CONSULTARE INC. GROUP

Prop 65 Compliance

for Dairy Powders

Heavy metals concentrate in protein. Disclosure laws are tightening. Plaintiffs are watching.

WHEY · CASEIN · NFDM · MPC / MPI · INFANT FORMULA BASE · CHEESE POWDERS · CREAMERS

PROPOSITION 65 RISK ASSESSMENT · AB 899 DISCLOSURE · REFORMULATION ROADMAP

APRIL 2026

A Category Under Disclosure Pressure

$2.5K
Per-day Prop 65 penalty exposure

60%
Heavy-metal NOVs in protein powders since 2023

AB 899
Baby food disclosure in force since Jan 2025

10×
Whey concentration ratio vs. fluid milk

Concentrated by Process

- Spray-drying removes water and concentrates everything else — including lead, cadmium, arsenic, and aflatoxin M1.
- A 10:1 milk-to-whey ratio means trace levels in fluid milk become Prop 65–relevant in finished powder.
- Cocoa-flavored proteins compound the problem with cocoa cadmium loading.

Active Plaintiff Pressure

- Consumer Reports (2010, 2018) and Clean Label Project (2018, 2023) keep heavy-metal protein-powder findings in the news.
- Settled Prop 65 actions against Optimum Nutrition, MusclePharm, Garden of Life, and others have established case law.
- Sports nutrition channel is plaintiff-attractive: premium price, health positioning, direct-to-consumer.

AB 899 Reframes Infant Formula

- California's Lead and Cadmium in Baby Food Act took effect Jan 1, 2024.
- Full QR-code disclosure of monthly heavy-metal test data was due Jan 1, 2025.
- Infant formula is a baby food. Manufacturers without sub-batch sampling protocols are out of compliance now.

What 'Dairy Powders' Actually Includes

Risk severity varies by product. Concentration ratio, sourcing region, channel, and end-use drive Prop 65 exposure differently across these subcategories.

Sports Nutrition — VERY HIGH

Whey isolate · Whey concentrate · Casein · Hydrolyzed whey · Plant-blend powders

Highest plaintiff scrutiny. Premium price, health claims, DTC channel.

Infant Formula Base — EXISTENTIAL

Demineralized whey · Lactose · MPC for stage formula · Caseinate

AB 899 disclosure now structural. Federal infant formula GMPs apply.

Clinical / Medical — HIGH

MPI · MPC · Sodium / calcium caseinate · Hydrolysate

Tube-feed and oral nutrition. Drug-grade documentation expected.

Bakery / Food Service — MODERATE

NFDM · Buttermilk powder · Whole milk powder · Cream powder · Butter powder

Volume B2B. Lower direct exposure but inherits NOV risk through finished goods.

Cheese Powders / Seasoning — MODERATE

Cheddar / parmesan / blue powders · Annatto-colored blends · Salt-cheese blends

Annatto and paprika colorant lead is a niche but recurring concern.

