DIETARY SUPPLEMENTS • FOOD • CALIFORNIA COMPLIANCE

Prop 65 Compliance

for Vegan Protein Products

80%

OF PLANT PROTEIN POWDERS

exceeded the Prop 65 lead limit in CLP's 2024–25 category study (n = 160)

"Plant-Based" ≠ "Contaminant-Free"

The category's core positioning — plant-based, organic, clean — correlates with higher Prop 65 exposure, not lower. Heavy metals enter through soil uptake, and the naturally-occurring defense requires evidence, not assertion.

The Regulatory Landscape

Vegan protein sits at the intersection of three enforcement regimes

PROP 65 WARNINGS

California — 1986

Clear & reasonable warnings for listed chemicals

Lead listed 1987 (cancer + reproductive). Cadmium and inorganic arsenic compounds also listed. MADL for lead is 0.5 µg/day — the most stringent heavy-metal threshold in U.S. law and ~25× below FDA's interim reference level.

27 CCR §§ 25600–25607.49

CITIZEN ENFORCEMENT

Bounty-hunter plaintiffs

Supplement category is a perennial top-10 target

Two plaintiff groups accounted for 83 of 187 Prop 65 settlements in a single year. Heavy metals in dietary supplements are a recurring theme. Settlements typically embed consent-decree thresholds lower than Prop 65 itself.

Cal. Health & Safety Code § 25249.7(d)

DIETARY SUPPLEMENT REGIME

FDA + USP + NSF

Overlapping federal & voluntary standards

DSHEA + 21 CFR Part 111 cGMP. USP <2232> elemental contaminant limits. FDA Closer to Zero initiative targets heavy metals in supplements. NSF Certified for Sport® and Informed Sport adopt stringent consent-decree-aligned thresholds.

21 CFR Part 111 + USP <2232>

Three regimes, one SKU — no single rulebook covers the full risk surface.

A product that meets FDA cGMP and carries NSF certification can still draw a Prop 65 NOV. A product that clears Prop 65 may still face FDA action under Closer to Zero. Vegan protein compliance requires simultaneous alignment across Prop 65, dietary supplement cGMP, and voluntary certification regimes.

Enforcement Trends

What's driving Prop 65 activity in vegan protein

80%

plant protein powders over Pb MADL

Plant-based products test worst for lead

Clean Label Project's 2024–25 study of 160 top-selling protein powders: nearly 80% of plant-based samples exceeded Prop 65's 0.5 µg/day lead MADL. Whey-based: 28%. Organic tested worse than non-organic — 3× more lead, 2× more cadmium on average.

$336K

Vega / Danone consent decree payments

Consent decrees now define category thresholds

Vega (acquired by Danone) paid ~$336K across 2013 and 2018 Prop 65 settlements over heavy metals in plant-based protein powders. The resulting consent decrees establish product-specific heavy-metal thresholds that function as de facto industry benchmarks.

LEAD (Pb)

MADL 0.5 µg/day

The category's headline chemical. Taken up from soil by pea, rice, hemp, soy, and cacao. Chocolate-flavored powders test 4× higher than vanilla. The 0.5 µg/day MADL is ~25× below FDA's interim reference level for adults.

CADMIUM (Cd)

MADL 4.1 µg/day

Accumulates heavily in cacao, hemp, flax, and some pea varietals. Chocolate protein powders tested up to 110× more cadmium than vanilla. Listed as a Prop 65 carcinogen and reproductive toxicant; OEHHA NSRL 0.05 µg/day (cancer endpoint).

