

CALIFORNIA PROPOSITION 65

Prop 65 Compliance

for Fruit Purees



System-Based Compliance. Not Just Testing.

Presented by: **Prop65Compliance.com**

Compliance Management by Consultare Inc. Group

Powered by *SystemsBuilder.pro*

5,000+

NOVs in 2025

~38%

Food Share

Why This Matters

California Prop 65 applies to all food — including fruit purees, baby foods, and ingredient bases.



⚠️ WARNING

This product can expose you to chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

— P65Warnings.ca.gov

Natural ≠ Exempt



Enforcement Is Aggressive

California requires warnings for exposure to listed chemicals — enforcement is driven by private lawsuits ('bounty hunters').



Penalties Are Real

Non-compliance leads to financial penalties, legal costs, relabeling, and product removal from shelves.



Applies to All Purees

No exemption for apple, pear, peach, sweet potato, carrot, banana — single-fruit, blends, baby food, or ingredient bases.

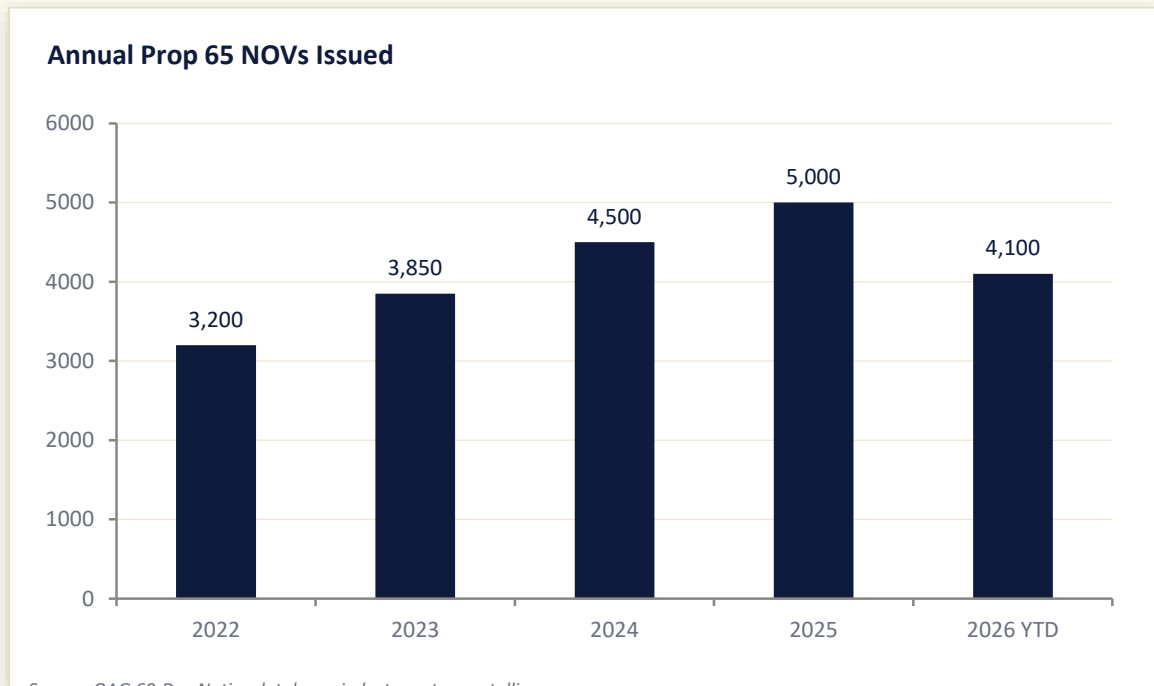


Documentation Is Your Defense

Without a compliance system, most companies settle. A defensible record is what ends threats cheaply.

Prop 65 Enforcement Trends (2024–2026)

Enforcement is increasing, not slowing down.



Source: OAG 60-Day Notice database; industry-category tallies.

~38%

Food & Supplements

Largest single category of Prop 65 enforcement in 2025.

~\$86M

2026 Settlements

Record enforcement activity — majority paid to attorneys.

Purees
Under Fire

Apple, Pear, Sweet Potato, Carrot

FDA Closer-to-Zero, the 2023 cinnamon-applesauce recall, and baby-food class actions have made purees a top target.

W H Y

Why Fruit Purees Are at Risk

Lead, cadmium & arsenic enter through soil, water, equipment, and ingredients — purees concentrate every input.



Soil Uptake

Apples, pears, root vegetables and stone fruit pull lead, cadmium & arsenic from orchard and field soils.



Cross-Contamination

Trace ingredients (e.g. cinnamon, colorings) introduced lead in the 2023 applesauce recalls.



