

CALIFORNIA PROPOSITION 65

Prop 65 Compliance for Fish Oil Supplements

The Most-Litigated Supplement Category in Prop 65 History.

Presented by: Prop65Compliance.com

Compliance Management by Consultare Inc. Group

Powered by SystemsBuilder.pro



90 ng

PCB NSRL

2010

Landmark Suit

Why Fish Oil Sits at the Heart of Prop 65

The landmark 2010 *Manthey v. CVS* case named 8 defendants and created the template for supplement PCB enforcement.



LANDMARK CASE

Manthey v. CVS Pharmacy (2010): 8 fish oil manufacturers and retailers sued for undeclared PCBs. Plaintiffs argued 'default zero' because no MADL existed.

— SF Superior Ct. Case 10-497334

The Template Is Set



Fat Concentrates Contaminants

PCBs, dioxins, and methylmercury accumulate in fish lipid tissue — which is literally what fish oil IS. The product is the concentrator.



Named Defendants Set the Pattern

Nature Made, GNC, Solgar, NOW Foods, Twinlab, Omega Protein — the category's biggest names were already on the complaint.



GOED Settlement Created a Standard

Feb 2012 consent judgment covering 30 member companies established PCB/dioxin limits — but only for signatories.



Non-GOED Brands Face Default-Zero Risk

Plaintiffs still argue brands outside the settlement must meet a 'zero detection' threshold unless they prove otherwise.

Fish Oil Is a Proven, Ongoing Target

15+ years of continuous plaintiff focus on omega-3 supplements.

Annual Prop 65 NOVs Issued (All Categories)



Source: OAG 60-Day Notice database. Fish oil PCB litigation continues post-2012 GOED settlement for non-signatory brands.

90 ng

PCB Cancer NSRL

Per-day limit for PCBs under Prop 65 — orders of magnitude below FDA's 2 ppm food tolerance.

70x

Brand-to-Brand Spread

Tested products ranged 12 ng to 850+ ng PCB per dose — origin and refining drive the delta.

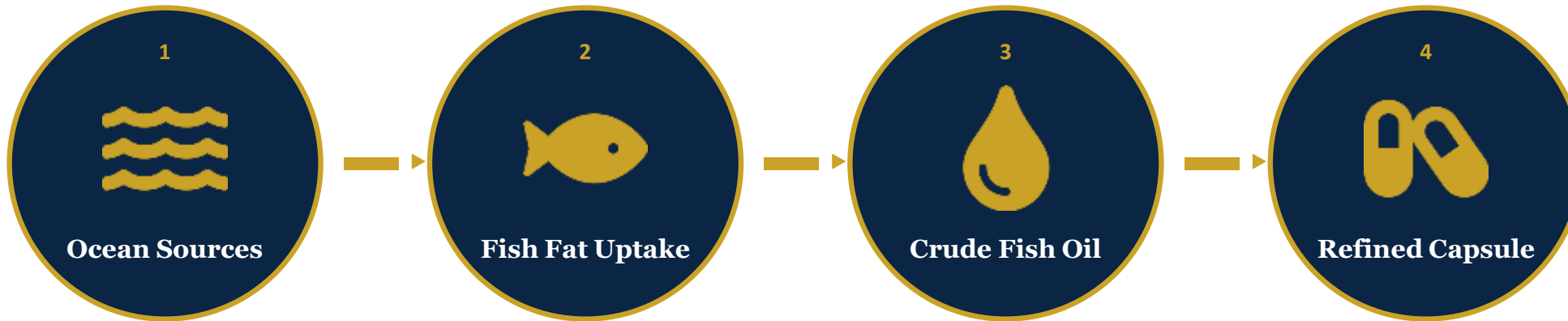
PCBs
Hg
Dioxins

Fish Oil Target Set

The specific carcinogens and reproductive toxicants that drive omega-3 enforcement.

How Contamination Reaches the Capsule

Ocean sediment → fish fat → crude oil → refined product. Each stage is a control point.



PCBs, dioxins, and methylmercury persist in ocean water and sediment from legacy industrial pollution

Lipophilic contaminants bioaccumulate in fish body fat — the same fat that's extracted for omega-3

Raw oil contains the full contaminant load from the source fish — before any refining has occurred

Molecular distillation can reduce PCBs 90%+ — but only if executed and verified per-lot



Fish oil IS the fat contaminants concentrate in — refining is the only real defense.

Per-lot post-distillation PCB/dioxin verification separates defensible brands from default-zero risk.

Inside the Benchmark, or Outside It?

The 2012 GOED Consent Judgment created the category's safe harbor — but only for signatories.



GOED-SETTLEMENT BRAND

Operating certainty

- Settlement PCB/dioxin limits apply
- Plaintiff-suit protection via consent
- GOED Voluntary Monograph testing
- IFOS third-party certification available



NON-SIGNATORY BRAND

Default-zero exposure

- Plaintiffs argue zero-detection threshold
- Burden of proof is on YOU to establish safe harbor
- Each lawsuit re-litigates the limit
- Defensibility comes from your own documentation

A private compliance system replicates GOED-level defensibility — without requiring GOED membership.