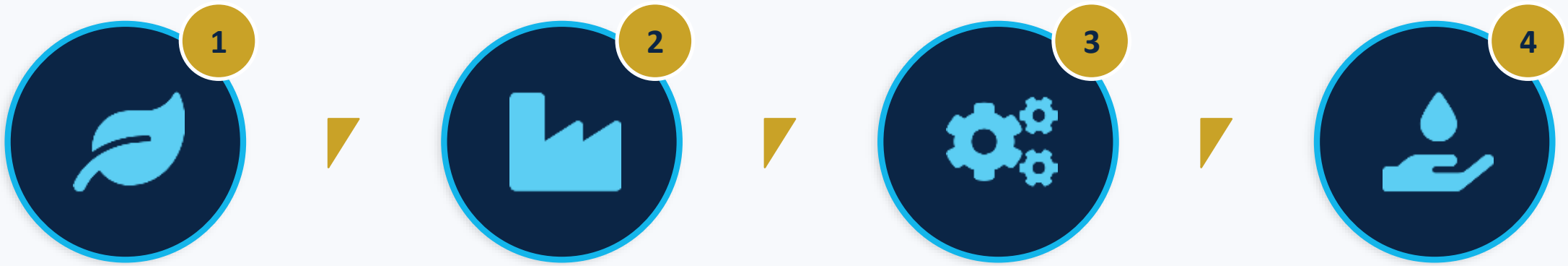
ARSENIC (inorganic As)

MADL 10 µg/day (reproductive)

Primary risk vector in rice-based protein. Inorganic arsenic listed as a Prop 65 carcinogen (NSRL 10 µg/day cancer). Mercury (methylmercury MADL 0.3 µg/day) rounds out the panel — all four tested by ICP-MS under the same workflow.

The Exposure Pathway

How heavy metals enter vegan protein products — and reach the consumer



SOIL & ROOT UPTAKE

Pea, rice, hemp, soy, cacao absorb Pb, Cd, As, Hg from soil. Agricultural region and prior land use materially affect metal load.

INGREDIENT PROCESSING

Concentration step — protein isolation removes water but concentrates metals. 80% protein isolate ≈ 4–5× the metal load of the starting flour.

FORMULATION & FLAVOR

Cacao, spirulina, matcha, and mineral-premix additions add independent metal sources. Chocolate ≈ 4× lead, 110× cadmium vs. vanilla.

SERVING EXPOSURE

30–40 g serving × daily use × body-weight assumptions → reasoned-estimate daily exposure compared against the 0.5 µg/day MADL for lead.

Concentration is the decisive step.

A whole-pea flour that tests compliant can become a concentrated isolate that does not. Every stage — soil sourcing, processing yield, flavor system, serving-size calculation — is a control point that moves the final exposure number up or down. The naturally-occurring defense under 27 CCR § 25501 applies only when the manufacturer can prove levels are at the 'lowest currently feasible' — which demands evidence at every stage.

The Qualified Individual (QI)

Every compliance determination requires a documented, signed-off owner

QUALIFIED INDIVIDUAL

Owns the no-warning determination

Designated in writing. Signs the dated determination record. Re-certifies on formulation, supplier, or process change.

Minimum competency profile

- Working knowledge of Cal. H&S Code § 25249.5 et seq. and 27 CCR §§ 25600–25607.49
- Familiarity with OEHHA listed chemicals, MADL, and NSRL safe-harbor levels
- Ability to interpret ICP-MS heavy-metal results, CoAs, and supplier chemical disclosures
- Understanding of reasoned-estimate exposure methodology under 27 CCR § 25821
- Authority to halt shipment, require re-testing, or mandate warning application

WRITTEN DESIGNATION

QI is designated in a dated, signed document naming specific product scope and authority.

DETERMINATION RECORD

Every no-warning call is captured in a dated record citing evidence, methodology, and conclusion.

EVIDENCE INDEX

CoAs, ICP-MS reports, supplier declarations, and exposure calcs are cross-referenced in a single file.

REASSESSMENT TRIGGERS

New OEHHA listing, formulation change, supplier change, or complaint each re-opens the determination.

Chemical Screening

Matching product formulation against the OEHHA Prop 65 list

Screening Matrix — 4 Input Streams

Every candidate chemical is mapped against all four. Gaps = unverified formulation.

Ingredient Sourcing

Origin geography, soil-testing data, prior agricultural use, and supplier heavy-metal history for every plant input (pea, rice, hemp, soy, cacao, etc.).

Incoming CoA Review

Per-lot Pb, Cd, As, Hg concentrations from accredited labs; methodology (ICP-MS), detection limits, and compliance to internal AQL thresholds.