Processing

Pulping, milling and concentration steps multiply heavy-metal levels per gram of finished puree.



Infant Consumers

Purees are a primary food for infants — FDA action level for lead is 10 ppb, MADL is 0.5 µg/day.



Organic & 'baby-safe' claims do not eliminate heavy-metal exposure risk.

Lead in fruit & vegetable purees is on FDA's Closer-to-Zero target list — enforcement against baby food and applesauce makers is established and ongoing.

Business Impact of Non-Compliance

A Prop 65 action hits the balance sheet long before a verdict.



60-Day Notice of Violation

Plaintiff's attorney files with the AG; clock starts immediately on response.



Settlement Exposure

Typical settlements \$20K–\$100K+ per action — plus attorney fees.



Relabeling & Reformulation

Product pulled, warning labels added, ingredient sourcing reviewed.



Retail & Distributor Pressure

Buyers demand evidence of compliance before reinstatement or renewal.

Most companies settle — not because they're guilty, but because their documentation is weak.

WHAT

Why Prop65Compliance.com

Compliance-focused. Not a law firm. System-based — not one-time testing.



Compliance-Focused

We don't litigate — we build the system that prevents litigation.



System-Based Approach

Testing alone doesn't protect you. A documented program does.



Managed by Consultare Inc. Group

Operational oversight from a dedicated compliance management team.



Built on SystemsBuilder.pro

Artifact-based system, document control, and AI-assisted workflows.



OUR PROMISE

*We build and manage
your defensible
compliance system.*

So when a 60-day notice arrives,
you already have the answers.

WHAT

What We Deliver

An end-to-end Prop 65 compliance program — not a one-time report.



**Product Risk
Assessment**



**Chemical Testing
Oversight**



**Exposure
Evaluation**



**Compliance
Determination**



**Warning Label
Strategy**



**Supplier
Compliance Program**



**Documentation
System**



**Ongoing
Monitoring**

Each component is documented, traceable, and audit-ready.

Core Technical Components

The compliance stack underneath every determination we issue.



Heavy Metal Testing

Oversight of lead, cadmium, arsenic & inorganic mercury in finished purees and incoming fruit at ISO 17025 labs — FDA Closer-to-Zero & Prop 65 aligned.



Exposure vs MADL Evaluation

Serving-size, daily-exposure, and infant/toddler intake calculations to determine whether a warning is required for each SKU.



Supplier COA Verification

Incoming fruit, concentrate & ingredient Certificates of Analysis cross-checked against FDA action levels and Prop 65 screening thresholds.



Lot-Level Compliance Review

Every batch is logged, reviewed, and tied to a compliance determination on file — with full chain of custody from grower to finished pouch.



Warning Label Determination

Clear 'warn vs no-warn' logic documented and defensible against private enforcement, retailer audits, and class-action discovery.

Supply-Chain Compliance Control

Prevent the issue upstream — before it reaches your label.



Supplier Attestation

Certification & declarations collected from every grower, packer, concentrator, and ingredient supplier.



Origin Risk Mapping

Inputs classified by orchard region, soil profile, and crop-specific heavy-metal exposure risk.



COA & Action-Level Verification

Every batch COA verified against FDA Closer-to-Zero action levels and Prop 65 thresholds.



Corrective Action (SCAR)

Supplier corrective actions logged, verified, and closed out — with re-test before lot release.

Prevent exposure issues before they reach the consumer — and the courtroom.

The SystemsBuilder Approach

Artifact-based compliance — pay for structure, not repetition.

ARTIFACTS vs RECORDS



You pay for the structure — not the records.

Build once. Use forever.

Example:

ARTIFACT (you pay)

Testing Program

One document that defines how all testing is conducted, reviewed, and documented.



Generates unlimited

RECORDS (no added cost)

Unlimited Lot Test Results

Every lot tested fills out the same framework — no new artifact needed.

→ *Scalable, predictable, cost-efficient.*

How It Works

A three-phase program. Setup once. Monitor continuously.

01 STEP Setup

- Product intake & scoping
- Risk identification by category
- Testing plan creation
- Documentation structure

02 STEP Implementation

- Lab coordination (ISO 17025)
- Exposure & MADL calculations
- Compliance determination
- Warning-label decisions

03 STEP Monitoring

- Monthly compliance oversight
- Lot & batch review
- Trend analysis
- Audit-ready reporting

Setup Pricing — One-Time Investment

Build your defensible Prop 65 compliance system.

COMPLIANCE SYSTEM SETUP

\$1,500

up to 3 finished products

+ \$150

each additional finished product

One-time investment to build your system.

