

Prop 65 Compliance

for Nuts and Nut Butters

Heavy metals, aflatoxins, and a category-specific reproductive-toxicity exposure.

1,385+

Prop 65 NOVs (Jan–Apr 2025)

20 ppb

FDA aflatoxin action level

May 2025

Acrylamide cancer warning enjoined

Nuts Sit at a Unique Prop 65 Crossroads

Naturally occurring heavy metals + a Prop 65-listed mycotoxin family + complex multi-state additive rules.



Heavy Metals Lead Enforcement

Lead and cadmium dominate 2025 NOVIs. Tree nuts and nut butters carry naturally occurring trace levels that often exceed the 0.5 µg/day MADL.



Aflatoxins Are Prop 65 Listed

Aflatoxins B1, B2, G1, G2 are listed carcinogens. Peanuts, pistachios, almonds, and Brazil nuts are the highest-risk substrates.



Acrylamide — Half Enjoined

Cancer warnings enjoined May 2025 (CalChamber v. Bonta). Reproductive-toxicity listing (140 µg/day MADL) remains enforceable.



Documentation Is the Defense

Naturally Occurring Allowance, COAs, supplier audits, and exposure assessments are the only evidence that holds up against bounty hunters.

The 2025 Enforcement Picture

Three numbers that define the operating environment for any nut-category brand selling into California.

0.5 µg/day

Prop 65 lead MADL

Reproductive-toxicity safe harbor for lead. Naturally occurring background in tree nuts can rival or exceed this without warning.

20 ppb

FDA aflatoxin action level

Total aflatoxins \leq 20 ppb in human-grade peanuts. Prop 65 has no separate safe harbor — exposure-based assessment required.

May 2025

Acrylamide injunction

Bonta v. CalChamber permanently enjoins cancer warnings for dietary acrylamide. Reproductive listing remains in force.

Sources: 27 CCR §§ 25801–25821 (Prop 65 safe harbor levels) · FDA CPG 570.375 · Cal. Chamber v. Bonta, E.D. Cal. May 2, 2025.

Five Regulatory Fronts Converge on Every Jar

Every nut or nut-butter SKU sold into California is exposed to multiple overlapping rules at once.



Prop 65 Heavy Metals

Lead, cadmium, inorganic arsenic — naturally taken up from soil. Lead MADL 0.5 µg/day; cadmium MADL 4.1 µg/day.



Prop 65 Aflatoxins

Aflatoxin B1, B2, G1, G2 — listed carcinogens. No published safe harbor; reasoned-estimate assessment required.



Acrylamide (Repro Track)

Cancer warning enjoined; 140 µg/day reproductive MADL still applies to roasted/baked nut products.



Allergen Cross-Contact

Undeclared peanut and tree-nut allergens are the #1 FDA recall driver across the category.



Salmonella & Sanitation

Pistachio cream, peanut paste, and nut butters — recurring outbreak vectors. PCA, Emek pistachio cream (Jul 2025).

Five fronts. One SKU. Each ingredient lot inherits all five risks simultaneously.

Listed Chemicals of Concern for the Category

Each entry is a Prop 65-listed chemical with documented enforcement against nut or nut-butter products.

Chemical	Prop 65 Endpoint	Safe Harbor	Primary Source in Category	Enforcement Status (2025)
Lead	Cancer + Repro	0.5 µg/day MADL	Soil uptake; processing equipment	Active — top 2025 NOV driver
Cadmium	Cancer + Repro	4.1 µg/day MADL	Soil uptake (especially sunflower, peanut)	Active — frequent NOVs
Aflatoxin B1, B2, G1, G2	Cancer	No safe harbor	Aspergillus mold on peanuts, pistachios, almonds	Active — reasoned-estimate basis
Acrylamide	Repro (140 µg/day)	Cancer warning enjoined	Roasting / high-heat processing	Cancer claims enjoined May 2025; repro intact
Inorganic arsenic	Cancer + Repro	10 µg/day MADL	Groundwater / soil; rare in nuts	Low frequency in category
BPA / BPS	Repro	3 µg/day BPA MADL; BPS no SH	Metal jar lid liners, can linings	Rising — 2025 packaging NOVs
DEHP (phthalate)	Cancer + Repro	410 µg/day MADL	Plastic tubing, gaskets, seals	Active — supply-chain materials

