

CALIFORNIA PROPOSITION 65

Prop 65 Compliance for Nicotine Pouches

Nicotine is a Listed Chemical. Your Warning Strategy Must Be Defensible.

Presented by: Prop65Compliance.com

Compliance Management by Consultare Inc. Group

Powered by SystemsBuilder.pro



Repro Tox

Listed 1990

TSNAs

Listed

Nicotine Is a Listed Chemical

Unlike most categories, the warning requirement isn't in question. The defense is.



⚠ WARNING

This product can expose you to nicotine, a chemical known to the State of California to cause reproductive harm.

— *Safe-harbor warning language*

Warning is Mandatory



Nicotine = Reproductive Toxicant

Listed for developmental toxicity in 1990. Warning is effectively mandatory — no exposure defense to build.



TSNAs Add Cancer Exposure

Tobacco-Specific Nitrosamines (NNN, NNK) are separately listed carcinogens. Manufacturing process matters.



PMTA + Prop 65 Overlap

FDA PMTA filings create a documentation trail plaintiffs will reference. Inconsistent records = exposure.



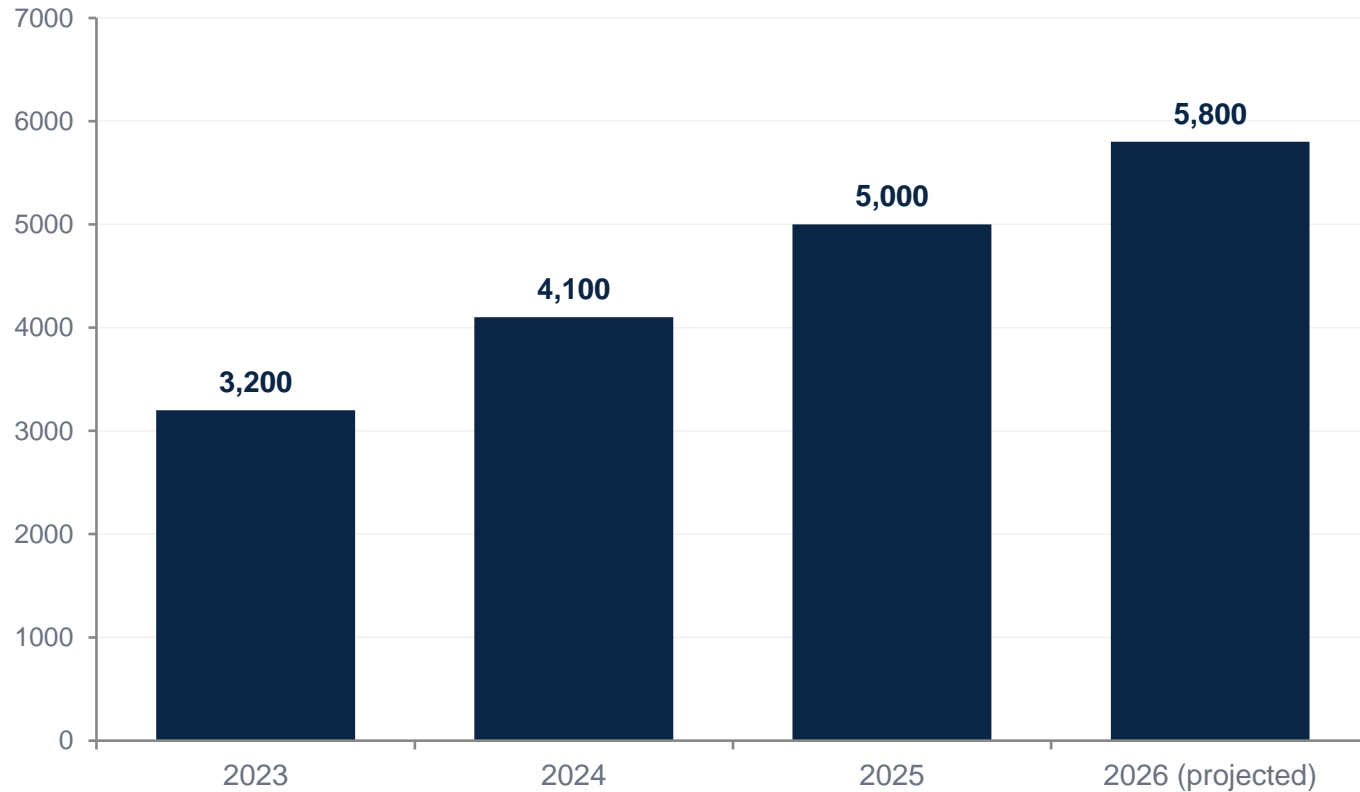
Defense = Warning + Docs

Your warning label design, placement, and documentation trail are the entire defense. We build both.

Nicotine Enforcement Is Accelerating

Modern oral-nicotine products are the newest frontier of Prop 65 enforcement.

Annual Prop 65 NOVs Issued (All Categories)



Source: OAG 60-Day Notice database. Nicotine-product enforcement intensified post-2025 warning-label changes.

