

FOREIGN SUPPLIER EVALUATION

21 CFR 1.505(a) — evaluation of a foreign supplier's performance and the risk posed by a food

Importer

SAMPLE — Example Foods Co.

Foreign supplier

Example Nut Processing Ltd. (fictional)

Food

SAMPLE-001 — Roasted cashews, 25 kg cartons (fictional)

Type

Initial evaluation

Evaluation date

2026-09-10

FACTORS CONSIDERED

Hazard analysis of the food, including the nature of each hazard requiring a control (§ 1.505(a)(1)(i))

Hazard analysis for roasted cashews signed 2026-09-08 (fictional): Salmonella (biological), aflatoxin (chemical), metal fragments (physical).

Entity or entities that significantly minimize, prevent or verify control of those hazards (§ 1.505(a)(1)(ii))

The supplier controls Salmonella with a roasting step and metal with a metal detector; aflatoxin is controlled by the supplier's incoming raw-nut testing.

The supplier's procedures, processes and practices related to the safety of the food (§ 1.505(a)(1)(iii)(A))

Reviewed the supplier's food safety plan, roasting validation summary and metal detector check records on 2026-09-02, and the onsite audit report of 2026-08-20 (all fictional).

FDA compliance: subject of an FDA warning letter / import alert / other food-safety compliance action (§ 1.505(a)(1)(iii)(B))

Warning letter: No Import alert: No Other action: No

Checked FDA's warning letter and import alert listings for the supplier's name on 2026-09-09 (fictional).

Food safety history — testing results, audit results, responsiveness in correcting problems (§ 1.505(a)(1)(iii)(C))

No earlier shipments from this supplier. Certificates of analysis for the supplier's last three lots were within the importer's specifications, and the onsite audit of 2026-08-20 recorded no significant deficiencies (fictional).

Other factors, such as storage and transportation practices (§ 1.505(a)(1)(iv))

Shipped in sealed cartons in dry containers; no temperature control needed for this food.

CONCLUSION AND DECISION

Conclusion

The importer's qualified individual concluded the supplier's controls are suitable to approve, with the verification below (fictional).

Decision (§ 1.505(b))

APPROVED

Verification activities and frequency determined (§ 1.506(d)(1)(i))

Salmonella is controlled by the supplier and has a reasonable probability of serious adverse health consequences, so: an onsite audit of the supplier by a qualified auditor before the first import (done 2026-08-20) and at least every 12 months (21 CFR 1.506(d)(2)); sampling and testing of one lot every 3 months; and a review of the supplier's food safety records every 12 months (fictional).

Reevaluate at least every 3 years, and promptly on new information (21 CFR 1.505(c)).

SIGNATURE (21 CFR 1.510(a)(2))

I reviewed this record. It is accurate and complete to the best of my knowledge, and I sign and date it as required by 21 CFR 1.510(a)(2).

Signed by

Alex Sample, FSVP qualified individual (fictional)

Date

2026-09-10

Sample — not signed or filed. The signer named above is fictional; no signature, filing record or hash exists for this document.

Prepared in Aleph from the importer's own answers; Aleph did not assess them. FDA prescribes no form for this record (21 CFR 1.510(a)(1)).

FOR REFERENCE ONLY