

CALIFORNIA PROPOSITION 65

Prop 65 Compliance

for Artificial Colors

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

~53%

Food & Supp. Share

W H Y

Why This Matters

Artificial colors are under unprecedented regulatory pressure — and it's accelerating.

WARNING

This product can expose you to chemicals including benzidine and 4-aminobiphenyl — contaminants of certified FD&C dyes — known to the State of California to cause cancer.

— Prop 65 + FDA + State Bans

Four Regulatory Fronts



Red 3 Already Banned

FDA revoked Red 3's food authorization (Jan 2025). Effective 2027 for food, 2028 for drugs.



Big 6 Phase-Out by 2027

Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, Green 3 — voluntary phase-out but market-enforced.



State Laws Outpace FDA

CA, WV, UT, AZ, VA, TX + others. ~11 school bans enacted; ~140 bills introduced in 2025.



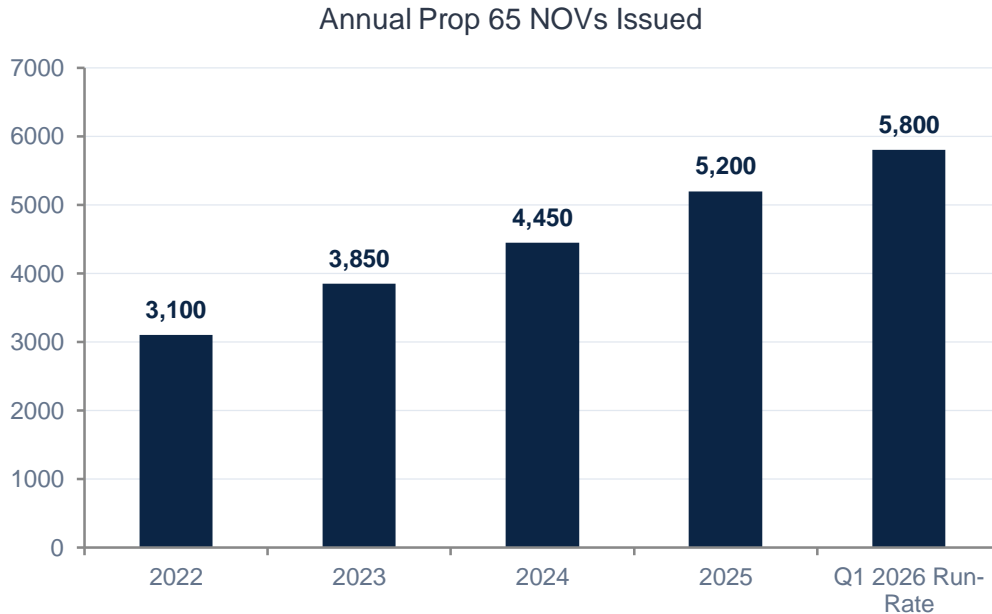
Documentation Is Your Defense

Reformulation timelines, supplier audits, and testing records are the only evidence that holds up.

W H Y

Prop 65 Enforcement Trends (2024–2026)

Enforcement is accelerating — not slowing down.



Source: OAG 60-Day Notice database; Bureau Veritas CPS quarterly summaries.

~53%

Food & Supplements

Largest single category of Prop 65 enforcement in Q4 2025.

~\$98M

2026 Settlements

Record enforcement activity — majority paid to attorneys.

2027-28

Deadline Wall

FDA phase-out target, CA school ban, WV statewide — all converge 2027–2028.

W H Y

Why Artificial Colors Are at Risk

Four regulatory fronts converge on every SKU that contains FD&C dyes.



Prop 65 (California)

Benzidine & 4-aminobiphenyl — dye contaminants — are listed carcinogens.



FDA Federal Action

Red 3 revoked. Big 6 under voluntary phase-out — 2026–2027 industry target.



State Bans (11+ states)

CA AB 418, AB 2316; WV HB 2354; UT, AZ, VA, TX — school & retail bans.



Consumer & Retail Pressure

Class actions, retailer delistings, & 'no artificial colors' claim litigation.



YOUR PRODUCT PORTFOLIO



Any SKU Using FD&C Dyes

*Four regulatory fronts.
One system to manage them all.*

Prop 65 is the enforcement hook — but reformulation timelines, state laws, and retailer policies now drive the decision.