2025

New Warning Rules

OEHHA's revised safe-harbor warnings (eff. Jan 2025) require chemical-specific labeling.

~\$86M

2026 Settlements

Record enforcement activity — majority of payments go to plaintiff attorneys.

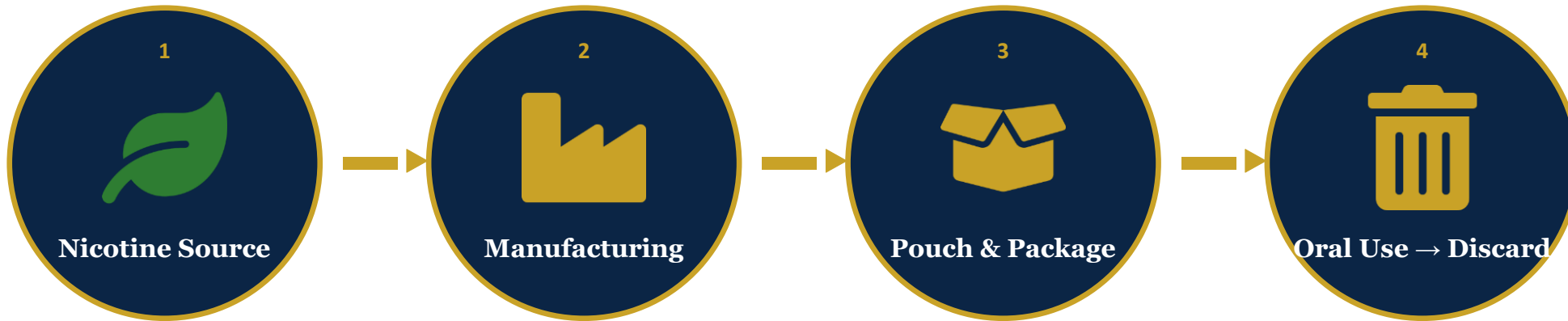
Pouches
Vapes
TSNAs

Active Target Set

Oral pouches, e-liquids, and TSNA impurities drive current supplement-adjacent NOV's.

Why Nicotine Pouches Are High-Risk

Oral + discarded-after-use = exposure, disposal, and child-access all in one SKU.



Tobacco-derived or synthetic — both covered under Prop 65 listings

Extraction and processing can introduce TSNAs (NNN, NNK)

Packaging surfaces, adhesives, and printing inks are separately listed

Used pouches discarded — environmental and child-access liability



Every stage of a pouch's life cycle triggers a different Prop 65 listing.

Nicotine, TSNAs, packaging chemicals, and disposal-site exposures are each independently actionable.

Business Impact of Non-Compliance

For nicotine pouch brands, Prop 65 exposure stacks on top of FDA and state tobacco enforcement.



60-Day Notice of Violation

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



Tobacco-Product Settlements

Nicotine-product settlements routinely run \$50K–\$250K+ per action — higher than supplement category.



Retailer & Distributor Delisting

Convenience chains and distributors pull SKUs at the first NOV. Re-listing requires full compliance file.



