Holding your supplier's HACCP plan is not verification.

FDA's inspection program tells investigators that if the plan you hold misses a hazard the Hazards Guide lists for that species, your affirmative step is inadequate. Keelsure reads every supplier's plan against the Guide and cites its work, keeps each supplier-product current, and produces the file an investigator asks for.

44–74%
of inspected importers had compliant written verification procedures and specifications
FDA SEAFOOD HACCP EVALUATION, FY2006–14

4
warning letters to named US seafood importers under §123.12, January to May 2026
FDA WARNING LETTER DATABASE

79%
of shrimp entry lines refused for antibiotics in 2026 came from BAP-certified plants
SOUTHERN SHRIMP ALLIANCE, THROUGH AUG 2026

$3,000–12,000
what a consultant charges to review one supplier's HACCP plan — once
INDUSTRY RATE GUIDES AND PRACTITIONER FORUMS

In 2026, FDA started naming importers.

Jan 16, 2026 — Warning letter
New Hyde Park, NY · specialty importer
"You have not implemented an affirmative step …"
Five separate products.

Feb 19, 2026 — Warning letter
Chicago, IL · tilapia and shrimp
"Your written verification procedures do not identify which affirmation step(s) you have chosen … was not signed and dated at the time of the activity."
Response rejected: promised, didn't document.

Apr 15, 2026 — Warning letter
Boston, MA · "hundreds of suppliers"
"You do not have or have not implemented an affirmative step … as required by 21 CFR 123.12(a)(2)(ii)."
One supplier's document was not current.

May 26, 2026 — Warning letter
Houston, TX · Asian specialty importer
"You do not have or have not implemented written verification procedures, product specifications and an affirmative step."
A repeat of the August 2019 observation.

THE SAME FOUR FAILURE MODES, EVERY TIME

No affirmative step identified per supplier-product

Specifications missing a hazard the Guide lists — parasites in tilapia, histamine in tuna (2023)

Records not signed and dated at the time of the activity

The same finding years apart, because nothing changed in between

Holding the plan is not enough. Someone has to read it.

Species by species, process by process, against the current edition of the Guide. Today that is a consultant at $3,000 to $12,000 a plan, once a year if you're diligent — or it is nobody. That check is what Keelsure does. Every finding carries the chapter and table it came from, against a stated edition of the Guide.

"When the processor's HACCP plan is maintained as an affirmative step and it fails to list a significant health hazard identified with the product in the Fish & Fisheries Products Hazards & Controls Guidance book, then the affirmative step is considered **inadequate** and should be recorded on the FDA Form 483."

FDA COMPLIANCE PROGRAM 7303.844, IMPORT SEAFOOD PRODUCTS · PART III, §G

What it does

- **Roster.** Every supplier-product with its affirmative step. The step is a required field; a row cannot exist without one.
- **Specifications.** Written from the Guide, not from memory — parasites in tilapia, histamine in tuna, aquaculture drugs in farmed shrimp — pre-filled, for you to sign.
- **Plan review.** Findings graded and cited to chapter and table, with the Guide text and a link to FDA's page.
- **Binder.** Procedures, specs, steps, evidence and an append-only log signed and dated at the time. Expiry sweeps run before a guarantee lapses.
- **Draft.** A free portal, in their language, for your processors to keep their plan and share it with you once.

The six affirmative steps, §123.12(a)(2)(ii): **a** lot records · **b** government or third-party certificate · **c** facility inspection · **d** English plan + written guarantee · **e** product testing + guarantee · **f** other appropriate measures. Records in English, signed and dated at the time of the activity, kept one year refrigerated or two years frozen.

What it does not do

- **It is not your trained individual.** Under 21 CFR 123.10 a trained person must perform the hazard analysis and review the records. Every plan review requires that person's attestation before it can be exported or counted.
- **It does not declare anyone compliant.** It reports what is on file and what is missing. It will not tell you, or FDA, that you meet a requirement.
- **Every finding is cited, or it is not a finding.** If the model cannot cite the Guide, it says it could not determine rather than inventing a control. The Guide edition is stamped on every output.

See whether your file would hold up.

Paste one supplier's HACCP plan — the messiest one you have — and get every finding, cited to the Guide, in minutes. No account, nothing saved, no card. Or book 30 minutes.

keelsure.com/demo
hello@keelsure.com

Built by **Brett Koonse**, who consults for FDA on seafood safety and trains processors in exporting countries in HACCP and Good Aquaculture Practices, and **Ben Koonse**, who builds the software and is the person on your first call. **Abraham Jones** built the first version of the plan drafter.