Business Impact of Non-Compliance

Omega-3 is a \$4B+ category. Non-compliance hits shelf space, retailer relationships, and brand premium.



60-Day Notice of Violation

15+ years of plaintiff infrastructure targeting fish oil — your NOV doesn't surprise them, it repeats a known script.



Multi-Defendant Settlement Range

Supplement settlements run \$25K–\$150K per SKU. Omega-3 multi-defendant patterns multiply exposure.



Retailer & Distribution Pressure

Whole Foods, Sprouts, CVS, Amazon all require documented compliance for omega-3 category listings.



Premium Brand Damage

'Pharmaceutical-grade', 'purified', 'clean' claims are directly contradicted by every defensive Prop 65 warning.

Fish oil is the most-studied, most-tested, most-litigated supplement category in Prop 65 history.

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 a single batch doesn't protect you. A per-lot 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

**GOED-level defensibility
for every brand —
member or not.**

*Your own consent-judgment-equivalent
compliance file.*

What We Deliver

An end-to-end Prop 65 program — calibrated to the most-litigated supplement category.



**Species-Level
Risk Assessment**



**PCB, Dioxin & Hg
Testing Oversight**



**Per-Dose
Exposure Math**



**Compliance
Determination**



**Warning Label
Strategy**



**Supplier & Refiner
Program**



**Documentation
System**



**Ongoing
Monitoring**

Every component is documented, traceable, and audit-ready — per lot, per species, per refiner.

Core Technical Components

The compliance stack underneath every omega-3 lot determination we issue.



PCB Congener Panel

209-congener PCB analysis per USEPA Method 1668C — oversight for Prop 65's 90 ng/day cancer NSRL and dioxin-like PCB limits.



Dioxin & Furan TEQ Analysis

2,3,7,8-TCDD toxic equivalency quotient per USEPA 1613. The GOED consent judgment standard for defensibility.



Methylmercury Speciation

Total Hg AND methylmercury — the toxicologically relevant form for reproductive-toxicity exposure math.



Species & Origin Documentation

Small cold-water fish (anchovy, sardine, menhaden) vs larger species (tuna, mackerel) carry dramatically different risk profiles.

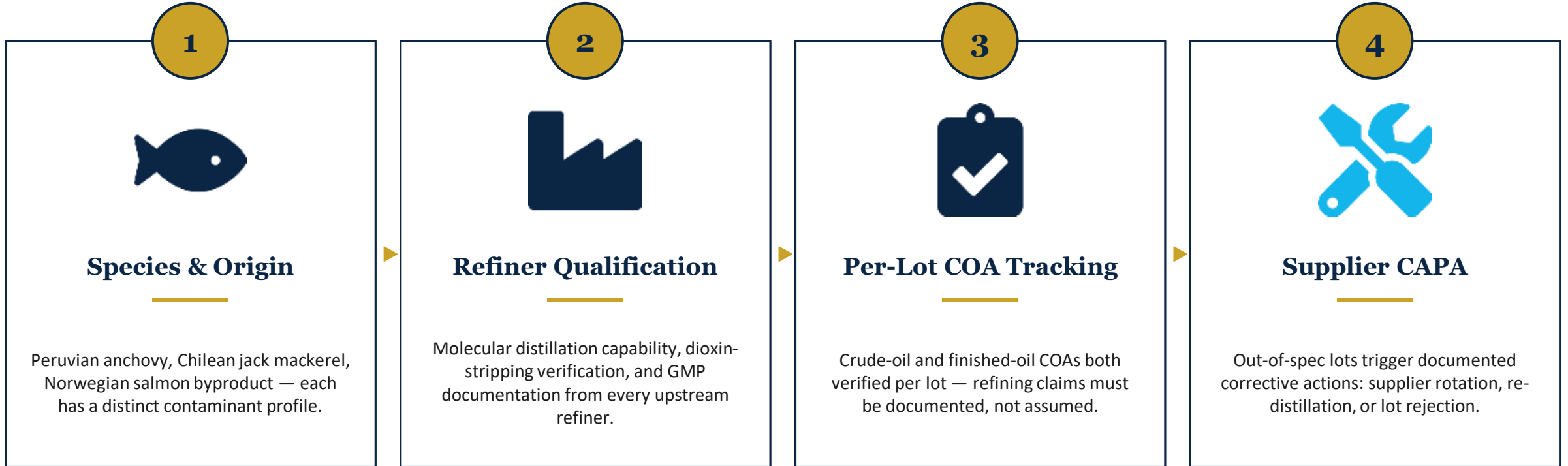


Per-Lot Compliance File

Each production lot: species inputs, crude-oil COA, post-distillation verification, final-product determination, warning decision.

Boat-to-Bottle Supply-Chain Control

Species, origin, and refining method drive the contamination profile. Compliance tracks all three.