Coffee Creamer — LOW–MODERATE

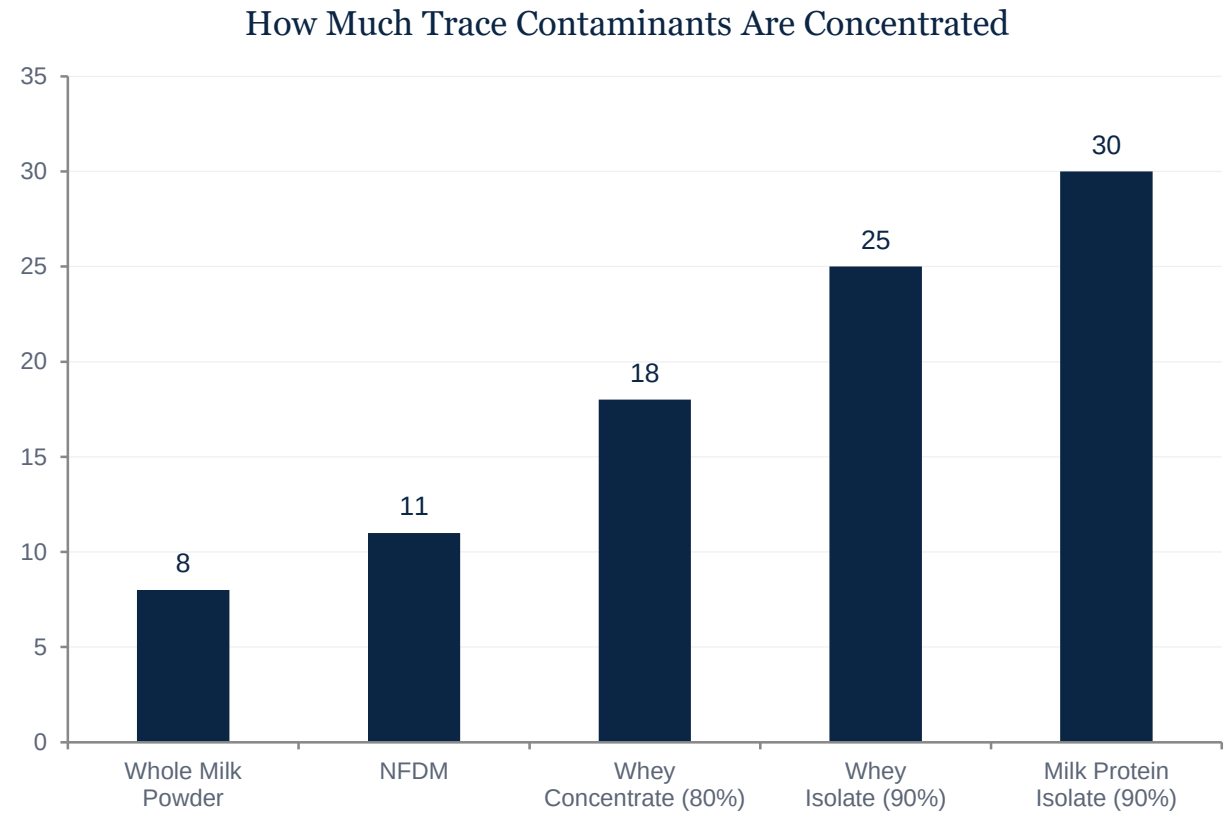
Sweet-cream powder · Flavored creamer base · Milk-protein creamer

Sucrose, oils, and flavorings expand the contaminant profile beyond pure dairy.

What's Actually in Play for Dairy Powders

Chemical	Listing Basis	Source / Pathway	MADL / NSRL	Severity
Lead	Carcinogen + Repro Tox	Soil → forage → milk; concentrated in WPC/WPI	0.5 µg/day MADL	VERY HIGH
Cadmium	Carcinogen + Repro Tox	Cocoa-flavored protein blends; pea-protein blends; soil	4.1 µg/day MADL	VERY HIGH
Arsenic (inorganic)	Carcinogen + Dev Tox	Water; rice-protein blend ingredients in flavored mixes	10 µg/day MADL	MODERATE
Mercury (methylmercury)	Developmental Toxin	Feed contamination; rare but documented	0.3 µg/day MADL	LOW
Aflatoxin (incl. M1)	Carcinogen	Contaminated dairy feed → milk → concentrated in powder	No NSRL set; LOQ basis	HIGH
Acrylamide	Carcinogen + Repro Tox	Maillard browning in caramelized whey, specialty creamers	Food enjoined May 2025	ENJOINED
3-MCPD esters / glycidyl esters	Process contaminant (FAO/WHO)	Vegetable-oil add-back in creamers, infant formula	EFSA limits; CA monitoring	EMERGING
Furan	Carcinogen	Retort / spray-drying of dairy	Listed; no NSRL	MONITOR
BPA / BPS	Repro Tox	Metal canister linings	3 µg/day MADL (BPA)	MODERATE
PFAS (PFOA, PFOS, etc.)	Carc + Repro Tox (subset listed)	Pouch liners, vacuum bags, processing aids	Var. — PFOA: 0.05 µg/day MADL	EMERGING

Why Trace-Level Milk Becomes a Prop 65 Problem in Powder



Source: Composition-based ratio of contaminant carriers (water, lactose, protein) removed during concentration.

