

CALIFORNIA PROPOSITION 65

# Prop 65 Compliance for Nootropics

*System-Based Compliance. Not Just Testing.*

Presented by: [Prop65Compliance.com](https://prop65compliance.com)

Compliance Management by [Consultare Inc. Group](https://consultare.com)

Powered by [SystemsBuilder.pro](https://systemsbuilder.pro)



**5,000+**

NOVs in 2025

**8/10**

Drug-Tainted

# Why This Matters

California Prop 65 applies to every ingredient — and nootropic stacks combine multiple trigger ingredients by design.



## ⚠️ 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](https://P65Warnings.ca.gov)

**Herbal ≠ 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 the Stack

Adaptogens, mushrooms, and synthetic compounds each carry independent risks. FDA cited Peak Nootropics in 2019 for 12 supplements classified as unapproved drugs.



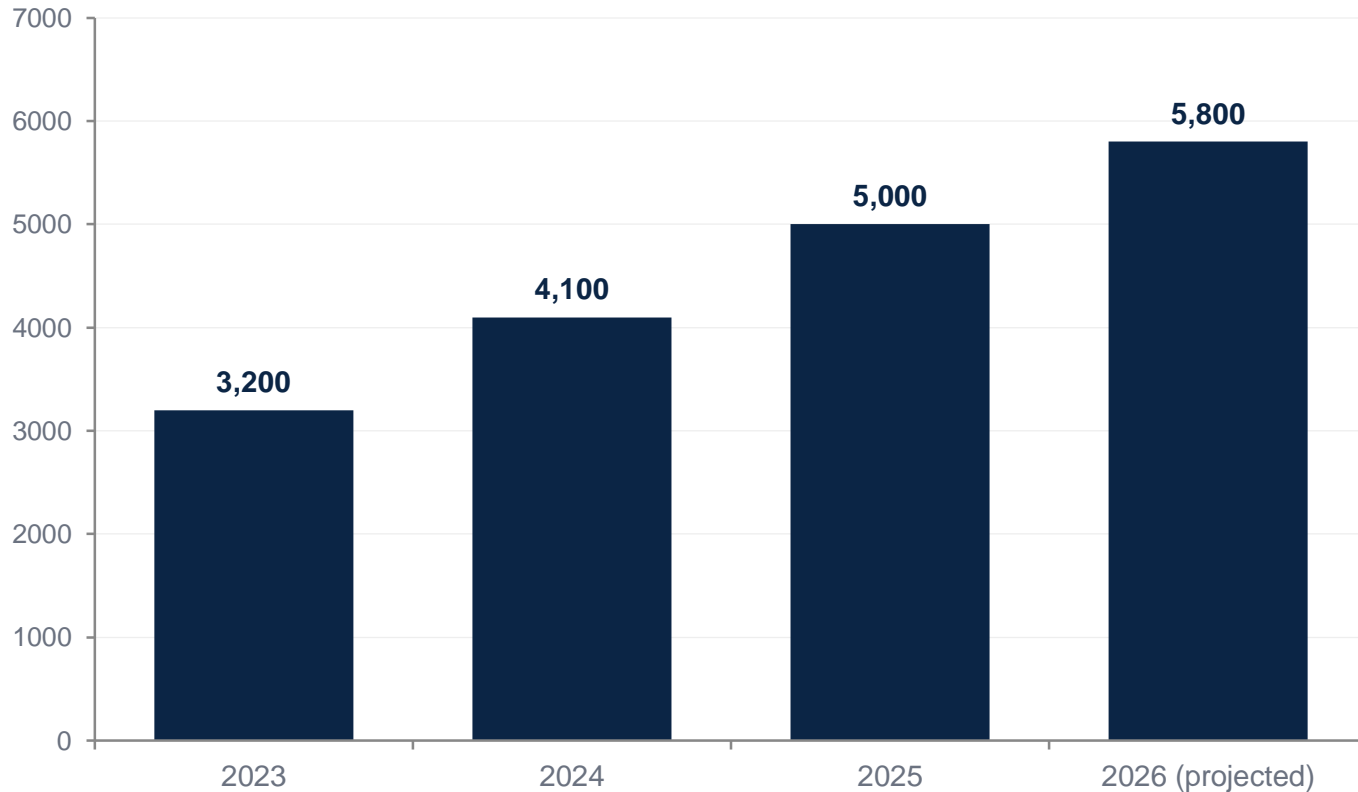
### Documentation Is Your Defense

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.

