Why U.S. Foods Are Recalled: Root Causes and Repeat Recalls in 9,012 FDA and FSIS Recalls

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Abstract

Background. U.S. food recalls are published one at a time, and the public record rarely says why a recall happened. Recall data are usually summarized by hazard, not coded for root cause or followed across a firm's repeat recalls.

Methods. All 9,012 food recall events in FDA's enforcement reports (2012 to 2026) and FSIS's recall archive (2014 to 2026) were coded for hazard, root cause, origin, discovery route, the recalling firm's role and product category. Two AI coders worked independently; disagreements were resolved by a blind third coder, and the remaining three-way splits and a random sample of 150 events were reviewed by the author. Root cause was coded only when the recall text stated it.

Results.

- Undeclared allergens were the most common hazard (3,332 events, 37%), followed by pathogens (2,251, 25%) and regulatory or non-safety issues (1,247, 14%).
- Most recalls do not say why they happened. A cause was stated in 42% of allergen recalls, 25% of pathogen recalls and 15% of foreign-material recalls.
- When an allergen recall stated a cause, it was a label or packaging error 87% of the time (1,219 of 1,406). When a pathogen recall stated a cause, it was a supplier or ingredient 90% of the time (514 of 570).
- 23% of manufacturers that recalled a product did so again, and these repeat firms account for 48% of manufacturer recall events. Repeats came a median of 406 days apart, and a first allergen recall was followed by another allergen recall 59% of the time.
- Sesame allergen recalls rose from 13 in 2020 to 2022 to 67 in 2023 to 2025, after sesame became a major allergen.

Conclusions. The most common, most preventable recall is an allergen left off a label, and a firm's first recall is a strong signal of its next. Because most recall notices do not state a cause, the public record cannot show which controls fail. A required one-line root-cause

field in FDA and FSIS recall reports would fix that at little cost.

1. Introduction

A recall tells the public that something went wrong, but rarely why. FDA's weekly enforcement reports and FSIS's recall notices describe the product, the hazard and the distribution, and only sometimes the cause. For a food company, the cause is the useful part: it says which control failed, and so which control to strengthen.

This study codes every food recall event in both agencies' public records for what went wrong and why, and follows recalling firms over time. It asks four questions: which hazards drive recalls; how often the record states a cause, and which causes it states; whether a firm's first recall predicts another; and whether recall patterns shifted around two policy changes, FSMA's preventive controls rules (compliance from 2016) and the FASTER Act's addition of sesame as a major allergen (January 1, 2023).

2. Data and methods

Sources. FDA's food enforcement reports were taken from the openFDA bulk download of November 2, 2026: 29,586 product-level records, grouped by recall number into 7,939 recall events, nearly all initiated from 2012 onward. FSIS's recall archive was taken from its public API on the same date: 1,243 English-language records, of which 1,073 are recalls (2014 to 2026) and 170 are public health alerts, which were excluded. The total is 9,012 recall events. Firms were matched across events on a normalized firm name.

Codebook. Each event was coded on six fields:

- **Hazard:** pathogen; undeclared allergen; foreign material; chemical; process or preservation failure; regulatory or non-safety; quality or spoilage; other.
- **Root cause:** label or packaging error; formulation change; allergen cross-contact; supplier or ingredient; facility environment; process control; equipment; regulatory or administrative; not stated.
- **Origin, discovery route, firm role** (manufacturer, co-packer, distributor or importer, retailer, foodservice) and **product category.**

The central rule was to code only what the recall text states. A recall that says "undeclared peanuts" names the hazard but not how the peanuts got there, so its root cause is "not stated". Root cause was coded as a label or packaging error only when the

text says the allergen was missing from the label, the Contains statement or a listed sub-ingredient, or that the wrong label or package was used.

Coding and review. Two AI coders coded all 9,012 events independently. Agreement (Cohen's kappa) was 0.97 for hazard, 0.91 for root cause, 0.85 for origin, 0.88 for discovery, 0.83 for firm role and 0.88 for category. A third coder, blind to the first two, coded the 486 events where they disagreed on hazard or root cause, and the majority answer was kept. The author resolved the 33 events that remained split three ways and reviewed a random sample of 150 events.