WHAT THIS MEANS IN PRACTICE

Lead in fluid milk at 0.5 µg/L

becomes 12.5 µg/kg in 25× whey isolate.

Single 30 g serving = 0.375 µg

or 75% of the daily Prop 65 MADL — from a single dose, before any other dietary lead exposure.

The Implication

Acceptable raw-milk lead levels are NOT acceptable downstream. Heavy-metal monitoring must occur on finished powder, not on milk intake. Most legacy QC programs sample the wrong stage.

ENFORCEMENT TIMELINE

Selected Prop 65 Actions Against Dairy & Protein Powders

A representative — not exhaustive — selection of public NOVs, settlements, and disclosure-driven actions involving dairy and protein powder products.

2010	**Consumer Reports protein powder study** Multiple major brands	**Pb, Cd, As, Hg** *Industry-wide reformulation conversations begin*
2018	**Clean Label Project — Protein Powder Report** 134 SKUs tested; 70% had detectable lead	**Pb, Cd, BPA, BPS** *Major media coverage, certification market emerges*
2020-22	**Optimum Nutrition Gold Standard settlement** ON; chocolate-flavored whey	**Lead** *Warning labels added, formulation review*
2023	**MusclePharm / various private-label NOVs** Multiple plant-blend whey products	**Cadmium (cocoa)** *Settlement and reformulation toward sourcing change*
Jan 2024	**AB 899 takes effect** All baby food incl. infant formula	**Pb, Cd, Hg, As** *Monthly testing required; QR disclosure due Jan 1, 2025*
Jan 2025	**AB 899 disclosure deadline** Infant formula manufacturers	**Heavy metals** *Public-facing test data; non-compliant SKUs subject to enforcement*
2025	**Garden of Life / private-plaintiff NOVs** Plant-based and dairy-blend protein powders	**Lead, cadmium** *Settlements; CR re-test cycle resumed*
2026	**Active hunting period** Premium DTC sports nutrition	**Heavy metals + PFAS** *Plaintiff bar specifically focused on category — present-day risk*

AB 899 — California Lead and Cadmium in Baby Food Act

INFANT FORMULA = BABY FOOD UNDER AB 899

Manufacturers and distributors of infant formula in California have full disclosure obligations as of January 1, 2025. Compliance is now structural, not aspirational.

What's Required

- Test each finished product batch for lead, cadmium, arsenic, and mercury — at minimum, monthly composite sampling.
- Disclose ALL test results to the California Department of Public Health (CDPH).
- Provide a QR code on the label linking to test results, by SKU, accessible to consumers.
- Maintain test records for at least three years; provide on CDPH request.

What Triggers Risk

- Sourcing from countries / regions with higher background metals (some EU, Asian sources).
- Cocoa-, fruit-, or grain-flavored toddler formulas — added ingredients amplify exposure.
- Demineralized whey: minerals removed but trace metals can be retained or even enriched depending on process.
- Co-packers without their own AB 899 program — brand owner remains liable.

What Compliance Looks Like

- Documented sampling SOP referencing 21 CFR 106 / 107 (federal infant formula GMP) plus AB 899.
- Method validation aligned with FDA elemental impurities guidance and AOAC 2015.01 / equivalent.
- QR code → public results page with date, lot, analyte, result, method, lab name, accreditation.
- Annual program review with Qualified Individual (QI) sign-off.

