive event: ≥ 1 positive RLMENVC form). Because an establishment-date may in principle contain more than one true sampling event, we flagged **ambiguous** event-days (multiple product categories or production alternatives, or form counts above the 99th percentile); the principal concurrent analysis uses all 2,945 coordinated establishment-date events, and restricting to the unambiguous subset is a

sensitivity analysis. We report the distribution of forms per event and treat same-day routine RTEPROD product—operationally not coordinated with RLMCONT—only as a comparator.

2.4. Analysis hierarchy and chronology

The analysis plan was prespecified in a time-stamped, version-controlled document (frozen 2026-06-23) with every post-freeze change recorded in a deviation log; it was **not** externally preregistered, and we use "prespecified," not "preregistered." The originally prespecified primary analysis was prospective; because it proved statistically sparse (Section 3.7), the concurrent-event analysis was **designated the principal analysis for the revised manuscript**, with the plan's establishment-level fallback and additional analyses elevated. The final hierarchy is: **primary**—concurrent association within coordinated RLM events; **key secondary**—establishment-level cumulative association (and its robustness to removing concurrent co-detection) and the FCS-versus-NFCS comparison; **exploratory**—temporally separated (prospective and establishment-year) analyses, recurrence, and the analyses below. Each analysis is labeled by status:

- **Prespecified:** the temporally separated (prospective) per-opportunity association; the FCS-versus-NFCS specificity comparison; the rare-event (Firth) strategy and separation of intensified verification testing (IVT) from routine sampling.
- **Prespecified fallback:** the establishment-level cumulative association (analysis-plan Fallback C).
- **Added after data inspection (principal):** the concurrent coordinated-event analysis, elevated to primary when the prospective analysis proved sparse.
- **Added after data inspection (sensitivity):** co-detection exclusion; analysis-specific tested cohorts; ambiguous-event restriction; detection-opportunity adjustment; first-event and modal-configuration analyses; the temporal split; the within-establishment permutation and reverse-time analyses.
- **Exploratory:** the FCS×NFCS interaction and four-level model; within-event positive-form burden; the establishment-year design; first-FCS-versus-first-product timing; and product-category descriptives.

Post-hoc *p*-values are interpreted as exploratory, not confirmatory; no formal multiplicity correction was applied to sensitivity analyses, whose exploratory status is made explicit.

2.5. Statistics

For each 2×2 we report full counts, absolute risks with exact (Clopper–Pearson) 95% confidence intervals, risk differences, risk ratios, and odds ratios; a Haldane–Anscombe 0.5 correction was applied only when a cell was zero. Establishment-clustered logistic regression and an establishment-level block (cluster)

bootstrap (5,000 resamples, percentile intervals, 0.5 correction applied within any replicate containing a zero cell, all replicates valid) provided clustered inference; product-testing opportunities within an establishment were never treated as independent [19]. To address unequal detection opportunity, the concurrent model was additionally adjusted for the number of FCS and product forms per event, and re-estimated within the modal sampling configuration. Establishment-level binary associations used Firth penalized logistic regression [20][21], appropriate for rare-event and separation-prone data [22], reported both minimally adjusted (commodity, years observed) and fully adjusted (additionally log product-test count, log FCS-test count, and product-program composition); the FCS-versus-NFCS comparison used a **four-level categorical exposure model** (neither / NFCS-only / FCS-only / both) on the both-tested cohort as the principal analysis, with adjusted marginal product-positive probabilities and risk differences by g-computation (establishment-bootstrap CIs), a Firth-penalized FCS×NFCS interaction test (with establishment bootstrap and leave-one-establishment-out checks), and a ratio-of-odds-ratios sensitivity across FCS/NFCS testing thresholds (≥ 1 , ≥ 2 , ≥ 5 , ≥ 10 of each). Cumulative associations were additionally estimated as product-positive **rates** (positives per product test; quasi-Poisson with a log product-test offset and overdispersion scaling) for ever-FCS-positivity, the co-detection-removed outcome, and the four-level groups, reducing the mechanical influence of unequal numbers of product tests in the binary "ever-positive" outcome; a quasi-binomial (binomial-denominator) model was run as a sensitivity, and the co-detection-removed outcome was constructed both by removing same-event product-positive results from the numerator and by removing same-event product tests from both numerator and denominator. Sparse temporally separated analyses emphasized descriptive risks with establishment cluster bootstraps and leave-one-exposed-positive-establishment-out checks rather than regression. The Firth estimates were independently reproduced by a from-scratch penalized-likelihood implementation (profile-likelihood CIs) coded separately from the firthlogist package. A within-establishment permutation test (shuffling FCS-positive status across an establishment's coordinated events, preserving its FCS and product burden) and a reverse-time analysis served as sensitivity analyses. A fixed seed (20260623) governed all stochastic procedures. Reporting follows the STROBE guidance for observational studies [23]. Analyses used Python (pandas, numpy, statsmodels, scikit-learn, scipy, firthlogist).

2.6. Ethics

The study analyzes public, establishment-level regulatory data; it involves no human participants or personally identifiable information. Analytical outputs use anonymized identifiers and no establishment is named or ranked.