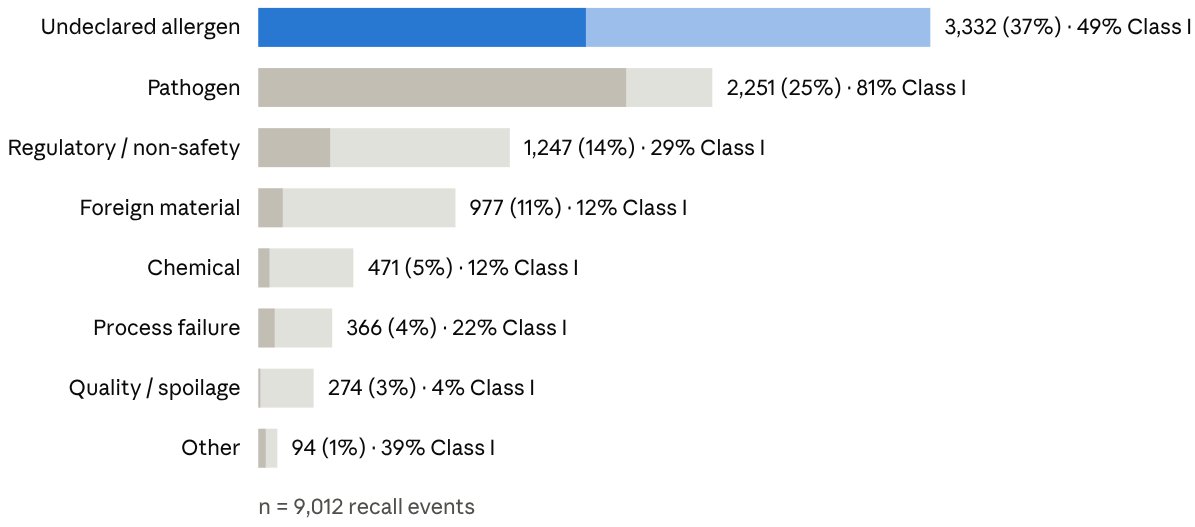
Analysis. All results are descriptive counts and shares. Repeat-recall analyses are limited to manufacturers and co-packers, because retailers and distributors mostly recall products made by others.

3. What gets recalled

Undeclared allergens were the most common reason for a food recall, at 37% of events, and pathogens the most serious: 81% of pathogen recalls were Class I, against 49% of allergen recalls.

Undeclared allergens cause more U.S. food recalls than any other hazard

Recall events by hazard, FDA 2012 to 2026 and FSIS 2014 to 2026. Darker segment = Class I (most serious).



Source: author's coding of 9,012 recall events, openFDA food enforcement reports and FSIS recall archive, downloaded November 2, 2026

The two agencies differ in emphasis. In FSIS's meat and poultry recalls, regulatory and non-safety issues such as products produced without inspection made up 27% of events, against 12% at FDA, and foreign material 16% against 10%. By product category, allergens dominate grains and bakery (63% of those recalls), snacks and confectionery (61%) and prepared foods (47%), while pathogens dominate fresh produce (62%) and nuts and seeds (51%).

4. Why: root causes

Most recall notices do not say why the recall happened. Across all 9,012 events, a root cause was stated in 3,279 (36%). The share varies sharply by hazard:

Hazard	Events	Cause stated	Most common stated cause
Process failure	366	309 (84%)	Process control (287)
Regulatory / non-safety	1,247	719 (58%)	Regulatory or administrative (380), label error (304)
Undeclared allergen	3,332	1,406 (42%)	Label or packaging error (1,219)
Pathogen	2,251	570 (25%)	Supplier or ingredient (514)
Chemical	471	76 (16%)	Supplier or ingredient (47)
Foreign material	977	144 (15%)	Supplier or ingredient (90), equipment (45)
Quality / spoilage	274	29 (11%)	Process control (15)

Allergens. When an allergen recall states a cause, it is a label or packaging problem 87% of the time: an allergen left out of the ingredient list or Contains statement, a sub-ingredient whose allergen was not carried onto the finished label, or the wrong label or package. Supplier problems (114), cross-contact (49) and unannounced recipe changes (22) together make up the rest. Most allergen recalls (58%) only say that the allergen was undeclared.

Pathogens. Three quarters of pathogen recalls give no cause beyond a positive test. When a cause is given, it is almost always an ingredient that came in contaminated (514 of 570), in some cases as part of a cascade in which one supplier's recall triggers recalls by many customers. Facility environment, such as Listeria harborage, is named in only 49.

Discovery. Only 14% of recalls say how the problem was found. Where they do, the most common routes are a supplier's notice (462), regulatory sampling (320) and consumer complaints (165).

5. Repeat recalls

A first recall is a strong signal of a second. Of 4,644 manufacturers and co-packers with at least one recall, 1,075 (23%) recalled again, and these repeat firms account for 3,237 of 6,806 manufacturer recall events (48%). Consecutive recalls at the same firm came a median of 406 days apart, and 48% came within a year.