Chemical Risk by Dairy Powder Subcategory

Subcategory	Lead	Cadmium	Arsenic	Aflatoxin M1	3-MCPD	BPA / Pkg	PFAS / Pkg
Whey concentrate (80%)	VERY HIGH	VERY HIGH	MODERATE	HIGH	LOW	MODERATE	HIGH
Whey isolate (90%)	VERY HIGH	VERY HIGH	MODERATE	HIGH	LOW	MODERATE	HIGH
Cocoa-flavored whey blends	VERY HIGH	VERY HIGH	MODERATE	HIGH	MODERATE	MODERATE	HIGH
Plant-blend protein powders	VERY HIGH	VERY HIGH	HIGH	MODERATE	MODERATE	MODERATE	HIGH
MPC / MPI	HIGH	HIGH	MODERATE	HIGH	LOW	MODERATE	MODERATE
Caseinates	MODERATE	MODERATE	LOW	MODERATE	LOW	MODERATE	MODERATE
NFDM (commodity)	MODERATE	MODERATE	LOW	MODERATE	LOW	LOW	LOW
Whole milk powder	MODERATE	MODERATE	LOW	MODERATE	LOW	MODERATE	MODERATE
Demineralized whey (infant)	HIGH	HIGH	MODERATE	HIGH	MODERATE	LOW	MODERATE
Cheese powder / annatto	MODERATE	MODERATE	LOW	MODERATE	LOW	LOW	MODERATE
Coffee creamer powder	LOW	LOW	LOW	LOW	HIGH	LOW	MODERATE

Severity reflects typical exposure relative to Prop 65 MADL/NSRL based on category-typical sourcing and processing. Individual SKU risk depends on supplier, region, and process controls — finished-product testing remains the only authoritative determination.

Sourcing Region & Supplier Selection

You can't formulate heavy metals out.

Heavy metals enter dairy through soil → forage → cow → milk. Once in the milk supply, they cannot be removed by spray-drying or fractionation — they concentrate.

Sourcing decisions made years ago — pasture location, water source, feed supplier — determine today's Prop 65 risk profile. Contracts, audits, and supplier qualification are the front line.

TIER 1 — LOW RISK

New Zealand, Ireland (West Coast), Pacific Northwest US, Wisconsin (most counties), specific Australia regions

TIER 2 — MODERATE RISK

Most US Midwest dairy belt, Netherlands, France, Germany, Denmark — region- and farm-specific

TIER 3 — ELEVATED RISK

Industrial-proximity zones globally, regions with historical mining or smelting, areas with documented lead-pipe water infrastructure

SUPPLIER QUALIFICATION FRAMEWORK

01 Region & Soil Disclosure

Require farm-of-origin GIS data + soil heavy-metal profile from supplier or regional regulator.

02 Water Source Documentation

Public water supply test data or private well analysis within last 12 months.

03 Feed Supply Chain

Traceable feed source(s), aflatoxin testing protocol, organic vs. conventional designation, and synthetic-mold-inhibitor disclosure.

04 Supplier Test Data

Annual finished-ingredient COA covering Pb, Cd, As, Hg, AfM1; ICP-MS method preferred (USP <232>/<233> alignment).

05 On-Site or Remote Audit

Pre-contract audit; annual verification thereafter. Document review of farm records, milking equipment, transport.

06 Failure Response Protocol

Pre-defined exit criteria, alternate qualified suppliers, and rebuild timeline if source becomes non-conforming.

Analytical Testing Stack

Finished-product analysis — not raw-milk testing — is the legally relevant determination. AB 899 and Prop 65 plaintiffs measure what's in the bag, not what entered the dryer.