3. Results

3.1. Cohort (Figure 2, Table 1)

From 256,080 downloaded rows we retained 256,079 unique form-level results, 254,149 with a determinate Lm result, 227,921 from FY2015–FY2025, and **201,927** routine (non-intensified) form-level results—4,071 RLMPRODC, 153,340 RTEPROD, 40,422 FCS (RLMCONT), and 4,094 NFCS (RLMENVC/RLMENVR) units. Of 3,529 product-testing establishments, the **FCS-cumulative cohort** comprised 2,200 (67 ever-FCS-positive, 2,133 tested-all-negative; 1,329 never-FCS-tested establishments excluded rather than coded negative); the **NFCS-cumulative cohort** comprised 2,196 (250 ever-NFCS-positive, 1,946 tested-all-negative; 1,333 excluded); and the **joint cohort** comprised 2,195 (209 product-positive). Across the routine data, product, FCS, and NFCS test (positive) counts were 157,411 (388), 40,422 (109), and 4,094 (299). There were **2,945** coordinated RLm events at 2,159 establishments.

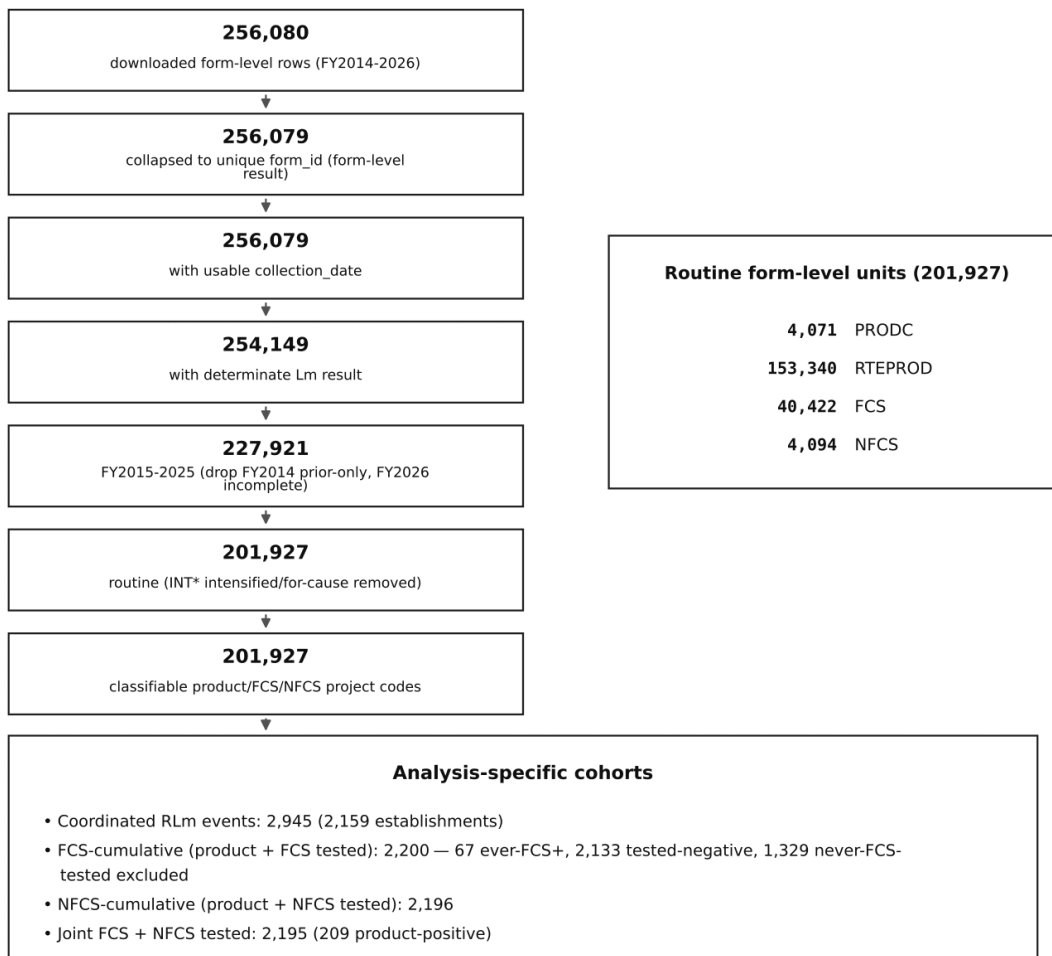


Figure 2. Sample harmonization, exclusions, and analysis-specific cohorts (FY2015-2025).

Characteristic	Value
Fiscal years	FY2015-2025 (11 complete)
Routine form-level results	201,927
RLMPRODC / RTEPROD / FCS / NFCS units	4,071 / 153,340 / 40,422 / 4,094
Product-testing establishments	3,529
FCS-cumulative cohort (product+FCS tested)	2,200 (67 ever-FCS+, 2,133 tested-neg; 1,329 never-FCS-tested excluded)
NFCS-cumulative cohort (product+NFCS tested)	2,196 (250 ever-NFCS+, 1,946 tested-neg; 1,333 excluded)
Joint both-tested cohort	2,195 (209 product+)
Coordinated RLM events	2,945 (2,159 establishments)
Product / FCS / NFCS tests (positives)	157,411 (388) / 40,422 (109) / 4,094 (299)

Table 1. Cohort summary, FY2015-2025.

