P Portmark

FOREIGN SUPPLIER VERIFICATION PROGRAM

Foreign supplier document file

Every document required for this supplier: what is on file, what it covers, when it expires, and what is still outstanding.

IMPORTER	(Sample) Rio Verde Imports LLC McAllen, TX 78503 · DUNS 00-000-0000 (sample)
FOREIGN SUPPLIER	(Sample) Agrícola San Miguel S.A. de C.V. Carretera Uruapan–Nueva Italia Km 12, Uruapan, Michoacán, Mexico
FOODS COVERED	Hass avocados, fresh, Persian limes, fresh
FILE REFERENCE	PM-SAMPLE-001 Revision 1.0 · prepared 27 Aug 2026
STATUS	DRAFT Awaiting Qualified Individual review and signature

This is an illustrative sample. The importer, supplier, dates and findings are fictional. The regulatory requirements, citations and record structure are real and reflect 21 CFR Part 1, Subpart L.

What is in this file

21 CFR PART 1, SUBPART L

This file gathers the supporting documents for one foreign supplier and tracks their status. Portmark obtains and organises the documents; the determinations and the sign-off belong to the importer's Qualified Individual.

HOW TO USE THIS FILE

Start at the outstanding items list — that is what is missing or expired right now. Sections marked as supplied by your Qualified Individual are filed here but not authored by Portmark.

SAMPLE FILE — FICTIONAL SUPPLIER, REAL REQUIREMENTS

Supplier profile

21 CFR § 1.505(A)(1)(II) · § 1.509(A)

LEGAL NAME	(Sample) Agrícola San Miguel S.A. de C.V.
FACILITY ADDRESS	Carretera Uruapan–Nueva Italia Km 12, Uruapan, Michoacán Mexico
FDA REGISTRATION	Not required — primary production farm
DUNS NUMBER	00-000-0001 (sample)
ENTITY RESPONSIBLE	Foreign supplier (grower/packer) Controls applied at the growing and packing operation, not by the importer
SUPPLIER CONTACT	R. Ficticio, Food Safety Manager calidad@example-supplier.mx
FIRST SHIPMENT	14 Mar 2024
ANNUAL VOLUME	≈ 310 shipments / 4,100 t
IMPORTER OF RECORD	(Sample) Rio Verde Imports LLC DUNS 00-000-0000 (sample)

FOODS IMPORTED FROM THIS SUPPLIER

FOOD	CATEGORY	FDA PRODUCT CODE
Hass avocados, fresh Whole, raw agricultural commodity	Produce — RAC	20-sample
Persian limes, fresh Whole, raw agricultural commodity	Produce — RAC	20-sample

WHY THIS PAGE EXISTS

Documents must tie to the specific facility that produced the food you received, not to a trading company or parent group. Portmark checks each document against the facility named here and flags any that do not match.

Hazard determinations on file

21 CFR § 1.504 — DETERMINATIONS MADE BY THE IMPORTER'S QUALIFIED INDIVIDUAL

WHAT THIS PAGE IS

Portmark does not determine hazards. This page records the determinations supplied by your Qualified Individual, notes where each one came from, and tracks the verification evidence each one calls for. Anything not yet supplied is listed as outstanding.

Salmonella spp. SAHCODHA

Avocados; limes

Recorded as requiring supplier control. Verification evidence tracked below.

Type: Biological **Requires control:** Yes **Controlled by:** Foreign supplier **Source:** Importer's QI, dated 12 Feb 2026 SATISFIED

Shiga toxin-producing E. coli (STEC) SAHCODHA

Avocados; limes

Recorded as requiring supplier control. Verification evidence tracked below.

Type: Biological **Requires control:** Yes **Controlled by:** Foreign supplier **Source:** Importer's QI, dated 12 Feb 2026 SATISFIED

Listeria monocytogenes SAHCODHA

Avocados; limes

Recorded as requiring supplier control. Verification evidence tracked below.

Type: Biological **Requires control:** Yes **Controlled by:** Foreign supplier **Source:** Importer's QI, dated 12 Feb 2026 SATISFIED

Pesticide residues above US tolerances, or residues of pesticides not approved for the commodity in the US

Avocados; limes

Recorded as requiring supplier control; evidenced per lot by residue analysis.

Type: Chemical **Requires control:** Yes **Controlled by:** Foreign supplier **Source:** Importer's QI, dated 12 Feb 2026 SATISFIED

Physical hazards — metal or glass fragments

Avocados; limes

Considered and recorded as not requiring a control.