FDA & State Exposure Amplifies

Inconsistencies between PMTA submissions, state tobacco filings, and Prop 65 records compound liability.

The warning is mandatory. The defense is whether you applied it correctly and documented it.

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

Warning labels alone don't protect you. A documented program does.



Managed by Consultare Inc. Group

Operational oversight from a dedicated compliance management team.



Built on SystemsBuilder + InterlinkIQ

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 We Deliver

End-to-end Prop 65 program — aligned with your PMTA and state tobacco filings.



SKU-Level Risk Assessment



TSNA & Impurity Testing Oversight



Warning Label Design & Placement



Multi-Chemical Warning Strategy



Packaging Chemical Review



Nicotine Supplier Program



PMTA-Aligned Documentation



Ongoing Monitoring

Every component is documented, traceable, and aligned with your FDA submissions.

Core Technical Components

The compliance stack underneath every pouch determination we issue.



TSNA Panel Testing

Oversight of NNN, NNK, NAT, and NAB at ISO 17025 labs — aligned with FDA HPHC testing protocols.



Warning Label Specification

Safe-harbor language, placement on primary display panel, font size, and conspicuity — documented per SKU.



Multi-Chemical Warning Logic

Nicotine (reproductive) + TSNA (cancer) + packaging chemicals may each require separate warning language.



Packaging Material Review

Pouch material, printing inks, adhesives, and carton stock all separately screened against the listed-chemicals set.

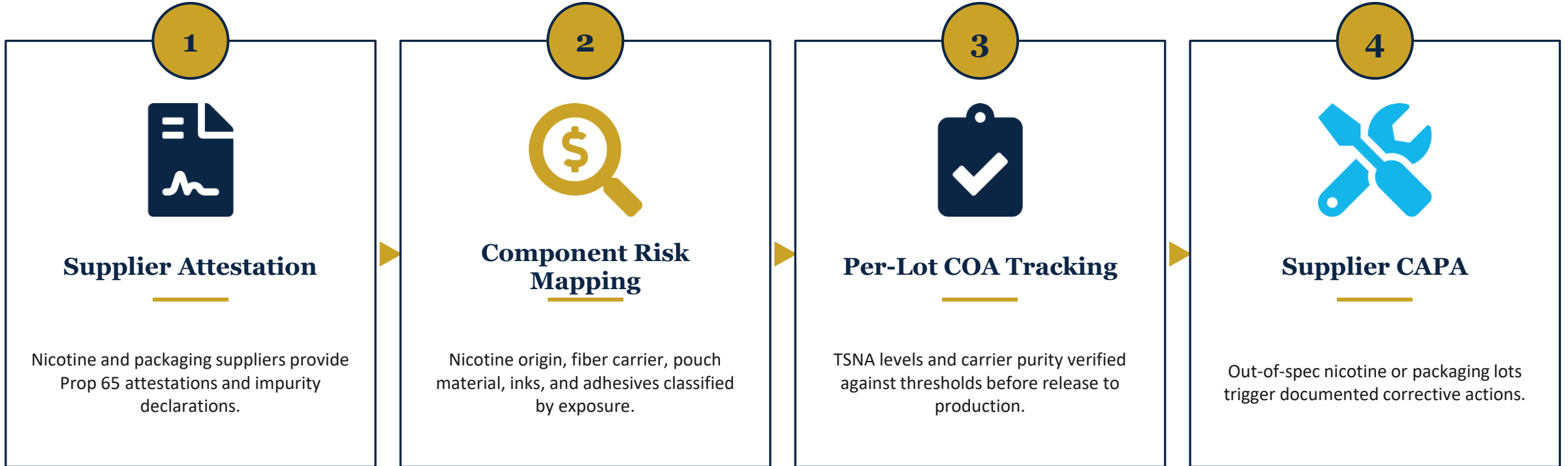


SKU-by-SKU Compliance File

Each flavor, strength, and format gets its own determination, cross-referenced to your PMTA batch records.