W H Y

Business Impact of Non-Compliance

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



60-Day Notice of Violation

Prop 65 plaintiff's attorney files with the AG; clock starts on response.



Class Action Exposure

'No artificial colors' claim litigation & false-advertising suits trail dye use.



Forced Reformulation

Natural alternatives cost 2–4× more; stability, shelf-life, and shade-match issues.



Retail & School Delisting

School-meal bans (CA, 8+ states); major CPGs already committed to phase out.

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**



**Dye Contaminant
Test Oversight**



**Exposure
Evaluation**



**Compliance
Determination**



**Warning Label
Strategy**



**Supplier
Compliance Program**



**Reformulation
Tracking**



**Multi-State
Deadline Monitoring**

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

WHAT

Core Technical Components

The compliance stack underneath every determination we issue.



Dye Contaminant Testing

Benzidine (NSRL 0.0000625 µg/day), 4-aminobiphenyl, aniline — ISO 17025 screening of every FD&C dye lot used.



Exposure vs Threshold Evaluation

Serving-size math for contaminants plus caramel color 4-MI (NSRL 29 µg/day) for applicable SKUs.



Supplier COA Verification

Every dye certification (FD&C batch certificate) verified — free and bound contaminant levels.



Reformulation Tracking

Per-SKU timeline against FDA 2026–2027 targets, state bans (CA, WV, UT, AZ, VA, TX), and retailer deadlines.



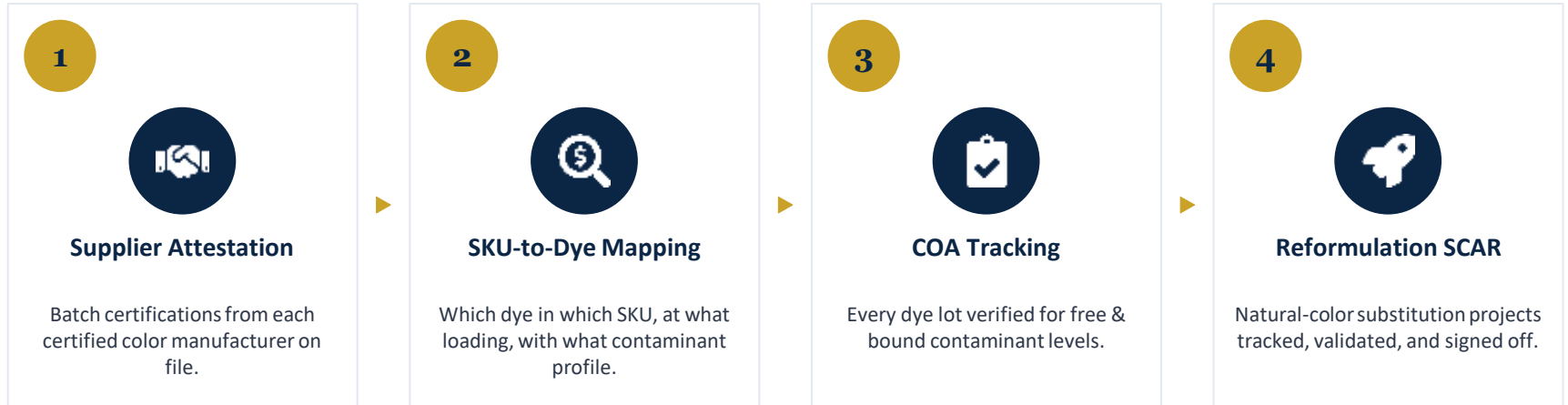
Warning Label & Claim Review

Prop 65 warn logic + defensibility of 'no artificial colors' / 'natural colors' claims during transition.

WHAT

Supply-Chain Compliance Control

Prevent the issue upstream — before it reaches your label.



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

HOW

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 defining how all dye testing, contaminant screening, and reformulation decisions are reviewed and recorded.