Formulation Contribution

Each flavor system, mineral premix, and botanical addition mapped to its heavy-metal contribution at the finished-product serving level.

Finished Product Testing

Retail-form ICP-MS panel on finished batches, per-serving exposure calculation, and comparison against Prop 65 MADL/NSRL + internal control limits.

900+

CHEMICALS ON THE OEHHA LIST

Protein-relevant categories:

- Heavy metals — Pb, Cd, inorganic As, methylmercury
- Pesticide residues — chlorpyrifos, carbaryl, others on plant inputs
- Processing contaminants — acrylamide, furan, nitrosamines
- Mycotoxins & allergen-adjacent — aflatoxin, ochratoxin (grain inputs)
- Flavor / color additives — select carotenoid & caramel compounds

Safe Harbor Framework

Comparing estimated exposure against OEHHA-established thresholds

NSRL — NO SIGNIFICANT RISK LEVEL

For carcinogens

Daily exposure at which lifetime cancer risk ≤ 1 in 100,000. Cadmium NSRL: 0.05 µg/day. Inorganic arsenic NSRL: 10 µg/day. Calculated from animal potency studies with a 1/100,000 risk factor.

MADL — MAXIMUM ALLOWABLE DOSE LEVEL

For reproductive toxicants

NOAEL ÷ 1,000 safety factor. Lead MADL: 0.5 µg/day — the category's binding threshold. Cadmium MADL: 4.1 µg/day. Methylmercury MADL: 0.3 µg/day. Inorganic arsenic reproductive MADL: 10 µg/day.

Margin of Compliance (MoC) Banding — internal decision framework

GREEN	AMBER	ORANGE	RED
MoC ≥ 10×	**1× ≤ MoC < 10×**	**0.5× ≤ MoC < 1×**	**MoC < 0.5×**
No warning + retain evidence	Re-test + monitor; add warning if trending up	Apply warning + initiate reformulation review	Halt shipment + immediate reformulation

For protein products, MoC banding runs in parallel with the naturally-occurring defense track.

Under 27 CCR § 25501, heavy metals that enter via soil uptake qualify for the naturally-occurring exemption — but only if the manufacturer can demonstrate levels are at the 'lowest currently feasible' through sourcing, processing, and reformulation evidence. The MoC banding is the internal control layer; the naturally-occurring file is the external defense. Both are needed.

Exposure Assessment Methodology

Reasoned-estimate framework under 27 CCR § 25821

INPUT VARIABLES

What feeds the reasoned estimate for vegan protein

1

Finished-product concentration

Measured Pb, Cd, As, Hg (µg/g) in the retail form — flavored, fully formulated, ready-to-ship.

2

Recommended serving size

Grams per scoop per label directions; accounts for single- and multi-scoop protocols.

3

Daily use frequency

Averaging assumption per OEHHA guidance — not worst-case; sourced from category consumption data.

4

Population & arithmetic

Exposure = concentration × serving × daily frequency. Compared against MADL / NSRL. Averaging over a reasonable period is permitted for chronic endpoints.

TESTING SCOPE

What a defensible vegan protein panel includes

- Heavy metals by ICP-MS — Pb, Cd, total As, inorganic As speciation, Hg
- Pesticide residue multi-residue screen (GC-MS/MS + LC-MS/MS) on plant inputs
- Processing contaminants — acrylamide, PAHs on roasted/heat-treated inputs
- Mycotoxin panel on grain/cereal inputs (aflatoxin, ochratoxin A, DON)

REASONED ESTIMATE ≠ WORST-CASE

OEHHA permits averaging for chronic endpoints — not every product is consumed every day. Document the consumption-frequency assumption (category research, brand-level data, NHANES) and the averaging period. "Worst-case daily use" without data is not a reasoned estimate and typically cannot support a no-warning determination.