Nicotine & Packaging Supply-Chain Control

Every input — nicotine, carrier, pouch, packaging — is independently screened.



One out-of-spec nicotine lot can compromise every SKU it touched. Catch it before packaging.

The SystemsBuilder Approach

Artifact-based compliance — built once, scales across every flavor and strength.



ARTIFACTS vs RECORDS

You pay for the structure — not the records.

Build once. Use for every SKU.

Example:

ARTIFACT (you pay)

Warning Label Program

One document defining warning language, placement, and documentation for every SKU.

↓ Generates unlimited ↓

RECORDS (no added cost)

Per-SKU Warning Determinations

Every flavor, strength, and format 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

- SKU catalog & PMTA scoping
- Component risk classification
- Warning label program design
- Documentation structure

02 STEP Implementation

- Lab coordination (ISO 17025)
- TSNA & impurity testing
- Per-SKU determination
- Warning-label sign-off

03 STEP Monitoring

- Monthly compliance oversight
- Per-lot TSNA review
- PMTA-aligned records
- Audit-ready reporting

Setup Pricing – One-Time Investment

Priced per SKU – every flavor and strength counts as a separate finished product.

COMPLIANCE SYSTEM SETUP

\$1,500
up to 3 finished SKUs

+ \$150
each additional SKU (flavor / strength)

One-time investment to build your system.

SETUP INCLUDES



SKU-level risk assessment



TSNA testing program design



Warning label specification



PMTA-aligned documentation



Compliance determination structure

Monthly Monitoring – Ongoing Oversight

Continuous compliance. Scales with your SKU catalog.

ONGOING COMPLIANCE OVERSIGHT

\$500
per month — up to 7 SKUs

+ \$50 / month
per additional SKU

Keeps you continuously compliant.

MONITORING INCLUDES



Per-lot TSNA review



Warning label verification



Monthly reporting



Trend analysis by supplier

Cancel anytime. No long-term contracts.

Testing Monitoring Fees

Per-event oversight — pay only when a lot is tested.

\$35

per testing monitoring event

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

WHAT THE \$35 COVERS

- Lab report review
- TSNA threshold comparison
- Per-SKU 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 — per SKU.



Per-SKU Warning Determinations

Each flavor/strength's warning rationale, label artwork approval, and reviewer sign-off.



Monthly Summary Reports

Rolling snapshot of all SKUs, testing events, warning-label status, and open action items.



TSNA Test Review Logs

Date-stamped per-lot TSNA log — traceable from raw nicotine lot through finished pouch.



Supplier & Packaging Records

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



Audit-Ready Documentation

Packaged for OAG inquiries, FDA cross-references, and retailer compliance requests 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 SKU determination has a record, a reviewer, and a date.



Verified Lab Testing

ISO 17025 TSNA and impurity results — no conflicts of interest.



Traceable Decisions

Supplier → nicotine lot → SKU → warning → determination — fully linked.