↓ Generates unlimited ↓

RECORDS (no added cost)

Unlimited Batch Test Results

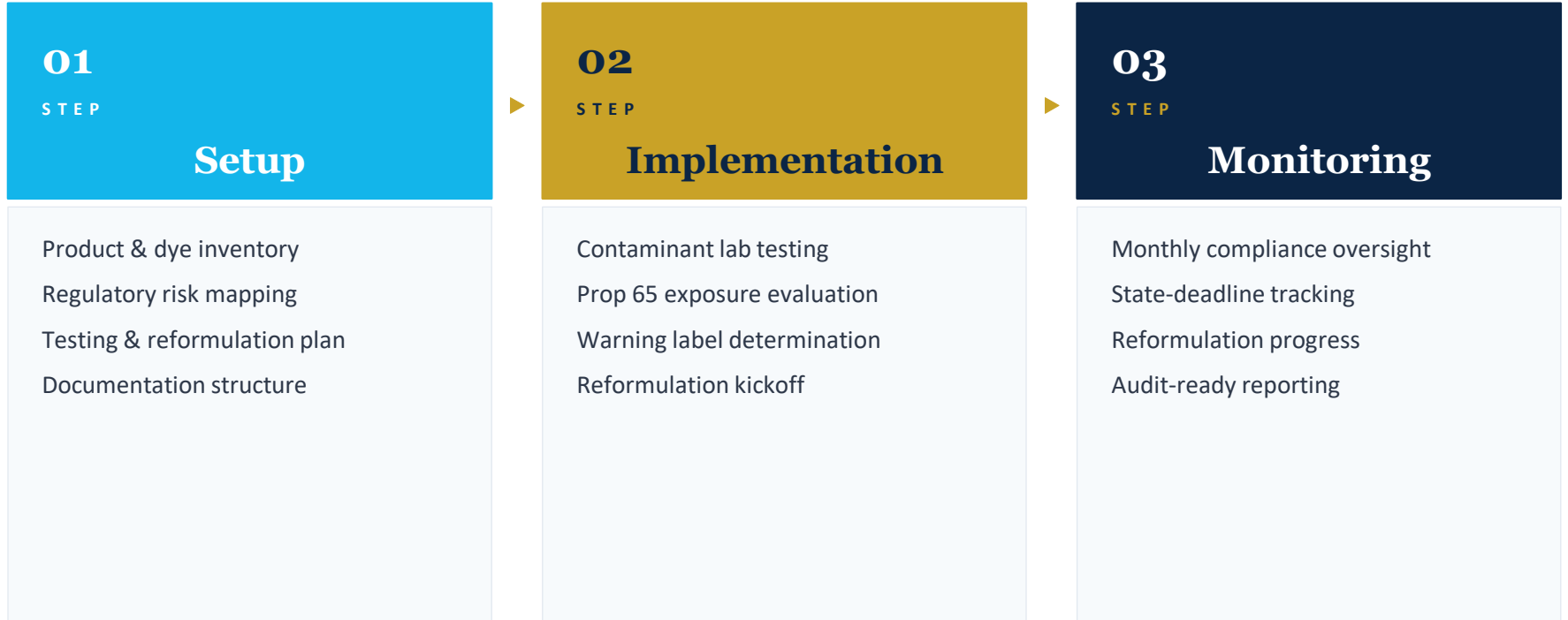
Every lot tested fills out the same framework — no new artifact needed.

→ *Scalable, predictable, cost-efficient.*

HOW

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 (SKUs)

+ \$150

each additional SKU

One-time investment to build your system.

SETUP INCLUDES

- ✓ Dye inventory & SKU risk assessment
- ✓ Testing program (benzidine, 4-AB, 4-MI)
- ✓ Multi-state regulatory deadline map
- ✓ Documentation system setup
- ✓ Reformulation tracking framework

PRICING

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 SKU

Keeps you continuously compliant.

MONITORING INCLUDES

-  Batch / lot test review
-  State deadline & law updates
-  Reformulation progress tracking
-  Monthly compliance reporting

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 (NSRL / 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

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.

HOW

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.

BOTTOM LINE

Your Risk Profile

Every one of these factors increases your exposure — independently.



CALIFORNIA PROP 65

Benidine & 4-AB

Contaminants of certified FD&C dyes are listed carcinogens — extremely low NSRLs (0.0000625 µg/day for benidine).



FDA FEDERAL ACTION

Big 6 Phase-Out

Red 3 revoked. Red 40, Yellow 5/6, Blue 1/2, Green 3 targeted end of 2026–2027 under MAHA initiative.



STATE LAW PATCHWORK

11+ State Bans

CA, WV, UT, AZ, VA, TX + others. School-meal bans effective now; retail bans 2027–2028.



MARKET PRESSURE

CPG Reformulation Race

General Mills, Kraft Heinz, PepsiCo, Mars, Nestle, Conagra, JM Smucker — all publicly committed.

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