

CALIFORNIA PROPOSITION 65

# Prop 65 Compliance

## *for Vitamin K2*

*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)



PROP 65  
DEFENSIBLE

**5,000+**

NOVs in 2025

**~45%**

Supplement Share

© Consultare Inc. Group | For Discussion Purposes

# Why This Matters

California Prop 65 applies to all dietary supplements — including vitamins.

## ⚠️ 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

## ***Vitamin ≠ Exempt***

**Supplements face STRICTER exposure rules than food.**



### Enforcement Is Aggressive

Private plaintiffs ('bounty hunters') file the majority of 60-Day Notices — the AG doesn't need to lead.



### Penalties Are Real

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



### Applies to All Supplements

No exemption for natural, organic, fermented, or small producers. If your product is sold in California, you're in scope.



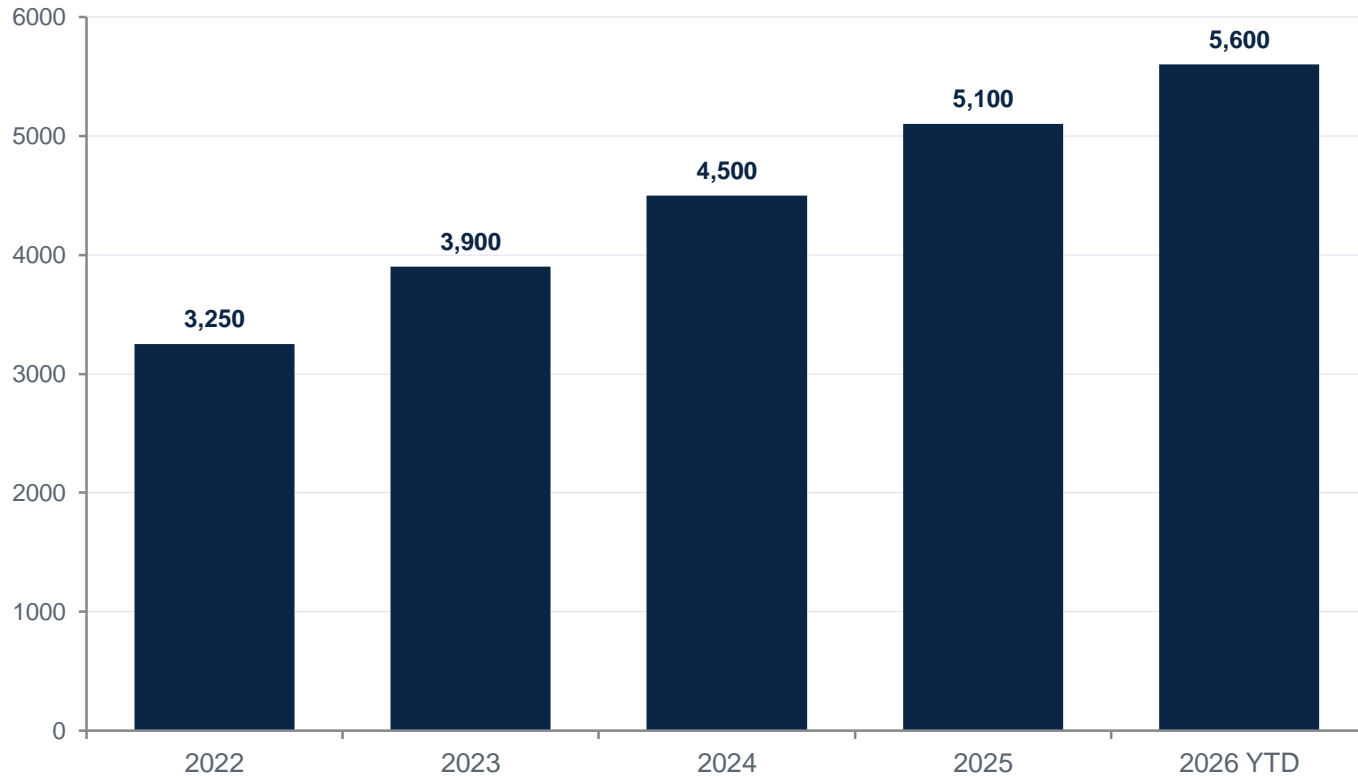
### Documentation Is Your Defense

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.

<b>~45%</b>	<b>Supplements &amp; Foods</b>  Largest combined category of Prop 65 enforcement in 2025.
<b>~\$86M</b>	<b>2026 Settlements</b>  Record enforcement activity — majority paid to attorneys.
<b>K2</b>	<b>Fermented / Natto, MK-7, MK-4</b>  Lead & cadmium from fermentation substrates and mineral co-formulations.

# Why Vitamin K2 Is at Risk

Heavy metals enter ingredient supply chains at multiple points.



## Fermentation Substrate

Natto / soy substrate absorbs lead & cadmium from soil & water



## Bacterial Culture

MK-7 produced by *Bacillus subtilis* — metals accumulate in culture



## Extraction & Carriers

Oils, MCT, or gel caps introduce further exposure paths



## Finished Capsule

Metals concentrate per dose — strict  $\mu\text{g/day}$  MADL applies

***Fermented and naturally-sourced does not eliminate heavy-metal exposure risk.***

Lead and cadmium are listed Prop 65 chemicals with strict MADL thresholds — naturally occurring does not equal exempt.

# 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.***

W H A T

# 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.

O U R P R O M I S E

*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 (MADL 0.5 µg/day), Cadmium (MADL 4.1 µg/day), Arsenic (NSRL 10 µg/day), Mercury (0.3 µg/day) at ISO 17025 labs.



## Exposure vs MADL Evaluation

Per-serving, per-capsule, and daily-dose exposure calculations to determine whether a warning is required.