Annual Prop 65 NOVs Issued



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.

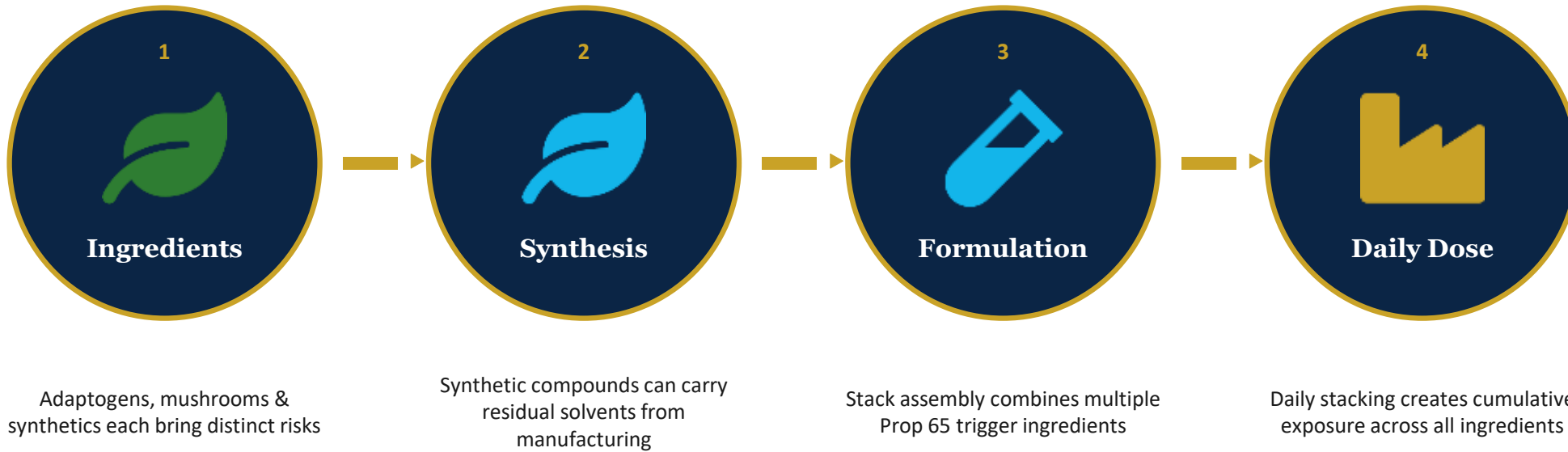
Stacking Multiplies Risk

### Ashwagandha, Lion's Mane, Racetams

A 2021 JAMA study detected unapproved drugs in 8 of 10 nootropic products. Typical warnings list lead, cadmium, arsenic, mercury & nickel.

# Why Nootropics Are at Risk

Every stacked ingredient adds a new contamination pathway — and the FDA-supplement line blurs for synthetics.



**A nootropic stack inherits the Prop 65 risk of every ingredient — and the supplement/drug line is itself at risk.**

*Lead, Cadmium, Arsenic, Mercury & Nickel are all listed Prop 65 chemicals — typical nootropic warnings name all five.*

# 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.*

# 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 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.*



## Chemical Testing

Oversight of Lead, Cadmium, Arsenic, Mercury & Nickel plus residual solvents & adulterant screening at ISO 17025 labs.



## Exposure vs MADL Evaluation

Serving-size, daily-exposure, and averaging calculations to determine whether a warning is required.



## Supplier COA Verification

Incoming raw-material Certificates of Analysis cross-checked against screening thresholds.



## Batch-Level Compliance Review

Every lot is logged, reviewed, and tied to a compliance determination on file.



## Warning Label Determination

Clear 'warn vs no-warn' logic documented and defensible against private enforcement.