Tested products ranged 12 ng to 850+ ng PCB per dose — that's a 70× brand-to-brand spread.

The SystemsBuilder Approach

Artifact-based compliance — built once, scales across every lot and every species input.



ARTIFACTS vs RECORDS

You pay for the structure — not the records.

Build once. Use for every lot.

Example:

ARTIFACT (you pay)

PCB/Dioxin Verification Program

One document defining how every species, every refiner, and every lot is screened and documented.

↓ Generates unlimited ↓

RECORDS (no added cost)

Per-Lot, Per-SKU Records

Every lot, every SKU, every refiner change fills 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 & species scoping
- Refiner & origin mapping
- Testing plan per lot
- Documentation structure

02 STEP Implementation

- Lab coordination (ISO 17025)
- PCB, dioxin, Hg testing
- Per-lot determination
- Warning-label decisions

03 STEP Monitoring

- Monthly compliance oversight
- Per-lot & per-refiner review
- Refiner-change re-determinations
- Audit-ready reporting

Setup Pricing – One-Time Investment

Priced per SKU – each concentration, form, and species blend is a separate compliance file.

COMPLIANCE SYSTEM SETUP

\$1,500
up to 3 omega-3 SKUs

+ \$150
each additional SKU (concentration / form / blend)

One-time investment to build your system.

SETUP INCLUDES



Species-level risk assessment



PCB, dioxin & Hg testing program



Per-dose exposure framework



Documentation system setup



Compliance determination structure

Monthly Monitoring – Ongoing Oversight

Continuous compliance. Scales with your production cadence.

ONGOING COMPLIANCE OVERSIGHT

\$500
per month — up to 7 SKUs

+ \$50 / month
per additional SKU

Keeps you continuously compliant.

MONITORING INCLUDES



Per-lot test review



Refiner-change re-determinations



Monthly reporting



Trend analysis by refiner

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

WHAT THE \$35 COVERS

- Lab report review
- Threshold comparison vs NSRL / MADL
- Per-lot 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 lot.



Per-Lot Compliance Determinations

Each production lot's PCB, dioxin, and Hg review with pass/fail determination and reviewer sign-off.



Monthly Summary Reports

Rolling snapshot of all SKUs, refiner trends, testing events, and open action items.



Compliance Monitoring Logs

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



Refiner & Species Records

Attestations, COAs, distillation verification, and corrective actions by supplier and species.



Audit-Ready Documentation

Packaged for OAG inquiries, retailer audits, and Amazon compliance requests on 24-hour notice.

Built for Defensibility

The 2010 lawsuit's burden-of-proof standard still applies to any non-GOED brand today.



Documented Due Diligence

Every lot determination has a record, a reviewer, and a date.



Verified Lab Testing

ISO 17025 PCB, dioxin, and methylmercury results — no conflicts of interest.



Traceable Decisions

Species → refiner → crude lot → finished lot → determination — fully linked.



Structured System

Not ad-hoc — a real management system plaintiff attorneys recognize.

Critical for plaintiff suits • Retailer audits • Amazon compliance • Regulatory inquiries

Managed Service vs. DIY

Same system. Different execution — you choose who drives.

MANAGED SERVICE

by Consultare Inc. Group

- Hands-off compliance execution
- Expert-managed refiner monitoring
- Monthly reporting delivered
- Best for: non-GOED brands scaling into California retail

DIY (SystemsBuilder)

at SystemsBuilder.pro

- Self-managed execution
- \$1-per-artifact library access
- In-house QA/regulatory team runs the program
- Best for: established brands with QA depth

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

Your Risk Profile

Every one of these factors increases your exposure — independently.



DOCUMENTED PRECEDENT

Multi-Defendant Lawsuit

2010 Manthey v. CVS named 8 fish oil companies. The plaintiff playbook is proven and repeatable.



LIPOPHILIC CONTAMINANTS

Fat-Bound Toxins

PCBs, dioxins, and methylmercury all concentrate in fish fat — the product IS the concentrator.



CONSENT-JUDGMENT GAP

GOED Non-Membership

Outside the 2012 settlement, plaintiffs argue default-zero exposure thresholds against you.



BRAND EXPOSURE

'Pharmaceutical-Grade' Risk

Premium positioning is directly undercut by defensive Prop 65 warnings applied 'just in case'.



The plaintiff infrastructure for fish oil is 15+ years old. Build your own consent-judgment equivalent.

CALL TO ACTION

Don't wait for a 60-Day Notice.

Build GOED-level defensibility — with or without membership.



MANAGED COMPLIANCE

Let us manage it for you.

- End-to-end Prop 65 system setup
- Per-lot PCB/dioxin/Hg monitoring
- Refiner-change re-determinations
- Expert-managed execution



DIY LIBRARY

Build it yourself.

- \$1-per-artifact library access
- Omega-3 compliance programs
- Forms, logs & templates
- Run it your way, in-house

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

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