SETUP INCLUDES

- ✓ Risk assessment
- ✓ Testing program design
- ✓ Exposure evaluation framework
- ✓ Documentation system setup
- ✓ Compliance determination structure

Monthly Monitoring — Ongoing Oversight

Continuous compliance. Keep your system alive.

ONGOING COMPLIANCE OVERSIGHT

\$500

per month — up to 7 finished products

+ \$50 / month

per additional finished product

Keeps you continuously compliant.

MONITORING INCLUDES

- ✓ Lot / batch test review
- ✓ Compliance verification
- ✓ Monthly reporting
- ✓ Trend analysis

Cancel anytime. No long-term contracts.

Testing Monitoring Fees

Per-event oversight — pay only when your product is tested.

\$35

per testing monitoring event

Per lot / batch — covers lab-report review, threshold comparison, compliance determination & documentation update.

WHAT THE \$35 COVERS

- ✓ Lab report review
- ✓ Threshold comparison vs MADL
- ✓ Compliance determination
- ✓ Documentation update

IMPORTANT — LAB FEE EXCLUSION

Laboratory testing fees are NOT included.

Testing is conducted by independent ISO 17025 accredited laboratories.

All lab costs are billed directly to the client by the laboratory.

We provide oversight and compliance review — not laboratory testing services.

Pay only for actual testing events • No markup on lab fees • Independent results ensure defensibility

What You Receive

Every client gets a defensible, audit-ready document package.



Lot Compliance Review Reports

Per-lot review with pass/fail determination, threshold comparison, and reviewer sign-off.



Monthly Summary Reports

Rolling snapshot of all testing events, compliance status, and open action items.



Compliance Monitoring Logs

Date-stamped log of every decision made — the backbone of defensibility.



Supplier Tracking Records

Attestations, COAs, risk ratings, and corrective actions by supplier.



Audit-Ready Documentation

Packaged for OAG inquiries, retailer audits, and legal counsel on 24-hour notice.

Built for Defensibility

Documentation is the difference between a quick close-out and a six-figure settlement.



Documented Due Diligence

Every decision has a record, a reviewer, and a date.



Verified Lab Testing

ISO 17025 independent results — no conflicts of interest.



Traceable Decisions

Supplier → material → lot → determination — fully linked.



Structured System

Not ad-hoc — a real management system reviewers recognize.

Critical for lawsuits • Retail audits • Regulatory inquiries

DIY Option — SystemsBuilder.pro

Prefer to manage it yourself? The same artifact library, à la carte.

COMMUNITY LIBRARY






\$1

per artifact

Build your own system on your own terms.

SystemsBuilder.pro

ACCESS THE FULL LIBRARY

-  Prop 65 Programs
-  Policies
-  Procedures (SOPs)
-  Forms (Artifacts)
-  Logs & Templates

Managed Service vs. DIY

Same system. Different execution — you choose who drives.

MANAGED SERVICE

by Consultare Inc. Group

- ✓ Hands-off compliance execution
- ✓ Expert-managed monitoring
- ✓ Monthly reporting delivered

Best for: growing brands without in-house QA capacity

DIY (SystemsBuilder)

at SystemsBuilder.pro

- ✓ Self-managed execution
- ✓ \$1-per-artifact library access
- ✓ Internal team runs the program

Best for: teams with existing compliance capability

Same system. Same artifacts. Same defensibility. — You choose who operates it.

Your Risk Profile

Every one of these factors increases your exposure — independently.



#1 ENFORCEMENT TARGET

Food Category

Food & supplements = largest Prop 65 enforcement category in 2025.



TOP LITIGATION DRIVER

Heavy Metals

Lead lawsuits, FDA Closer-to-Zero, and the 2023 cinnamon-applesauce recall have made fruit & vegetable purees a top current target.



NATURAL EXPOSURE RISK

Fruit Purees

Lead enters via soil uptake, ingredient cross-contamination, and processing — and infants are the primary consumer.



STRICT ENVIRONMENT

California

Most aggressive private-enforcement regime in the United States.

⚠ Your product is already in a high-risk category — even if you've done nothing wrong.

CALL TO ACTION

Don't wait for a 60-Day Notice.

Start your Prop 65 compliance system today.



MANAGED COMPLIANCE

Let us manage it for you.

- ✓ End-to-end Prop 65 system setup
- ✓ Ongoing monitoring & oversight
- ✓ Audit-ready documentation
- ✓ Expert-managed execution



DIY LIBRARY

Build it yourself.

- ✓ \$1-per-artifact library access
- ✓ Community programs & policies
- ✓ Forms, logs & templates
- ✓ Run it your way, in-house

“Build it yourself — or let us manage it for you.”