3.2. Concurrent association within coordinated RLM events (primary; Figure 3, Table 2)

Among the 2,945 coordinated events, product-test positivity was 20.3% (13/64; exact 95% CI 11.3-32.2) at FCS-positive events versus 0.21% (6/2,881) at FCS-negative events—an absolute risk difference of 20.1 percentage points (establishment cluster-bootstrap 95% CI 10.6-30.4). The relative measures were correspondingly large—risk ratio 98, odds ratio 122, establishment block-bootstrap OR 126 (95% CI 47-458)—but rest on only 19 positive events and are reported as secondary; we let the establishment cluster bootstrap, rather than a Fisher exact p-value (which ignores clustering), carry the inference. The absolute-risk contrast is the most stable and decision-relevant quantity, and we present this concurrent analysis as an exploratory characterization (Section 2.4).

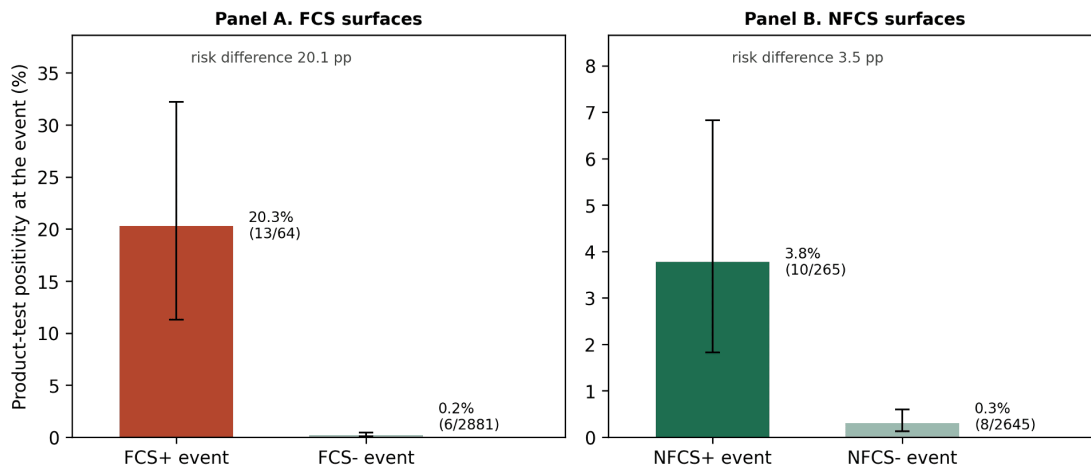


Figure 3. Concurrent product-test positivity within coordinated RLM events, FCS (Panel A) and NFCS (Panel B); exact 95% binomial CIs. Event-positive = ≥ 1 positive form of that type on the establishment-date; exact 95% binomial CIs

Metric	Value
FCS-positive events: product-positive	13/64 (20.3%, 95% CI 11.3–32.2)
FCS-negative events: product-positive	6/2,881 (0.21%)
Risk difference	20.1 percentage points
Risk ratio (95% CI)	98 (38–248)
Odds ratio (95% CI)	122 (45–334)
Block-bootstrap OR (5,000 reps)	126 (47–458)
Detection-opportunity adjusted OR	116
Modal-configuration OR (95% CI)	70 (17–294); 4/31
Unambiguous events (major sensitivity): OR; risk difference	OR 83.5 (27.7–251.4); RD 16.1 pp (6.4–27.3)
First-event-per-establishment OR (95% CI)	198 (51–767)
Replication OR: FY2015–2020 / FY2021–2025	130 / 115 (heterogeneity p=0.94)
Within-establishment permutation (n>=obs/n; p)	53/5000; p=0.011

Table 2. Concurrent association within coordinated RLM events (primary), with robustness checks.

Several checks (each with full counts and 95% CIs in Table 2 and Supplementary Table S3) reduced concern about artefactual explanations, though informative sampling cannot be excluded. **Detection opportunity:** the median number of FCS forms per event was identical (10) in FCS-positive and FCS-negative events, and product forms identical (1) in product-positive and product-negative events; adjusting the concurrent model for FCS- and product-form counts left the association essentially unchanged (OR 116, 95% CI 44–308), and restricting to the modal sampling configuration (10 FCS, 1 product form; 1,555 establishments) preserved it (OR 70, 95% CI 17–294; 4/31 vs unexposed). **Clustering:** the 13 exposed positives arose from 13 distinct establishments and the 6 unexposed positives from 6 distinct establishments, with no establishment contributing more than one product-positive event; a leave-one-positive-establishment-out analysis left the risk ratio between 91 and 117, and restricting to one (first) coordinated event per establishment gave 22.0% versus 0.14% (OR 198, 95% CI 51–767). **Ambiguity (major sensitivity).** 323 of 2,945 event-days (11.0%) were flagged ambiguous (multiple product categories or production alternatives, or FCS/product form counts above the 99th percentile), and 5 of the 13 exposed product-positive events fell on such days. Restricting to the 2,622 unambiguous events, product-test positivity was 16.3% (8/49) at FCS-positive versus 0.23% (6/2,573) at FCS-negative events—a risk difference of 16.1 percentage points (establishment cluster-bootstrap 95% CI 6.4–27.3); OR 83.5 (95% CI 27.7–251.4). The association thus persisted after excluding ambiguous establishment-date events, although both the exposed-positive count (13→8) and the relative estimate were attenuated. **Within-event burden:** a greater number of positive FCS forms at an event was associated with product positivity in an exploratory, hypothesis-generating analysis resting on 13 product-positive events (Supplementary Table S9); it is not interpreted as a dose-response.