The second recall usually repeats the first one's hazard:

First recall's hazard	Firms	Recalled again	Next recall had the same hazard
Undeclared allergen	1,818	403 (22%)	238 (59%)
Pathogen	1,136	312 (27%)	162 (52%)
Foreign material	474	120 (25%)	45 (38%)
Regulatory / non-safety	556	126 (23%)	42 (33%)
Chemical	230	42 (18%)	15 (36%)
Process failure	212	30 (14%)	8 (27%)

Across all consecutive pairs, the next recall had the same hazard 48% of the time but the same stated root cause only 9% of the time, mostly because causes are so often unstated.

The firms with the most recall events are large, multi-plant manufacturers: Dole Fresh Vegetables (28 events, 2012 to 2024, half of them pathogens), General Mills (21), Reser's Fine Foods (20), Coca-Cola (19) and Frito-Lay (16). Size explains part of this, since a firm with more plants and products has more chances to recall. The more useful signal for a small company is the repeat pattern itself: a firm with one allergen recall has, in effect, shown where its controls are weakest.

Retailers and distributors made 1,905 recalls (21% of all). They mostly recall products made by someone else, so their repeat counts reflect how many suppliers' problems reach their shelves rather than their own controls; they were left out of the repeat analysis.

6. Policy markers

FASTER Act and sesame. Sesame became the ninth major food allergen on January 1, 2023. Sesame allergen recalls rose from 13 in 2020 to 2022 to 67 in 2023 to 2025, while all allergen recalls stayed flat (579 and 603). Most of this rise is mechanical: before 2023, undeclared sesame was not a major-allergen labeling violation, so it rarely triggered a recall. These counts cannot show whether manufacturers began adding sesame to products deliberately, a practice FDA criticized in 2023; that question needs product-level ingredient data, not recall data.

FSMA preventive controls. Compliance with the preventive controls rule began in September 2016 for large firms and phased in for smaller firms through 2018. FDA's allergen recall share was 39% in 2013 to 2015, 41% during the phase-in and 38% from 2019 to 2025, so allergen recalls did not visibly fall as a share of the total. Pathogen recalls peaked in 2016 (330 events). FDA recall events per year fell from about 575 to 659 in 2013 to 2018 to about 477 from 2019 onward, but changes in reporting, inspection activity during the COVID-19 pandemic and the mix of products make that drop impossible to attribute to the rule from these data alone.

7. Discussion and recommendations

The most common recall is also the most preventable. Where the cause of an allergen recall is known, it is overwhelmingly a labeling failure: an allergen left off the ingredient list or Contains statement, an allergen in a sub-ingredient that never made it onto the finished label, or the wrong label or package. That is a document-control problem, not a contamination problem, and it is solved with label review against every ingredient's specification, not with testing.

The second lesson is that recalls cluster. Nearly half of all manufacturer recalls come from firms that have recalled before, and the next recall usually repeats the first one's hazard. A first recall should be treated as a diagnosis of the weakest control, with a corrective action aimed at that control rather than at the single lot.

The third lesson is about the record itself. Two thirds of recall notices do not say why the recall happened, and seven in eight do not say how the problem was found. That leaves regulators, researchers and other companies unable to learn which controls fail most often.

Recommendations:

1. **For companies:** review every finished label against the allergen statement of every ingredient and sub-ingredient, at each new supplier and each formula change. After any recall, find and fix the control that failed, because the same hazard is the most likely next recall.
2. **For companies using co-packers or ingredient suppliers:** pathogen recalls are mostly supplier-driven when the cause is known, so supplier approval and certificates of analysis matter more than any single test.
3. **For FDA and FSIS:** add a short, structured root-cause and discovery field to recall reports. Where the agency or the firm already knows the cause, a few structured words would cost little to publish and would make the record far more useful.

8. Limitations and conclusions

- **What the text says.** Codes reflect the recall notice, not the underlying investigation. A root cause marked "not stated" means the public text did not give one, not that none was found.
- **Coverage.** FDA's enforcement reports start in 2012 and FSIS's archive in 2014. FSIS covers only meat, poultry and processed egg products, and FDA's reporting practices changed over the period.
- **Firm matching.** Firms were matched on normalized names; subsidiaries and renamed firms may be split or merged.
- **Coding.** Codes were assigned by AI coders, with disagreements resolved by a third coder and the remaining splits and a random sample reviewed by the author. No separate accuracy figure is claimed.
- **Causation.** The policy comparisons are descriptive. They show what changed around each date, not what caused it.

In conclusion, undeclared allergens are the leading cause of U.S. food recalls, most of them are labeling failures when a cause is given, and a firm's first recall is a strong predictor of its next. The recall record would be far more useful if it said why each recall happened.

Data availability

Event-level codes for all 9,012 recalls are published with the Recall Risk Check at mendocinofoodconsulting.com. The codebook, scripts and coding files are available from the author on request.

References

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