Beyond California

The federal and multi-state landscape reaching vegan protein

FDA	CA	NY	WA	MA	USP
Closer to Zero	**California**	**New York**	**Washington**	**Massachusetts**	**USP <2232>**
Active	*Active*	*2024+*	*2025+*	*2025+*	*Industry*
Heavy-metal action levels in baby/supplement foods. Iterative reductions 2024–28.	Prop 65 MADLs + consent-decree thresholds defining category practice.	AG actions on supplement authenticity & contamination — plant-protein priority.	Safer Products for WA — heavy-metal & pesticide priority categories.	Proposed supplement-labeling bills targeting heavy-metal disclosure.	Elemental contaminants limits for dietary supplements — industry benchmark.

A California-only compliance program is no longer a complete program.

Vegan protein brands now face Prop 65 warning requirements AND FDA Closer to Zero action levels AND state AG scrutiny AND voluntary-certification thresholds (NSF, Informed Sport, USP). A single SKU is measured against four overlapping heavy-metal frameworks simultaneously.

SOURCE-AT-ORIGIN

The cheapest point of intervention is agricultural. Partner with growers on soil testing, crop rotation, and uptake-minimizing varietals. Metals removed at the farm don't need to be explained at the NOV table.

HARMONIZED THRESHOLD

Build internal specifications to the most stringent benchmark in scope (usually Prop 65 consent-decree levels or NSF Certified for Sport). One spec → satisfies FDA + Prop 65 + voluntary certifications simultaneously.

Supplier & Supply-Chain Controls

Where most vegan protein compliance failures actually originate

1

TIER 1 — Farms & Co-ops

Soil test history; regional heavy-metal baseline; crop rotation records; prior-use documentation; varietal selection data.

2

TIER 2 — Ingredient Processors

Per-lot ICP-MS on flour and isolate; concentration-factor documentation; residual solvent testing; allergen & GMO status.

3

TIER 3 — Flavor & Premix Suppliers

Cacao, vanilla, botanical, vitamin/mineral premix CoAs. Cacao carries independent high-metal risk and demands separate supplier qualification.

4

TIER 4 — Contract Manufacturers

cGMP compliance (21 CFR Part 111); blending & batch testing; finished-product retained sample program; label compliance review.

CONTRACTUAL INDEMNITY

Shifting liability upstream — while keeping the audit trail

Courts typically hold the entity closest to the defect responsible, but Prop 65 liability flows up and down the chain. Indemnity should name specific Prop 65 warranty obligations, require ingredient suppliers to bear defense costs in NOV actions, and preserve the brand's right to terminate on first material non-conformance or heavy-metal excursion.

SUPPLIER RISK-RATING INPUTS

Five dimensions scored per supplier, per qualification cycle:

- Origin geography — known soil heavy-metal baseline of sourcing region
- Testing rigor — per-lot ICP-MS at accredited (ISO 17025) labs
- Supplier consent decrees — any prior Prop 65 or FDA enforcement
- Process transparency — concentration factor & yield documentation
- Responsiveness — lead time on CoAs and out-of-spec investigations

Case Study — the Vega Precedent

What the 2013 & 2018 consent decrees teach about category thresholds

THE FACT PATTERN

Vega (Sequel Naturals / WhiteWave / Danone) — heavy-metal NOVs & settlements

2013

Initial Prop 65 Notice of Violation issued over lead and cadmium levels in plant-based protein powders. Vega enters consent decree with settlement payment and product-specific heavy-metal thresholds.

2018

Second round of Prop 65 enforcement produces additional consent decree and settlement. Cumulative settlement total across both actions: ~$336,000. No admission of wrongdoing.

2024

Consumer Reports publishes heavy-metal testing on protein powders; Vega notes the product in testing had since been renamed and reformulated with North American pea-protein sourcing (shifted from China).

2025

Clean Label Project's 2024–25 study finds 80% of plant-based protein powders exceed Prop 65 lead MADL. Vega now publishes consent-decree compliance and NSF Certified for Sport® status on its transparency page.

LESSON 1

Consent decrees set the ceiling

Once a category leader settles, the product-specific thresholds become de facto benchmarks. Competitors are measured against consent-decree numbers — not Prop 65's safe-harbor alone.