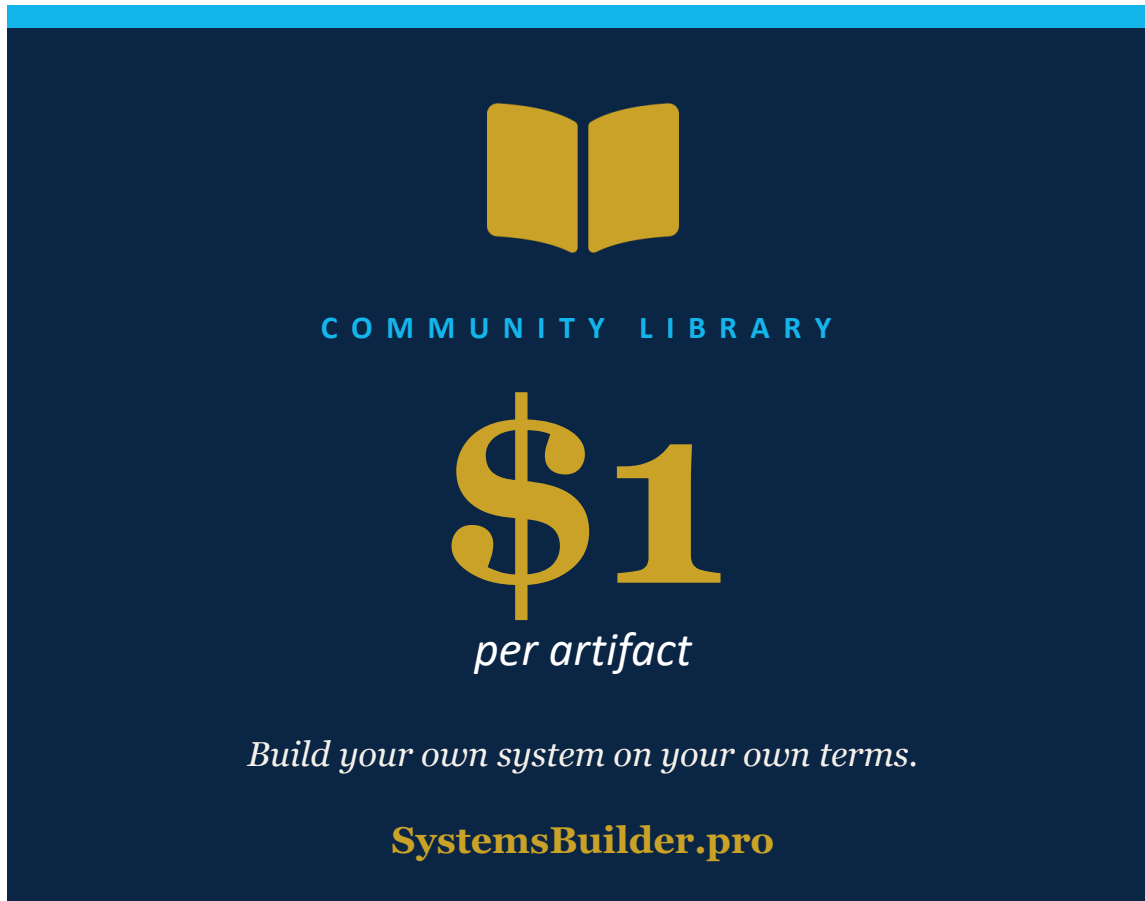
PMTA-Aligned System

Structure mirrors your FDA submissions — reviewers see consistency, not contradiction.

Critical for lawsuits • Retailer audits • FDA cross-references • State tobacco filings

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



Nicotine Product Programs



Warning Label SOPs



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: brands scaling across flavors and strengths

DIY (SystemsBuilder)

at SystemsBuilder.pro

- Self-managed execution
- \$1-per-artifact library access
- In-house regulatory team runs the program
- Best for: mature brands with existing PMTA infrastructure

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

Your Risk Profile

Every one of these factors increases your exposure — independently.



LISTED CHEMICAL

Nicotine Itself

Listed for reproductive toxicity (developmental) since 1990 — warning language is effectively mandatory.



IMPURITY DRIVER

TSNAs (NNN, NNK)

Separately listed carcinogens formed during nicotine processing — testable and litigable.



PACKAGING EXPOSURE

Pouch & Carton Materials

Inks, adhesives, and packaging components each carry independent Prop 65 screening obligations.



MARKETPLACE RISK

Retailer & FDA Scrutiny

Convenience-store distribution, PMTA records, and state tobacco filings all create public paper trails.



Your warning is mandatory. Your defense depends on whether you documented it correctly.

CALL TO ACTION

Don't wait for a 60-Day Notice.

Defend your warning strategy and your catalog — today.



MANAGED COMPLIANCE

Let us manage it for you.

- End-to-end Prop 65 system setup
- SKU-level warning & testing oversight
- PMTA-aligned documentation
- Expert-managed execution



DIY LIBRARY

Build it yourself.

- \$1-per-artifact library access
- Nicotine product programs
- Warning-label SOPs & templates
- Run it your way, in-house

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

Prop65Compliance.com • [SystemsBuilder.pro](#)