Analyte Group	Method	Standard / Reference	Lab Capability	Frequency
Lead, Cadmium, Arsenic, Mercury	ICP-MS / ICP-OES	USP <232>/<233>; AOAC 2015.01; FDA EAM 4.7	A2LA / ISO 17025 accredited	Per finished batch (AB 899 compliant) / minimum monthly composite
Aflatoxin M1	HPLC-FLD or LC-MS/MS	AOAC 2000.08; ISO 14501	ISO 17025 accredited	Per incoming milk lot + finished powder verification
3-MCPD esters / glycidyl esters	GC-MS direct or with derivatization	AOCS Cd 29a-13 / Cd 29c-13	ISO 17025 accredited	Quarterly for products with vegetable-oil add-back; per-batch for infant formula
BPA / BPS migration	LC-MS/MS migration testing	FDA migration protocol; EU Reg 10/2011	Packaging-specialist lab, ISO 17025	Annual + on package-component change
PFAS (PFOA, PFOS, PFHxS, etc.)	LC-MS/MS, multi-analyte panel	EPA 533 / 537.1 (adapted); ISO 21675	PFAS-specialist lab	Annual baseline; quarterly for fluorinated-pkg products
Furan	GC-MS headspace	FDA furan method	ISO 17025	Annual or process-change verification

Reformulation & Process Controls

Cocoa & Flavor System

BEFORE

Standard cocoa powder (Pb/Cd-elevated)

AFTER

Cadmium-screened cocoa (Tony's, Guittard certified <0.3 ppm); rebuilt fudge-flavor system using cocoa extract + vanilla

Cd reduction 60-80%

Plant-Protein Add-Back

BEFORE

Brown rice protein (As-elevated), pea protein (Cd-variable)

AFTER

Lower-As pea protein from screened EU sources; pumpkin / fava / chickpea blends as alternatives

As reduction 40-70%

Demineralization Process

BEFORE

Standard ion-exchange demineralization (some metals retained)

AFTER

Multi-stage demin with chelation step + activated carbon polish; verified by post-process ICP-MS

Pb reduction 30-50%

Spray-Drying Conditions

BEFORE

High-temp inlet (>200°C); long residence in dryer

AFTER

Tuned inlet/outlet temps reduce Maillard / acrylamide / 3-MCPD; closed nitrogen blanketing for sensitive products

Process contaminants ↓

Packaging Migration

BEFORE

Lined metal canisters (BPA risk); standard plastic film

AFTER

BPNI (BPA-Non-Intent) liners verified; PFAS-free pouch films with disclosure letter

BPA + PFAS eliminated

Lot Segregation / Blending

BEFORE

Continuous blending masks variability; no exit testing

AFTER

Lot-level COA gating; high-metal lots diverted to non-California, non-baby-food channels

California exposure ↓

Building a Defensible Compliance File

If a Prop 65 NOV arrives, you have 60 days to respond. The defense isn't built then — it's built before. Here's the file structure that withstands scrutiny.

REQUIRED ARTIFACT FILE

- Product Identification & Formulation Summary
- Bill of Materials with Prop 65 chemical screen per ingredient
- Supplier qualification records (each ingredient supplier)
- Finished-product test data — ≥ 12 months, by lot
- Method validation files for each analyte
- Lab accreditation certificates (ISO 17025)
- Reasoned-estimate exposure assessment (27 CCR § 25821)
- Safe-harbor MADL/NSRL comparison with margin-of-compliance banding
- Naturally-occurring defense file (27 CCR § 25501) where applicable
- AB 899 disclosure log (infant formula products)
- Packaging migration / extractables file
- QI approval signatures + 5-year retention notice

THE NO-WARNING DETERMINATION

Three-prong defense structure:

1 **Below MADL / NSRL**

Reasoned-estimate exposure analysis demonstrates daily intake at typical-use serving falls below the safe-harbor level for each listed chemical.

2 **Naturally Occurring**

For metals demonstrably from soil/feed/water and not introduced by manufacturing, 27 CCR § 25501 provides an affirmative defense — but requires source documentation.

3 **Margin of Compliance**

Banding framework (Green / Yellow / Red) demonstrates ongoing monitoring with documented action thresholds well below the legal limit.