LESSON 2

Sourcing is a compliance lever

The 2024 reformulation (pea-protein origin shift) demonstrates that geographic sourcing is a controllable input — and that the naturally-occurring defense demands this kind of evidence to hold.

LESSON 3

Transparency is protective

Publishing test results, consent-decree status, and NSF certification transforms a potential NOV posture into a marketable trust signal. Opacity invites bounty-hunter inquiry.

Warning Content & Format

When a warning is required — what must appear, and how

SAFE-HARBOR WARNING TEMPLATE

Short-form on-product warning (27 CCR § 25602(a)(4))

WARNING:

Cancer and Reproductive Harm — www.P65Warnings.ca.gov

FORMAT REQUIREMENTS

- Food and supplement warnings use the dedicated URL: www.P65Warnings.ca.gov/food
- 'WARNING' in bold, all caps, at least as large as surrounding consumer information
- Must appear on product label, online catalog page (for e-commerce), and any point-of-sale display
- Long-form naming the specific chemical (e.g., lead, cadmium) is often required by consent-decree terms

WHEN TO NAME THE CHEMICAL

Long-form warning is required when:

- Product area exceeds 5 square inches and space allows full text
- Settlement agreement or consent judgment requires specific chemical naming
- Brand strategy prioritizes transparency over minimal-disclosure posture

WARNING:

This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.

Documentation Architecture

The artifact set that makes a no-warning determination defensible

Heavy Metal Master Register

Per-SKU index of Pb, Cd, As, Hg concentrations across finished products, with CAS numbers and Prop 65 status flags.

Ingredient Screening Log

Lot-level ICP-MS results for every plant input and flavor component, with regional origin and supplier CoA cross-reference.

Naturally Occurring Defense Dossier

Evidence file under 27 CCR § 25501 — soil data, processing yields, varietal selection, and reformulation history demonstrating 'lowest currently feasible' levels.

No-Warning Justification File

QI-signed determination record with serving-size exposure calculation, MoC banding, and consent-decree threshold comparison.

Supplier Declaration Archive

Signed supplier Prop 65 statements, origin & agronomy attestations, indemnity clauses, re-qualification dates per tier.

Warning Determination & Change Log

Dated record of warning decisions, reformulation events, supplier changes, and reassessment triggers — full audit trail.

All six artifacts maintained under the same document-control SOP, with dated revisions, distribution lists, and QI sign-off at every change.

Monitoring & Reassessment

A no-warning determination is a dated snapshot — not a permanent state

REASSESSMENT TRIGGERS

- New OEHHA chemical listing (annual updates)
- Formulation change — protein source, flavor, premix
- Sourcing change — new region, farm, or co-op
- Harvest-year change — new crop cycle CoAs
- Consumer complaint alleging heavy-metal exposure
- NOV received, settled, or issued against peers

MONITORING FREQUENCY

- Quarterly — review of OEHHA list + enforcement bulletins
- Per-lot — ICP-MS on finished batches
- Per-harvest — full ingredient re-qualification
- Annual — supplier audit & on-site verification
- Per-change — QI sign-off on any formulation or sourcing mod
- Event-driven — NOV, complaint, or CR/CLP study release

RESPONSE ACTIONS

- Re-run exposure calculation against new serving-size data
- Update MoC band and naturally-occurring defense file
- Issue revised warning or continue no-warning
- Notify distribution channel & online catalogs if warning changes
- Re-train operations on new chemistry or supplier protocols
- Log reassessment event in determination file

Consumer Complaint Handling

Complaints are often the first signal of an NOV in preparation

1 INTAKE

Standardized form captures product lot, date of purchase, channel, complaint specifics, and user contact info.

2 TRIAGE

Classify by severity and chemical nexus within 24 hours. Escalate any exposure-related claim to QI immediately.

3 INVESTIGATE

Pull lot records, CoA, retained samples. Commission targeted chemical testing if the complaint references a listed chemical.

4 RESPOND

Documented response to complainant within defined SLA. Preserve all correspondence for potential litigation discovery.

5 CLOSE & LEARN

Root-cause analysis, CAPA if warranted, feed findings into the reassessment cycle. Update risk log.