3.3. Temporal internal consistency and sensitivity analyses (Figure 4)

The concurrent association was directionally consistent across an approximately balanced temporal split at the FY2020/2021 boundary (not tied to a specific documented program change): FY2015–2020 gave 18.9% versus 0.18% (7/37 vs 3/1,638; OR 130, 95% CI 32–526) and FY2021–2025 gave 22.2% versus 0.24% (6/27 vs 3/1,243; OR 115, 95% CI 27–491), with no evidence of period heterogeneity (interaction $p=0.94$); both rest on few positive events, so this is internal consistency rather than independent replication. In a within-establishment **permutation sensitivity analysis**—shuffling FCS-positive status across each establishment's coordinated events while preserving its FCS and product burden—the informative set was the 33 establishments with within-establishment variation in FCS status (of 2,159 contributing a

coordinated event; 646 had more than one event); 53 of 5,000 permuted risk ratios were at least as large as observed (exact empirical $p = (53+1)/(5,000+1) = 0.011$). Among establishments with such variation, the observed event-level association exceeded the permutation distribution, suggesting same-event concordance beyond establishment-level clustering; we treat this as a sensitivity analysis, not a principal inferential test, and do not interpret it as partitioning the association. A direct within-establishment (fixed-effects) design was not estimable—only 5 of the 33 establishments with FCS variation also had product-outcome variation, so conditional logistic regression was unstable—and the permutation controls for time-invariant establishment burden but not time-varying event-level confounders (fiscal period, product category, sampling configuration, regulatory suspicion). Descriptively, among these 33 establishments all five product-positive coordinated events occurred at FCS-positive events (5 of 33) and none at FCS-negative events (0 of 49), which is the empirical information underlying the permutation analysis. A **reverse-time** analysis (product positivity versus a *future* FCS positive 31–365 d later) yielded no exposed positive outcomes and was too sparse to be informative; same-day routine RTEPROD product co-occurred at only 110 events with no product positives and was likewise uninformative.

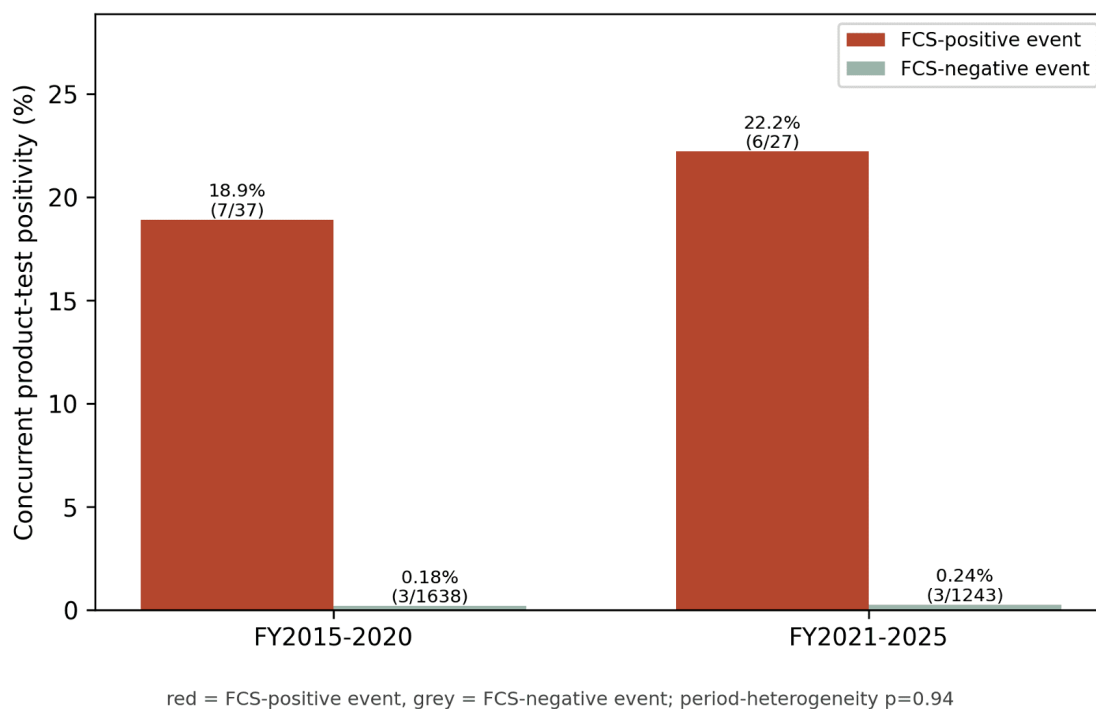


Figure 4. Temporal internal consistency of the concurrent association across two fiscal periods.