## Supplier & Ingredient COA Verification

Incoming MK-7 / MK-4 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.

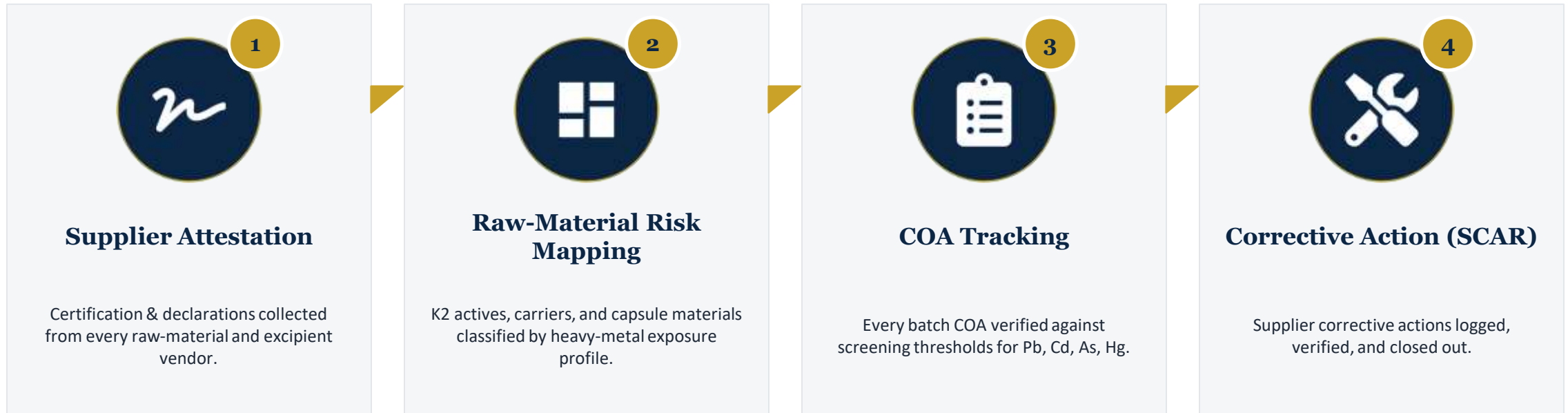


## Warning Label Determination

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)

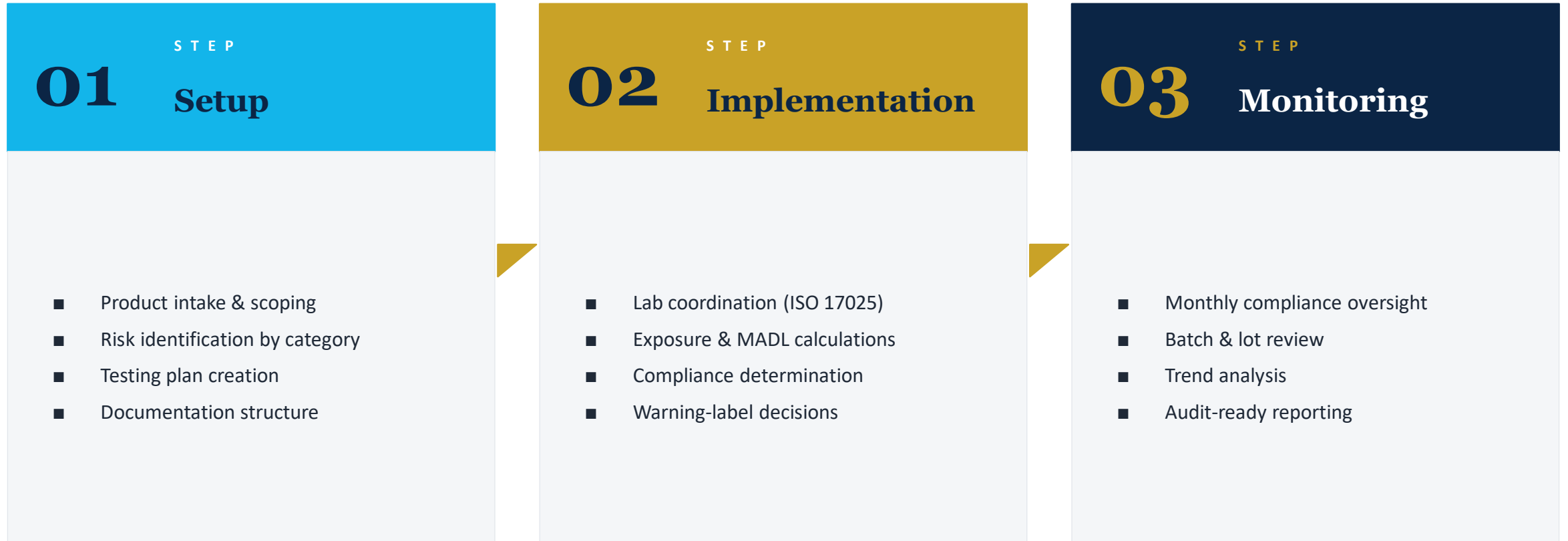
## Unlimited Batch Test Results

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.*



# 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 (SKU)

*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 → ingredient → batch → 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

## Supplement Category

Supplements & foods = largest Prop 65 enforcement category in 2025.



TOP LITIGATION DRIVER

## Heavy Metals

Lead and cadmium lawsuits dominate 2025–2026 supplement enforcement.



NATURAL EXPOSURE RISK

## Vitamin K2

Fermentation substrates and capsule materials concentrate trace metals — natural is not a shield.



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](https://Prop65Compliance.com) • [SystemsBuilder.pro](https://SystemsBuilder.pro)