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Product Recall Readiness Checklist

If You Got the Call Today, Would You Be Ready?

A product recall is the moment your documentation infrastructure either protects your business or exposes it. This checklist walks you through the first 72 hours, the records you need, and the preparation that determines whether you recall one lot — or your entire inventory.

■ The First 2 Hours — Scope and Decision

- ■ Identify the specific lot number(s) implicated — complaint, adverse event, or test result.
  A targeted recall starts with a specific lot. Without lot-level traceability, you cannot limit scope.
- ■ Pull the batch record for the implicated lot immediately.
  The batch record tells you what raw material lots were used, who produced it, and when.
- ■ Run a forward traceability search: which finished goods lots used the same raw material lot?
  If one lot of an ingredient is the issue, every finished goods batch using that lot is potentially affected.
- ■ Run a distribution search: which customers/retailers received the implicated finished goods lots?
- ■ Determine recall scope: can you limit to specific lots, or must you pull all inventory?
  Manufacturers with complete lot traceability can target. Those without must pull everything.
- ■ Notify your legal counsel and regulatory consultant immediately.
- ■ Do not destroy any records, samples, or inventory before legal review.

■ Hours 2–8 — Stakeholder Notifications

- ■ Notify the FDA via MedWatch or direct contact if the recall involves a serious health hazard.
  Class I recalls (serious health risk) require FDA notification. Class II and III may also require notification.
- ■ Contact affected retail accounts directly — before they hear about it from another source.
  Retailers who learn about a recall from a customer or the media lose confidence in you as a supplier.
- ■ Prepare a customer notification letter with: product name, lot numbers, reason for recall, return instructions.
  The FDA has model recall letter templates. Use them.
- ■ If selling on Amazon or other marketplaces: contact seller support to initiate listing suspension for affected ASINs.
- ■ Notify your co-manufacturer if production was outsourced — they may have inventory you do not control.
- ■ Alert your raw material supplier if the root cause is a supplier ingredient quality issue.

■ Hours 8–24 — Physical Inventory Control

- ☐ Place a physical hold on all in-house inventory of affected lots — label clearly as "QUARANTINED."
- ☐ Contact all distribution partners with instructions to hold and return affected product.
- ☐ Document all inventory quarantine actions with dates, quantities, and responsible parties.
- ☐ Do not release any new production using the same raw material lot until investigation is complete.
- ☐ Confirm finished goods count in quarantine matches distribution records — identify any unaccounted inventory.

☐ 24–72 Hours — Root Cause Investigation

- ☐ Retain retain samples of the affected lot for independent laboratory analysis.
- ☐ Review the complete batch record for the affected lot — every step, every operator, every quantity.
- ☐ Review the COA and receiving record for every raw material lot used in the affected batch.
- ☐ Interview production operators who worked on the affected batch.
  Document all interviews in writing with date and attendees.
- ☐ Review any deviations, complaints, or OOS results linked to the affected lot or time period.
- ☐ Document preliminary root cause findings even before investigation is complete.
  Regulators expect to see your investigation process documented, not just the conclusion.

☐ Recall Readiness Self-Test — Run This Before There Is a Problem

- ☐ Can you identify every finished goods lot that used a specific raw material lot — in under 10 minutes?
  If no: your traceability system cannot support a targeted recall. You will pull all inventory by default.
- ☐ Can you identify every customer who received a specific finished goods lot — in under 10 minutes?
- ☐ Does every production run have a complete batch record with actual lot numbers for each ingredient?
  Without lot numbers in the batch record, traceability is broken at the most critical link.
- ☐ Are finished product test results linked to batch numbers — not filed separately by date?
- ☐ Do you have a written recall SOP that your team has reviewed in the last 12 months?
- ☐ Does your team know who to call first if a serious adverse event is reported?
- ☐ Have you identified which of your products would be Class I vs. Class II risk if recalled?