3.4. Establishment-level cumulative association and co-detection (key secondary; Figure 5A, Table 3)

On the FCS-cumulative cohort ($n=2,200$), ever-FCS-positive establishments were product-positive in **43.3% (29/67)** of cases versus **8.4% (180/2,133)** otherwise; the association was OR 8.0 (95% CI 4.8-13.4) minimally adjusted and **9.2 (95% CI 5.4-15.7)** fully adjusted (209 product-positive establishments). Because the ever/ever framing can count a single positive RLM episode in both variables, we removed product positives concurrently co-detected with an FCS positive. Same-event (same-day) exclusion removed 13 product-positive forms across 13 events and changed the binary outcome of 10 establishments, reducing the adjusted association to **4.6 (95% CI 2.6-8.1)**; widening the window to 7, 30, and 90 days removed 14-16 forms but changed no additional establishment's outcome, leaving the estimate at 4.6 throughout (199 product-positive establishments remaining). The cumulative association is thus **partly attributable to concurrent co-detection but does not disappear**, and we describe FCS positivity as identifying establishments with a broader history of product-test positivity rather than as an effect independent of co-detection. Because the binary "ever-positive" outcome is mechanically inflated by testing opportunity, we also modeled the product-positive **rate** (positives per product test; quasi-Poisson with a log-test offset): the rate ratio for ever-FCS-positive versus tested-negative establishments was **4.6 (95% CI 3.2-6.8)**. The co-detection-removed rate—excluding same-event product tests from both the positive numerator and the test denominator (the cleaner construction)—was **3.2 (95% CI 2.0-5.0)**, essentially unchanged across 7-, 30-, and 90-day exclusion windows (2.8-3.1) and similar to a numerator-only removal (3.1). A quasi-binomial log-link model gave a consistent rate ratio (4.6; a logit-link version gave an odds ratio of 4.7), the quasi-Poisson dispersion was modest (1.23), and the estimate was stable to dropping the highest-volume 1% of establishments (4.7); the cumulative association thus persisted after expressing outcomes per product test, although informative sampling (risk-based targeting, product mix, facility size) remains possible. The direction persisted across product programs: ever-FCS-positive-versus-tested-negative rate ratios were 38.5 (95% CI 15.2-97.4) for RLM-coordinated product (RLMPRODC; 22 positives), 3.7 (2.0-6.9) for random (RTEPROD_RANDOM; 100 positives), and 2.9 (1.6-5.3) for risk-based (RTEPROD_RISK; 126 positives) product testing (full counts, per-group rates, and CIs by program and exclusion window in Supplementary Table S10). Critically, the routine programs (RTEPROD_RANDOM, RTEPROD_RISK)—which are not coordinated with FCS sampling—were essentially unchanged when co-detected tests were removed from both numerator and denominator (3.8 and 2.5 at a 30-day window), whereas the RLMPRODC estimate, being the product component of the coordinated

visit, was largely concurrent co-detection: it fell to 5.6 (95% CI 0.7–47.7) when same-event tests were removed and was unestimable at 30 days. The co-detection–stable persistence in the routine programs is therefore the stronger program-specific evidence. This rate model is a **retrospective establishment-history comparison**: it contrasts long-term product-test positivity between establishments classified by whether they were ever FCS-positive during the study period, and does not require FCS positivity to precede the product tests; it is therefore not an exposure–effect estimate. Among the 29 establishments positive for both FCS and product over the study period, the first FCS positive preceded the first product positive in 12, followed it in 6, and fell on the same date in 11 (median signed interval 0 days, IQR 0–596), so the cumulative co-occurrence reflects a mix of same-episode co-detection and FCS–preceding sequences rather than a consistent temporal order (and first recorded positivity is not first biological contamination).

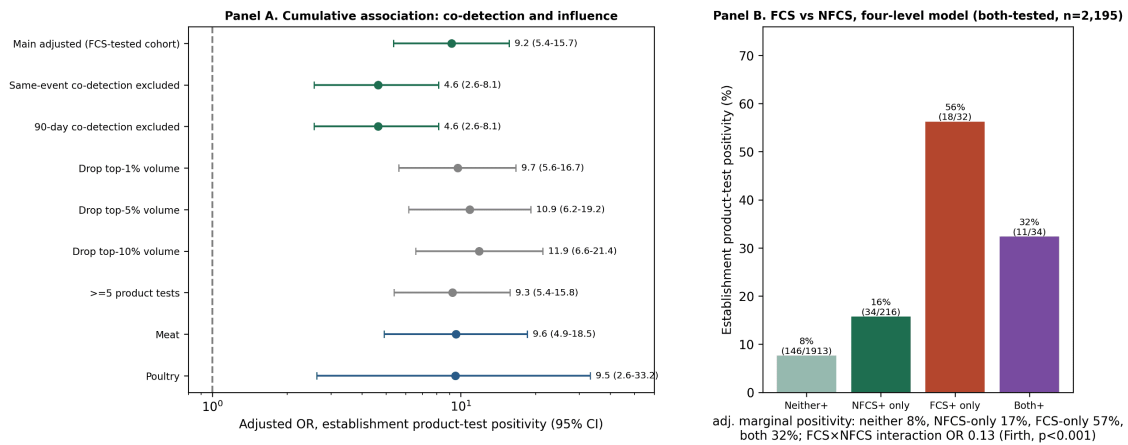


Figure 5. Establishment-level cumulative association with co-detection and influence checks (Panel A) and the FCS–vs–NFCS contrast (Panel B).

Outcome definition	Product-pos establishments	Adjusted OR	95% CI
All product positives (no exclusion)	209	9.2	5.4-15.7
Exclude same-event co-detected	199	4.6	2.6-8.1
Exclude within 7 d	199	4.6	2.6-8.1
Exclude within 30 d	199	4.6	2.6-8.1
Exclude within 90 d	199	4.6	2.6-8.1

Table 3. Establishment-level cumulative association and robustness to removing concurrently co-detected product positives.