Risk Profile by Product Format

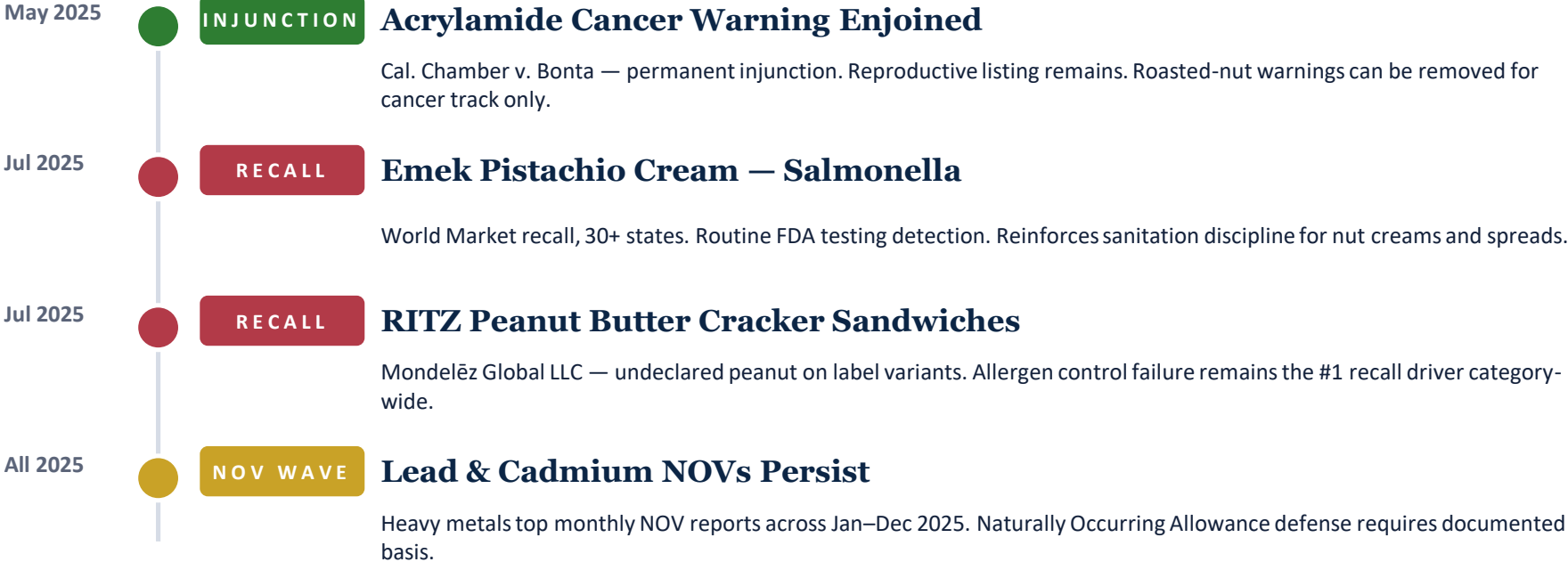
Every nut format carries a different mix of regulatory exposures. Reformulation alone won't fix it.

Product Format	Heavy Metals	Aflatoxins	Acrylamide (Repro)	Allergens	Microbiological
Roasted Tree Nuts	HIGH	MED	HIGH	MED	MED
Raw / In-Shell	HIGH	HIGH	LOW	MED	MED
Peanut Butter	MED	HIGH	MED	HIGH	HIGH
Almond / Cashew Butter	MED	MED	MED	HIGH	MED
Pistachio / Hazelnut Cream	MED	HIGH	MED	HIGH	HIGH
Trail Mix w/ Nuts	MED	MED	MED	HIGH	MED

Legend: ■ LOW ■ MED ■ HIGH

Where the Pressure Is — 2025 Signals

Real recalls and rulings from the past 12 months that should reshape how the category is documented.



A Five-Pillar Compliance Program

Each pillar maps to a specific regulatory front from Slide 4 — and to a specific deliverable.