Type: Physical **Requires control:** No **Controlled by:** n/a **Source:** Importer's QI, dated 12 Feb 2026 SATISFIED

Undeclared allergens

Avocados; limes

No determination on file for this hazard. Requested from your Qualified Individual.

Type: Chemical (allergen) **Requires control:** No **Controlled by:** n/a **Source:** Not yet supplied MISSING

Supplier record

COMPILED FACTS — EVALUATION UNDER 21 CFR § 1.505 IS MADE BY YOUR QUALIFIED INDIVIDUAL

Factual record compiled by Portmark from public sources and supplier correspondence. The evaluation and approval decision under § 1.505 are made by your Qualified Individual, not by Portmark.

FACTOR CONSIDERED	FINDING
Hazard determinations on file § 1.505(a)(1)(i)	Five determinations supplied by your QI on 12 Feb 2026; one hazard has no determination on file. See previous section.
Entity applying the controls § 1.505(a)(1)(ii)	Supplier states all controls are applied at the growing and packing operation. No intermediate handler is named on the shipping documents reviewed.
Supplier procedures on file § 1.505(a)(1)(iii)	Harvest hygiene and packing sanitation procedures received 11 Jan 2026. Environmental monitoring programme referenced in those procedures; supporting records not received.
FDA compliance history checked § 1.505(a)(1)(iii)	Checked against FDA import alerts, warning letters and enforcement reports on 27 Aug 2026: no listing found. Import refusal history: none in the period searched.
Supplier responsiveness § 1.505(a)(1)(iii)	Nine document requests sent since Mar 2024; seven answered, median 14 days. Two outstanding, see correspondence log.
Storage and transport § 1.505(a)(1)(iv)	Refrigerated transport with continuous temperature monitoring; no repacking between the packing house and entry, per shipping documents reviewed.

APPROVAL DECISION — FOR YOUR QUALIFIED INDIVIDUAL

To be recorded by your Qualified Individual.

Two items bearing on the recorded hazards are outstanding: the third-party audit certificate expired 14 Mar 2026, and agricultural water testing records have not been received. Both are listed as outstanding items and are being chased.

Status: Not yet recorded · to be approved by the Qualified Individual named on the signature page · re-evaluation required at least every 3 years — § 1.505(c)(2)

Verification evidence

TRACKING AGAINST 21 CFR § 1.506 — ACTIVITIES SELECTED BY YOUR QUALIFIED INDIVIDUAL

Each recorded determination is matched to the evidence that supports it, with the expiry Portmark tracks and re-requests against. Portmark obtains and files this evidence; it does not select the verification activities or judge their adequacy.

HAZARD ADDRESSED	ACTIVITY	FREQUENCY	LAST	NEXT DUE	STATUS
Salmonella, STEC, Listeria	**Annual onsite audit of the supplier's operation** Hazards for which there is a reasonable probability that exposure will result in serious adverse health consequences or death	Annual	14 Mar 2025	14 Mar 2026	EXPIRED
Salmonella, STEC, Listeria	**Review of the supplier's agricultural water testing records** Supporting evidence between audits; water quality is the dominant route for these hazards	Per season	—	On receipt	MISSING
Pesticide residues	**Sampling and testing — multi-residue panel** Lot-level evidence against US tolerances	Per lot	02 Aug 2026	Next shipment	CURRENT
All hazards requiring control	**Review of the supplier's relevant food safety records** Ongoing verification between audits	Quarterly	—	Pending	PENDING

> *You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.*
>
> 21 CFR § 1.506(b)

> *...conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that... other supplier verification activities... and/or less frequent onsite auditing are appropriate.*
>
> 21 CFR § 1.506(d)(2) — applies to the three hazards marked SAHCODHA above

Document register

21 CFR § 1.510

Nine documents are required for this supplier. Three are current, one has expired, and five have not been obtained.

DOCUMENT	TYPE	ISSUED	EXPIRES	STATUS
Third-party food safety audit certificate PrimusGFS (sample certificate body)	Audit	14 Mar 2025	14 Mar 2026	EXPIRED
Third-party audit report, full findings PrimusGFS (sample certificate body)	Audit	14 Mar 2025	14 Mar 2026	EXPIRED
Produce Safety Rule compliance attestation Supplier	Attestation	—	—	MISSING
Agricultural water testing results, current season Accredited laboratory	Test record	—	—	MISSING
Pesticide residue certificate of analysis, lot AV-2608 Accredited laboratory	COA	02 Aug 2026	Lot-specific	CURRENT
Harvest hygiene and packing sanitation procedures Supplier	Procedure	11 Jan 2026	Under annual review	CURRENT
Environmental monitoring records, packing house Supplier	Monitoring record	—	—	MISSING
Worker hygiene training records Supplier	Training record	—	—	MISSING
Traceability and lot coding procedure Supplier	Procedure	11 Jan 2026	Under annual review	CURRENT

Expiry dates are tracked from the document itself, not from the date it was received. Portmark re-requests each document from the supplier ahead of its expiry. Records must be kept at least 2 years (§ 1.510(c)(1)), produced promptly to FDA on request, and — if held offsite — retrievable within 24 hours (§ 1.510(b)).