3.5. Food-contact versus non-food-contact (key secondary; Figure 5B)

Because the FCS/NFCS relationship proved non-additive, the **four-level categorical model is the principal FCS/NFCS analysis**. On the both-tested cohort (n=2,195), adjusted marginal product-positive probabilities (g-computation; adjusted for testing intensities, program composition, commodity, and years observed) were 7.6% (95% CI 6.5-8.7) for neither surface positive, 16.9% (12.0-22.8) for NFCS-positive only, 57.3% (39.4-74.2) for FCS-positive only, and 32.3% (15.4-48.3) for both positive—risk differences versus neither of +9.3, +49.7, and +24.8 percentage points (raw cells 146/1,913, 34/216, 18/32, 11/34). FCS-positive-only establishments thus had the highest observed adjusted product-positive probability and rate. The relationship was, however, **non-additive**: the both-positive group sat below the FCS-only group, and a formal FCS×NFCS interaction was significantly sub-multiplicative and stable to bias reduction and influence checks (Firth interaction OR 0.13, 95% CI 0.04-0.38; establishment bootstrap 0.03-0.38; leave-one-FCS-establishment-out 0.11-0.14). The two FCS-positive groups (FCS-only n=32, both n=34) were closely similar in product-, FCS-, and NFCS-test counts, years observed, and commodity, so the lower both-positive value was not accounted for by the measured product-, FCS-, and NFCS-test counts, years observed, or broad commodity classification, and—on 32-34 establishments—unmeasured establishment heterogeneity and chance cannot be excluded; we do not give it a biological interpretation. Among the 34 both-positive establishments, first FCS and first NFCS positivity were frequently concurrent (25 same-date; 7 NFCS-first, 2 FCS-first; median gap 0 days), although temporal heterogeneity remained (~21% separated by more than a year), so temporal separation does not readily account for the lower both-

positive rate but cannot be fully excluded. A single additive FCS-versus-NFCS ratio of odds ratios is therefore **not an adequate summary**: under the additive model it was 4.1 (95% CI 1.7-10.1) but fell to 2.8 (1.0-7.9, $p=0.06$) when restricting to establishments with ≥ 2 FCS and ≥ 2 NFCS tests and was unstable and non-significant at ≥ 5 of each ($n=101$), so the contrast depends on model specification and testing intensity. The NFCS-cumulative association was weaker (fully adjusted OR 2.6, 95% CI 1.8-3.8) and essentially identical whether non-food-contact was defined as RLMENVC only or RLMENVC plus the 29 RLMENVR forms (all negative; Section 2.2). A product-positive **rate** model reproduced this ordering—adjusted 2.0, 3.4, 13.3, and 7.7 positives per 1,000 product tests for neither, NFCS-only, FCS-only, and both (rate ratios versus neither 1.7, 6.5, and 3.8)—so the non-additive “both below FCS-only” pattern survives per-test normalization (the ordering persisted after normalizing product-positive results by the number of product tests), although informative sampling cannot be excluded. We therefore conclude that **FCS-positive-only establishments had the highest observed adjusted product-positive probability and rate, although the four-group relationship was non-additive, based on small groups (32 and 34 establishments), and sensitive to testing structure—not an intrinsic biological specificity**. This comparison is a secondary, exploratory result.

3.6. *Recurrence (exploratory)*

Recurrent FCS positivity could not be characterized because only two establishments had more than one distinct FCS-positive visit (Supplementary Table S5); we make no claim of dose-response or strain persistence.

3.7. *Temporally separated associations (exploratory)*

Among 135,384 routine product opportunities at 3,064 establishments (median 37 opportunities each, IQR 13-69), each with ≥ 365 d of prior in-data observation (required so prior FCS-testing history could be fully and consistently ascertained, avoiding left truncation), and keeping three **non-exchangeable** exposure groups distinct, product-test positivity was 1.12% (4/357) following a prior FCS positive, 0.19% (28/14,785) following prior FCS testing that was all-negative, and 0.24% (292/120,242) with no FCS testing in the lookback. With only four exposed positive events the prospective estimate was **imprecise and exploratory rather than unestimable**: the prior-FCS-positive-minus-tested-negative risk difference was 0.9 percentage points (establishment cluster-bootstrap 95% CI 0.04-2.07), but this rests on four exposed positives from four distinct establishments and falls to ≈ 0.7 percentage points on leave-one-establishment-out, so the small number of exposed outcomes prevents a reliable assessment of

prospective predictive utility; we present descriptive risks with a cluster bootstrap rather than a regression model, and do not emphasize whether any single interval excludes zero; interval splits (31-90/91-180/181-365 d, Supplementary Table S6b) were too sparse for stable estimates. A complementary establishment-year design (21,044 establishment-years from 3,119 establishments, 2,764 contributing multiple years; FCS status in fiscal year t , any routine product positive in $t+1$, tested-negative years separated from untested, the final observed year used only as an outcome year) gave product positivity of 10.0% (5/50) after an FCS-positive year versus 1.15% (27/2,353) after a tested-all-negative year and 1.51% (282/18,641) after a year without FCS testing—an absolute risk difference of 8.9 percentage points (establishment cluster-bootstrap 95% CI 1.2-17.8). The five exposed positives came from five distinct establishments, and leave-one-establishment-out left the exposed-year risk at 8.2%; we treat this as imprecise and exploratory and do not report a reliable effect magnitude. We do not conclude that FCS monitoring lacks anticipatory value, nor that corrective action was effective; the data are too sparse to support either conclusion.