Continuous loop — feedback to Pillar 1 on every change

What Consultare Builds for the Nut Category

Six core artifacts tailored to nut and nut-butter operations — each tied to a specific regulatory trigger.



Applicability Assessment SOP

Determines whether each SKU triggers Prop 65 obligations. Per 27 CCR §§ 25600–25607.



No-Warning Justification File

Reasoned-estimate exposure assessment + Naturally Occurring Allowance support.



Aflatoxin Sampling & Test Plan

Supplier COA verification + on-site LC-MS/MS protocols. Aligned to FDA CPG 570.375.



Warning Label Standards

Short-form, long-form, and on-product placement rules. CA Prop 65 + multi-state harmonized.



Supplier Compliance Pack

Indemnification clauses, COA cadence, audit triggers, and traceability data flows.



Reassessment & Records SOP

Five-year retention, trigger events (formula change, NOV, list update), QI signature.

Verification Testing — What, How, How Often

Test plans aligned to FSMA PCQI and Prop 65 reasoned-estimate documentation.

ANALYTE PANEL

Heavy metals (Pb, Cd, As, Hg)	ICP-MS	<i>Per lot, raw + finished</i>
Aflatoxin total + B1	LC-MS/MS	<i>Per lot, raw nuts</i>
Salmonella / Listeria	Environmental + FPM	<i>Weekly Zone 1–4</i>
Allergen (Peanut, Tree Nut)	ELISA swab	<i>Pre-op + changeover</i>
Acrylamide (repro defense)	LC-MS/MS	<i>Annual + reformulation</i>

SAMPLING DISCIPLINE

- Composite incoming lots per AOAC sampling plan; retain 10% for reanalysis.
- Stratified sampling for aflatoxins — kernel size + visible damage scoring.
- Chain-of-custody documentation from supplier hub to QA lab.
- ISO/IEC 17025-accredited labs only; method LOD \leq 50% of Prop 65 MADL.
- Trend-track results in QMS — investigate any 30% upward shift.

The Naturally Occurring Allowance

27 CCR § 25501 is the most important regulation for nuts. Done right, it is a shield. Done wrong, it is a trap.

§ 25501 IN PRACTICE

A chemical that occurs naturally in a food is exempt from warning to the extent it is naturally present and could not have been avoided by good agricultural and manufacturing practices.

THREE BURDENS THE COMPANY MUST CARRY:

- Source: prove the chemical is naturally present in the raw nut.
- Avoidance: prove that GAPs and GMPs were used to minimize it.
- Quantification: prove the level is no higher than the natural baseline.

WHERE COMPANIES LOSE THE DEFENSE

No baseline data

No documented natural-background concentration — no ceiling to compare to.

Processing contribution

Equipment leaching, roasting drum residue, or rework treated as 'natural'.

Stale records

More than 3 years between source surveys; supply origin shifts unrecorded.

Aggregation error

Per-serving exposure calc not propagated to warning decision.

90-Day Implementation Plan

Move from gap to documented program in three sprints. QI sign-off at each phase gate.

DAYS 1–30

DISCOVER

- SKU-level chemical inventory and supplier mapping
- Pull existing COAs, recall history, and warning posture
- Site visit + GMP review with QI
- Initial gap report

DAYS 31–60

BUILD

- Applicability Assessment SOP + No-Warning Justification template
- Sampling & test plan; lab onboarding
- Supplier compliance pack rollout
- Warning decision matrix

DAYS 61–90

VALIDATE

- Mock NOV / tabletop response
- Internal audit + corrective actions
- QI approval and document control hand-off
- Reassessment trigger schedule live

Phase gates: each phase closes with a Qualified Individual review and signed approval before the next sprint begins.

LET'S TALK

Build the program before the next NOV finds you.

Consultare Inc. Group designs and operationalizes Prop 65 programs for nut and nut-butter manufacturers — from applicability assessment through warning decision and document control.

01

Discovery Call

60 minutes, structured intake, no commitment.

02

Gap Assessment

Two-week review, written findings report.

03

Program Build

Templates, SOPs, test plans, supplier pack.

04

Audit-Ready Hand-Off

QI sign-off, training, ongoing reassessment cadence.