Outstanding items

DOCUMENT STATUS AS AT 27 AUG 2026

What is missing or expired right now, and what Portmark is doing about each one. These are statements about documents, not an assessment of your compliance.

1 No consolidated supplier file existed before this one

Documents for this supplier were held across email threads and a shared drive, with no single register and no expiry tracking. This file is that register.

> *You did not develop an FSVP for any of the foods you import from the foreign suppliers indicated in the attached list.*
>
> Representative language, FDA FSVP warning letters 2025–2026

Authority: — **Action:** Complete — file established and now maintained **Owner:** Portmark **Target:** Complete SATISFIED

2 Approval decision not recorded

No dated record of a supplier approval decision was found in the documents provided. The record page in this file is prepared for your Qualified Individual to complete.

Authority: § 1.505(b) **Action:** Awaiting your QI **Owner:** Your QI **Target:** On sign-off GAP

3 Third-party audit certificate expired 14 Mar 2026

The certificate on file expired 166 days ago. The supplier has not sent a replacement. Portmark has contacted both the supplier and the certificate body.

Authority: § 1.506(d)(2) **Action:** Chasing supplier and certificate body; third request sent 21 Aug 2026 **Owner:** Portmark **Target:** Within 45 days GAP

4 Agricultural water testing records never obtained

Requested from the supplier three times since 12 May 2026. The supplier confirms testing is carried out but has not sent results. Escalated to their food safety manager.

Authority: § 1.506(d)(1), (e)(1)(iii) **Action:** Chasing in Spanish; importer copied on the last request **Owner:** Portmark **Target:** Within 21 days GAP

Outstanding items (continued)

5 One hazard determination not supplied

Determinations were supplied for five of the six hazards listed in your food safety documentation. Nothing is on file for the sixth.

Authority: § 1.504 **Action:** Requested from your Qualified Individual **Owner:** Your QI **Target:** On sign-off GAP

6 Documents were not held in English

Supplier procedures and audit documents were supplied in Spanish. English translations are now filed alongside each original, and records must be produced to FDA promptly on request.

Authority: § 1.510(b)(1) **Action:** Complete — translations filed **Owner:** Portmark **Target:** Complete SATISFIED

Correspondence and actions

CHASE RECORD

What was asked of the supplier, when, and what came back. A dated record of attempts matters when a document genuinely cannot be obtained.

DATE	ISSUE AND ACTION TAKEN	OWNER	STATUS
18 Jun 2026	**Residue panel for lot LI-2606 returned a result above the US tolerance for one active ingredient** Lot rejected before entry; supplier provided application records and revised pre-harvest interval; two subsequent lots tested clear	Portmark / supplier	CURRENT
03 May 2026	**Audit certificate lapsed without notice from the supplier** Escalated to the supplier's food safety manager and the certificate body; re-audit booked	Portmark	PENDING

Qualified Individual review and sign-off

21 CFR § 1.503 · § 1.500

> *A qualified individual must develop your FSVP and perform each of the activities required under this subpart.*
>
> 21 CFR § 1.503(a)

ATTESTATION

Portmark obtains, translates, organises and tracks the documents in this file. Portmark does not determine hazards, evaluate or approve suppliers, or assess compliance. Those are the responsibility of the Qualified Individual, who records them below.

- The hazard determinations recorded in this file are mine, and reflect the hazards for each food listed.
- I have evaluated this foreign supplier and record my approval decision on this page.
- The verification activities listed are the ones I consider appropriate to those hazards.
- I have reviewed the documents filed here and the outstanding items listed.
- I have the education, training, or experience necessary to perform this review, and I am able to read and understand the language of the records I have reviewed.

Signature of Qualified Individual	Date
Printed name and title	Telephone

A qualified individual is a person with the education, training, or experience necessary to perform the activity, who can read and understand the language of the records reviewed (§ 1.500). Onsite audits are separate: they must be conducted by a qualified auditor (§ 1.503(b)). Portmark is neither, and does not act as either.