# Supply-Chain Compliance Control

*Prevent the issue upstream — before it reaches your label.*



*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 Batch 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
- Batch & lot 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



Batch / lot 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.*



## Batch 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 → batch → determination — fully linked.



## Structured System

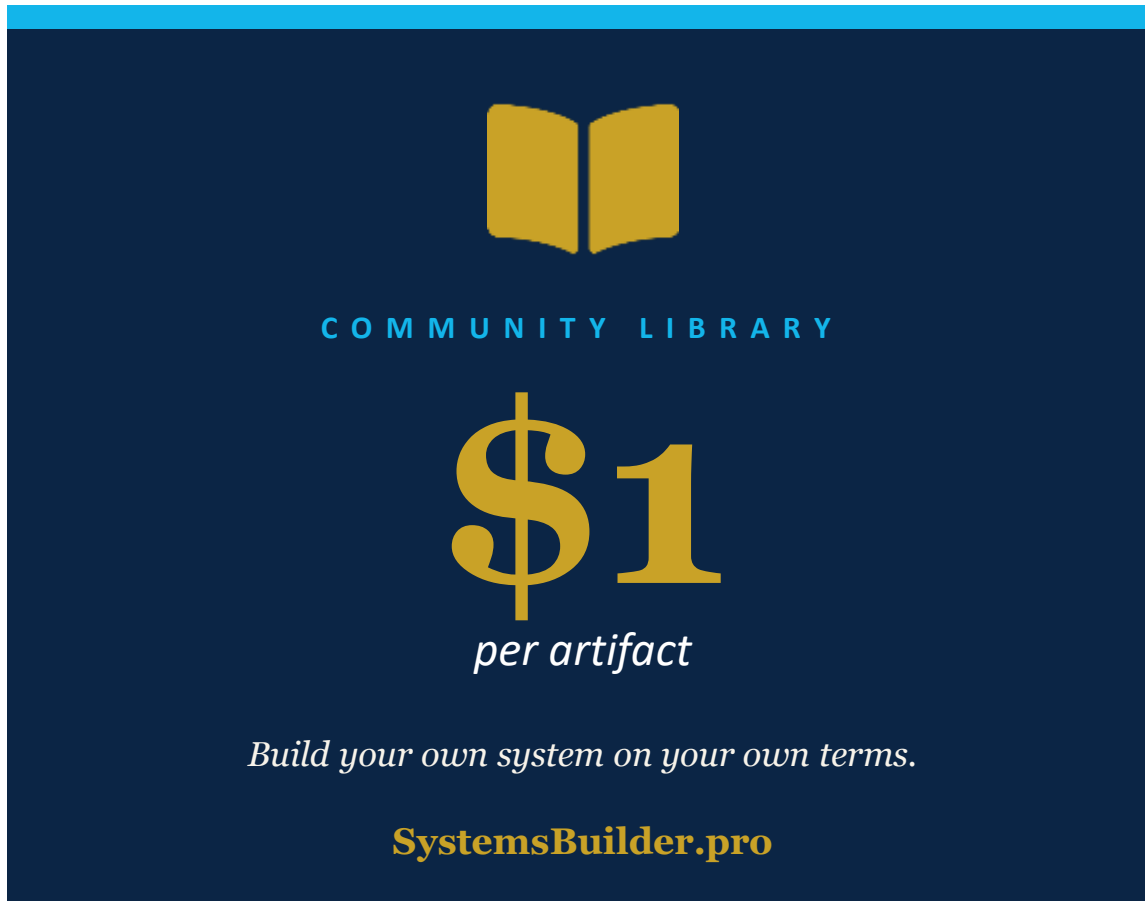
Not ad-hoc — a real management system reviewers recognize.

Critical for lawsuits • Retail audits • Regulatory inquiries

OPTION

# 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. A 2021 JAMA study detected unapproved drugs in 8 of 10 nootropic products tested.

## TOP LITIGATION DRIVER



### Heavy Metals

Lead, cadmium, arsenic, mercury & nickel — each ingredient in the stack can contribute a different metal.

## NATURAL EXPOSURE RISK



### Nootropic Stack

Every stacked ingredient brings independent risk — and synthetic nootropics may cross the FDA supplement-drug line.

## 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.”*

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