Prop 65 Controls That Earn Credit Across Other Schemes

Heavy-metal monitoring built for Prop 65 satisfies — partially or fully — multiple parallel regimes. Build once, demonstrate compliance many times.

Control	Prop 65	AB 899	FSMA / 21 CFR 117	Infant Formula 21 CFR 106/107	GFSI (SQF/BRCGS/FSSC)	USP <232>/<233>	EU Reg 1881/2006
Heavy metal screening (Pb/Cd/As/Hg)	✓	✓	✓	✓	✓	✓	✓
Aflatoxin M1 monitoring	◐	—	✓	✓	✓	—	✓
Method validation + accredited lab	✓	✓	✓	✓	✓	✓	✓
Supplier qualification program	◐	✓	✓	✓	✓	—	◐
Finished-product COA gating	✓	✓	✓	✓	✓	✓	✓
Public disclosure / QR code	—	✓	—	—	—	—	—
Reasoned-estimate exposure assessment	✓	—	—	—	—	✓	—
Hazard analysis / HACCP integration	◐	—	✓	✓	✓	—	✓
Recall / withdrawal procedure	✓	✓	✓	✓	✓	—	✓
Five-year record retention	✓	✓	✓	✓	✓	✓	✓

✓ *Fully addressed* ◐ *Partially addressed* — *Not in scope*

ROADMAP

Twelve-Month Implementation Plan

MONTHS 1–2

Diagnostic & Triage

- SKU-level Prop 65 / AB 899 risk screen
- Existing test-data inventory; gap analysis vs. analytical stack
- Sourcing audit — origin documentation review for each ingredient
- Plaintiff-bar exposure check (DTC channel, California sales volume)

MONTHS 3–5

Build the File

- Stand up finished-product testing program (lab onboarding, SOPs, sampling plan)
- Reasoned-estimate exposure assessment per SKU
- Naturally-occurring defense file where supportable
- AB 899 disclosure infrastructure (QR codes, public results page) for infant formula SKUs

MONTHS 6–8

Reformulate & Source

- Cocoa and flavor-system replacement for elevated cadmium SKUs
- Plant-protein supplier re-qualification for elevated arsenic SKUs
- Process-control tuning (spray-dry, demin) where indicated
- Packaging migration testing + BPNI / PFAS-free supplier qualification

MONTHS 9–12

Operationalize

- Lot-level COA gating live; non-conforming lots diverted from CA / baby food channels
- QI approval and signature of full artifact file; 5-year retention live
- Annual program review SOP; cross-framework demonstration package
- Training rollout to QA, procurement, and channel-management teams

Risk by Sales Channel — One Powder, Different Exposures

The same dairy powder faces dramatically different Prop 65 risk depending on where it's sold and to whom. Channel strategy is risk strategy.

EXTREME

Direct-to-Consumer Sports Nutrition

Premium price = plaintiff-attractive economics · Health/performance claims invite scrutiny · Direct California sales = jurisdiction nexus · Influencer marketing creates testimonial discovery

Examples: Whey isolate tubs, casein nighttime blends, mass-gainer powders sold via brand websites and Amazon

VERY HIGH

Retail Sports Nutrition (GNC, Vitamin Shoppe, big-box)

Retailer indemnity provisions push risk back to brand · Private-label SKUs face same exposure as branded · California store presence = automatic jurisdiction

Examples: Branded protein powders, sports-nutrition private-label, meal-replacement shakes

EXISTENTIAL

Infant Formula / Baby Food Retail

AB 899 mandatory disclosure (Jan 2025) · Federal infant formula GMPs (21 CFR 106/107) · Highest-stakes consumer subgroup · Reputational damage potential is catastrophic

Examples: Stage 1/2/3 powdered infant formula, toddler formula, specialty medical formulas

MODERATE

Foodservice / Commercial B2B

Customer (restaurant, baker, manufacturer) inherits exposure · Spec-sheet and COA expectations are technical · Volume contracts include indemnity/warranty language