3.8. Robustness and independent model validation (Figure 5A)

The establishment-level cumulative association was stable to influence checks: excluding the highest-volume 1%, 5%, and 10% of establishments gave OR 9.7 (95% CI 5.6-16.7), 10.9 (6.2-19.2), and 11.9 (6.6-21.4); restricting to ≥ 5 product tests gave 9.3 (5.4-15.8); commodity-stratified estimates were similar for meat (9.6, 95% CI 4.9-18.5) and poultry (9.5, 95% CI 2.6-33.2). The Firth coefficients from the firthlogist package matched an independent from-scratch penalized-likelihood implementation (profile-likelihood CIs) coded separately, to four decimals, for all three principal establishment models—main cumulative FCS (2.2181 vs 2.2181), joint FCS (2.0392 vs 2.0392), and joint NFCS (0.6341 vs 0.6341; absolute differences 0)—supporting numerical correctness.

4. Discussion

Principal findings. Using 11 complete fiscal years of national FSIS data, an FCS Lm test-positive was **strongly associated with a concurrent product-test positive** within coordinated RLM events (20.3% vs 0.21%; absolute risk difference 20.1 percentage points, establishment cluster-bootstrap 95% CI 10.6-30.4). Ever-FCS-positive establishments had a higher product-positive **rate** (rate ratio 4.6 per product test, 3.2 after removing same-event co-detection), so the cumulative association persisted after per-test normalization, although informative sampling remains possible. The concurrent association was

directionally consistent across two fiscal periods, robust to adjustment for numerical detection opportunity, not driven by any single establishment, and exceeded a within-establishment permutation distribution. The cumulative association was **largest for food-contact-positive-only establishments** (adjusted 13.3 vs 2.0 positives per 1,000 tests when neither surface was positive), in a non-additive FCS/NFCS relationship sensitive to testing structure and reported as secondary. Temporally separated associations were directionally positive but imprecise and exploratory.

What the finding offers, and what is not new. That the processing environment and finished product co-contaminate is established [\[4\]\[5\]\[18\]](#); we do not claim to discover it. Our contribution is to quantify, in national regulatory data, the **magnitude** of the concurrent FCS–product association, the finding that **the highest observed adjusted product-positive rate was among food-contact-positive-only establishments, in a non-additive FCS/NFCS pattern sensitive to testing structure, and its persistence after excluding contemporaneously co-detected positives and after accounting for measured detection opportunity** (including a per-test rate model). For a regulator or processor this is **potentially informative for concurrent detection and risk-based scheduling**: a food-contact-surface positive flags a visit—and an establishment—with elevated current product-positive yield, of plausible use for targeting verification and prioritizing environmental-monitoring effort, though we did not directly evaluate any sampling schedule, decision threshold, or operational outcome. Prospective predictive utility, by contrast, could not be established: temporally separated outcomes were too sparse to demonstrate or exclude forecasting value, and the cumulative marker reflects co-occurring history rather than prospective risk.

Interpreting the concurrent association. That a contaminated establishment yields positive product and food-contact results within one coordinated event is mechanistically unsurprising; the contribution here is to quantify, at national scale and with transparent counts, how large the FCS–product concordance is and how the observed FCS event-level contrast compares descriptively with the corresponding NFCS contrast, and to show that it persisted after adjustment for numerical detection opportunity, was not driven by any single establishment, and remained elevated (though attenuated) when ambiguous event-days were excluded—although informative sampling (which surfaces and products were selected, sanitation timing, regulatory suspicion, facility complexity) cannot be excluded. Critically, concurrent positivity is compatible with several non-exclusive explanations—direct transfer in either direction, a common upstream source, shared harborage, or targeted sampling—and our design cannot distinguish among them (Figure 1). The very large odds ratio should be read alongside its small event counts and the absolute-risk contrast, which is the more stable quantity. The observed concurrent association exceeded

the within-establishment permutation distribution, suggesting same-event concordance beyond that expected from establishment-level clustering alone (the observed and permuted risk ratios are not additively decomposable).

Why the prospective estimate is imprecise, not null. Product-test positivity is rare, and conditioning on a prior FCS positive with full prior observation leaves few exposed events; a positive also triggers intensified verification and corrective sanitation that may alter subsequent testing and risk. These data therefore cannot determine whether a temporally separated association is small, absent, or masked. A higher point estimate following a prior FCS positive (1.1% vs 0.2%) is hypothesis-generating only. The three exposure groups (prior FCS-positive, prior FCS tested all-negative, never FCS-tested) are **not exchangeable**—the never-tested group in particular likely differs in eligibility, product mix, observation time, sampling intensity, and regulatory targeting—so these comparisons are descriptive and exploratory rather than a predictive evaluation. Because intensified testing is excluded, the estimand is association with later **routine** product-test positivity under the observed regulatory-and-corrective-action system; it is not untreated future contamination risk, total post-positive detection, or corrective-action effectiveness. We explicitly avoid claiming that FCS positivity "does not predict" product positivity or that corrective action was "effective."