A well-documented complaint process is the best affirmative defense.

Citizen-enforcer NOV actions routinely subpoena complaint logs. A consistent, dated, response-tracked process demonstrates good-faith compliance posture — often materially reducing settlement exposure even in otherwise-adverse cases.

Training & Organizational Readiness

Compliance is a capability, not a document — people make it work

Qualified Individual

- Full competency profile (slide 5)
- Annual continuing education ≥ 16 hrs
- Role-specific authority documented

Operations & Production

- Awareness of listed chemicals in scope
- Escalation path for formulation changes
- Understanding of warning-application procedures

Procurement & Supply Chain

- Supplier qualification criteria
- Indemnity & declaration language
- Risk-rating input roles

Quality & Lab

- ICP-MS methodology & heavy-metal speciation
- Reasoned-estimate calculation inputs
- Record-keeping & chain-of-custody

Regulatory & Legal

- Current Prop 65 list & safe-harbor regulations
- NOV handling & settlement patterns
- Multi-state disclosure landscape

Customer Service

- Complaint intake & triage SOP
- Escalation criteria to QI
- Correspondence preservation protocol

Economics of Compliance vs. Non-Compliance

The cost framework that drives internal prioritization

COST COMPARISON — per SKU, per year

CATEGORY	PROACTIVE PROGRAM	REACTIVE / NOV
Testing & screening	$4–10K / yr	$20–50K emergency
Legal & advisory	$2–5K / yr	$25–150K defense
Settlement / penalty	$0	$50K–$400K+ typical
Reformulation / sourcing	Planned	Rush: 2–4× normal
Channel disruption	None	Amazon / retailer delistings
Brand trust damage	None	CR / CLP report inclusion

10–20×

TYPICAL COST DELTA

Reactive response to a Prop 65 NOV typically costs 10–20× a proactive compliance program for the same SKU portfolio.

And this excludes:

- Class-action exposure
- Attorney General action
- CR / CLP report fallout
- NSF certification loss
- Management time diverted

WHAT THE LIBRARY DELIVERS

Professional compliance templates — day one.

- Word-native .docx templates with Navy / Cyan / Gold brand system
- Every template includes QI approval notice at five canonical placements
- Customization notice: 'this template must be customized for its intended process and approved prior to use and implementation'
- Referential to specific CFR sections, 27 CCR provisions, and OEHHA materials
- Cross-mapped to GFSI, ISO, and FSMA schemes where applicable

VEGAN PROTEIN TEMPLATE SUITE

Naming convention: SBP-P65-PROT-xxx

SBP-P65-PROT-HMR-001	Heavy Metal Master Register
SBP-P65-PROT-SCRN-002	Ingredient Screening Log (ICP-MS)
SBP-P65-PROT-NOD-003	Naturally Occurring Defense Dossier
SBP-P65-PROT-NWJ-004	No-Warning Justification File
SBP-P65-PROT-SUP-005	Supplier Declaration & Risk Rating
SBP-P65-PROT-WDL-006	Warning Determination & Change Log
SBP-P65-PROT-CMPL-007	Consumer Complaint Log & SOP
SBP-P65-PROT-TRN-008	Training & Competency Assessment

Four converging forces on one product category

FOOD & SUPPLEMENTS

#1 enforcement target

Food and dietary supplements remain the single largest Prop 65 enforcement category by NOV volume. Heavy metals in plant-based supplements are a perennial bounty-hunter focus.

MULTI-METAL RISK

Pb, Cd, As, Hg all in play

Four distinct heavy metals, each with independent MADL/NSRL thresholds, each potentially present in any plant input. Testing must cover all four; defense must address all four.

PLANT-BASED UPTAKE

Natural exposure risk

Plants absorb soil metals by biological design. The 'healthier' positioning that defines this category (plant-based, organic, whole-food) is precisely what drives higher metal loads vs. whey.

CONSENT-DECREE ENVIRONMENT

Strict environment

Vega / Danone consent decrees plus published CR and CLP studies have established de facto category benchmarks below Prop 65's statutory MADLs. New entrants are measured against this tighter bar.