Examples: NFDM in 50-lb bags to industrial bakeries; whey concentrate to ice-cream manufacturers; cheese powder to seasoning blenders

LOW–MODERATE

Export / Non-California Domestic

Prop 65 is California-specific; AB 899 also CA-only · EU has tighter limits in some cases (1881/2006) · Other states increasingly considering similar disclosure laws

Examples: Bulk dairy powders to Asia, Mexico, Middle East; non-CA domestic foodservice contracts

COST OF INACTION

What an NOV Costs — and Why Insurance Won't Cover It

$2,500

Per-day, per-violation civil penalty under Prop 65

$50K–500K

Typical settlement range for protein-powder NOVs

60 DAYS

Window to respond to a 60-Day Notice — the defense file is built before this

25%

Of settlement payments go to the plaintiff's attorneys' fees, by statute

10+

Years a single Prop 65 lawsuit can stay in litigation and discovery

0%

Of standard product liability insurance that covers Prop 65 — most policies expressly exclude it

The structural insight: Prop 65 isn't a regulatory program — it's a private-attorney-general statute. Plaintiffs' lawyers are the enforcement mechanism, and the category is on their list.

The Consultare Engagement Model for Dairy Powders

01 Diagnostic Assessment

SKU-level Prop 65 / AB 899 risk screen against actual sales channels and product specs. Deliverable: prioritized risk register with action thresholds.

02 Sourcing & Supplier Qualification

Build the upstream defense — supplier audits, region-of-origin documentation, qualification SOPs, and exit criteria for non-conforming sources.

03 Analytical Program Build

Lab onboarding, method validation, sampling plan design, COA gating workflows, and technical liaison with ISO 17025 facilities.

04 Documentation & Defense File

Produce the 12-element artifact file: exposure assessment, naturally-occurring defense, MoC framework, QI approval — built to withstand a 60-day notice.

05 AB 899 Infrastructure

Stand up the public-facing disclosure system: QR codes, public results page, monthly testing cadence, and CDPH submission workflow for infant formula products.

06 Reformulation & Channel Strategy

Identify the right combination of process changes, sourcing shifts, and channel segmentation to minimize CA exposure while preserving brand economics.

Why Dairy Powders Sit in a Distinct Category

Four converging factors make this category structurally different from adjacent CPG segments:

01 Concentration Math

Spray-drying is, by design, a contaminant-concentration step. A 25× ratio means trace-level inputs become regulator-relevant outputs. No other major food category has this multiplier across the board.

02 Two New Disclosure Regimes in 18 Months

AB 899 (effective 2024, disclosure 2025) and ongoing Prop 65 enforcement against protein powders converged. Infant formula manufacturers face mandatory QR disclosure on heavy metals — a structural change.

03 Plaintiff-Active Channel

Sports nutrition is one of the most-targeted Prop 65 categories of the last decade. Consumer Reports + Clean Label Project + private plaintiffs sustain a continuous testing-and-litigation flywheel that is not slowing down.

04 Insurance Doesn't Cover It

Standard product liability and general commercial liability policies almost universally exclude Prop 65 claims. The cost of an NOV is paid out of operating cash, which makes prevention an enterprise-financial issue, not a QA issue.

NEXT STEPS

Building Your Prop 65 + AB 899

Compliance Defense for Dairy Powders

01 Diagnostic Call (60 min)

SKU portfolio review, channel-mix analysis, and exposure sizing — no obligation, no cost.

02 Risk-Register Sprint (2 weeks)

Prioritized SKU-level risk register with action thresholds. Suitable for board / leadership presentation.

03 Defense-File Build (90 days)

Complete 12-element artifact file with QI approval. Ready for plaintiff response or AB 899 disclosure.

04 Annual Program Management

Ongoing testing oversight, supplier requalification, and disclosure maintenance with cross-framework leverage.