Cumulative marker, with caveats. Adjusting for testing intensity did not explain the establishment-level association, and excluding the highest-volume establishments left it essentially unchanged, arguing against pure volume confounding; however, sampling intensity is itself plausibly influenced by prior positives and regulatory targeting, so adjustment for measured intensity does not eliminate surveillance-driven selection [24]. We therefore report minimally adjusted (commodity, years observed) and fully adjusted (adding testing intensities and program composition) models side by side and treat neither as automatically more valid, because testing intensity may be simultaneously a confounder, a consequence of prior positives, a targeting variable, and a size proxy. The ever/ever framing measures **cumulative establishment-level co-occurrence** over the study period—a broader history of product-test positivity—not prospective risk, temporal prediction, or environmental exposure preceding product positivity.

Comparison with prior work. We extend national FSIS occurrence descriptions [15] to a multi-scale characterization of the environment-product relationship in regulatory test data, consistent with premises-to-product links reported in smaller and retail settings [16][17] and with the biological plausibility of environment-product pathways [4][5][6][8]. Our contribution is to separate concurrent, cumulative, and temporally separated dimensions, to assess robustness after excluding

contemporaneously co-detected results and accounting for measured sampling intensity, to compare food-contact with non-food-contact surfaces formally, and to subject the concurrent association to a temporal consistency analysis and a within-establishment permutation sensitivity analysis. To our knowledge, no prior peer-reviewed study has jointly quantified concurrent, cumulative establishment-level, and temporally separated FCS–product associations using national establishment-specific USDA-FSIS regulatory sampling data.

Strengths. National scale; a coordinated-event definition tied to the RLm program; full 2×2 counts, absolute risks, and exact intervals alongside ratios; analysis-specific tested cohorts that separate tested-negative from never-tested; establishment-clustered and 5,000-replicate block-bootstrap inference; detection-opportunity adjustment; a four-level FCS/NFCS analysis with adjusted marginal probabilities and a formal interaction test; temporal internal consistency and a within-establishment permutation sensitivity analysis; and an independent re-implementation of the rare-event estimator.

Limitations. Regulatory product-test positivity is not contamination prevalence, and a positive environmental sample is not proof of transfer. No official event identifier exists, so coordinated events are an operational construct (establishment-date), not verified lot-level linkage. The concurrent and prospective analyses rest on few positive events; the prospective estimate is imprecise, and the reverse-time analysis yielded no exposed positive outcomes and was too sparse to be informative. The establishment-level analysis pools over time, and adjustment for measured sampling intensity cannot remove targeting-driven selection. Important **unmeasured establishment characteristics**—production volume and size, specific product type and post-lethality exposure, sanitation practices, production alternative, number of lines and facility complexity, prior enforcement history, and inspector or regional effects—may partly underlie the cumulative associations. Broad meat-versus-poultry strata could not resolve biologically relevant product heterogeneity (deli meats, hot dogs, fully cooked poultry, sliced versus unsliced, production alternatives) at the available event counts. Composite structure of physical samples is not encoded in the public data. Isolate-level genomic linkage of environmental and product samples is a natural next step.

5. Conclusions

In U.S. FSIS-regulated RTE meat and poultry establishments, food-contact-surface *Listeria monocytogenes* positivity was strongly associated with concurrent product-test positivity within operationally defined coordinated USDA-FSIS RLm sampling events. FCS-positive establishments also had greater cumulative

product-test positivity after concurrent co-detection was removed, although the association was substantially attenuated. Food-contact-positive-only establishments showed the highest cumulative product-positive rate, but the FCS/NFCS relationship was non-additive and sensitive to testing structure, and is reported as a secondary, exploratory comparison. Temporally separated associations were directionally positive but too sparse for precise estimation. The concurrent finding is potentially informative for detection and risk-based scheduling; prospective predictive utility could not be established. All findings describe regulatory test positivity and are associational. Without isolate-level genomic linkage, the study cannot distinguish food-contact-to-product transfer, product-to-food-contact transfer, a shared contamination source, common harborage, targeted sampling, or a linked regulatory investigation; transfer direction and strain identity remain unknown, as do corrective-action effectiveness, biological persistence, and future risk.

Supplementary Materials: S1 classification dictionary; S2 per-fiscal-year counts and project-code distribution; S3 concurrent-event date-window sensitivities and the RTEPROD comparator; S4 establishment-level co-detection-exclusion series; S5 recurrence; S6 prospective three-group and interval tables; S7 robustness/influence; S8 manual record-verification audit sheet; S9 within-event positive-FCS-form burden (exploratory); S10 program-specific co-detection-removed rate ratios.

Statements and Declarations

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Potential Competing Interests

The author declares no conflict of interest.

Author Contributions

Conceptualization, Y.Y.; Methodology, Y.Y.; Software, Y.Y.; Validation, Y.Y.; Formal analysis, Y.Y.; Data curation, Y.Y.; Writing—original draft, Y.Y.; Writing—review and editing, Y.Y.; Visualization, Y.Y. The author has read and agreed to the published version of the manuscript.

Institutional Review Board

Not applicable.

Informed Consent

Not applicable.

Data Availability

The data analyzed are publicly available from the USDA-FSIS Laboratory Sampling Data portal (<https://www.fsis.usda.gov/science-data/data-sets-visualizations/laboratory-sampling-data>).

Reproducible code, the classification dictionary, exclusion and deviation logs, the coordinated-event construction algorithm, the prespecified analysis plan, analysis scripts, and figure/table source data will be deposited in a public repository, with a persistent DOI inserted at acceptance. Raw data were not altered and may be retrieved from the original public source.

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