

2015 ASTA Regulatory Workshop

California Proposition 65
What Does It Mean for Spices?

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California Proposition 65

Safe Drinking Water and Toxic Enforcement Act of 1986 – Prop 65

- Requires warnings for any exposure to carcinogens or reproductive toxins, including through food and consumer products

Several hundred individual substances are listed by the Office of Environmental Health Hazard Assessment (OEHHA)



California Proposition 65

OEHHA has listed as carcinogens several natural constituents of spices

- Acetaldehyde
- Estragole
- Methyleugenol
- Pulegone
- *B*-Myrcene

Furfuryl alcohol - now proposed for listing



How does Prop 65 work?

Substances can be listed two ways

Scientific review committees

- One for carcinogens
- One for reproductive toxins

Authoritative bodies

- If an “authoritative body” (EPA, FDA, NTP, others) concludes a substance is a carcinogen or reproductive toxin then the substance can be listed without further review.
- Most common listing mechanism
- Sierra Club litigation

How does Prop 65 work?

Substance is listed, warning requirement takes effect, and then the fun begins.

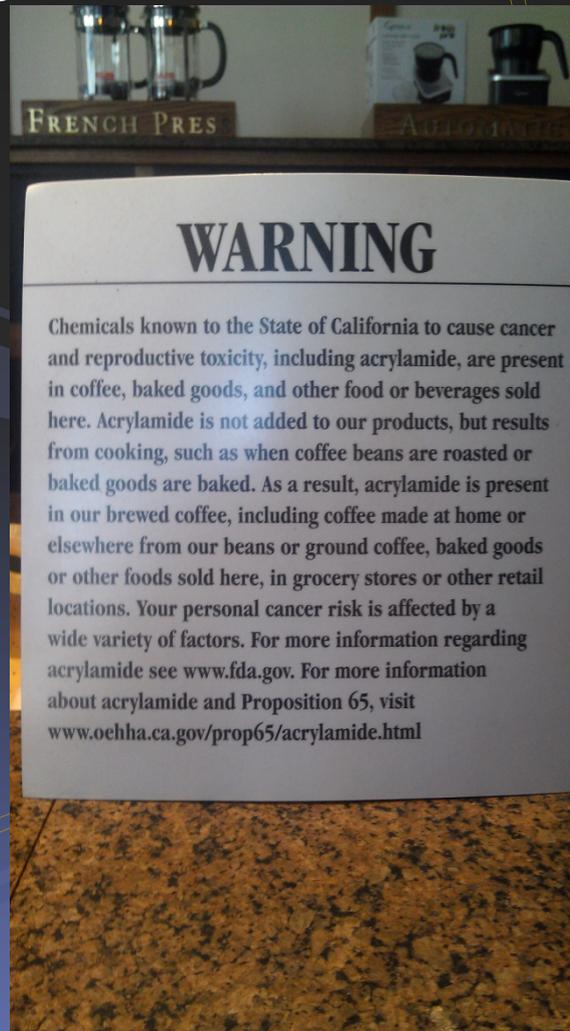
Enforcement actions may begin 1 year after listing

- “Bounty hunters” evaluate the list and select products for enforcement.
- File 60-day notices with OEHHA initiating legal action akin to blackmail
- Negotiations and settlement



California Proposition 65

Prop 65 acrylamide
warning



How can Prop 65 issues be addressed?

Oppose proposed listings

- Little success

Litigate listings

- Little success

Assert available exemptions

- Naturally occurring exemption
- Safe harbor level/No significant risk level

Naturally occurring exemption

If a listed substance is naturally occurring in food then an exposure does not occur and no warning is required

- Current interpretation is that substances occurring naturally in food may also be present in non-food consumer products with no resulting exposure, therefore no warning required

Safe harbor levels/No significant risk levels

Level in products below which an exposure does not occur

- Safe harbor levels may be determined by OEHHA and established by regulation.
- NSRLs and MADLs
- Usually not good – too low.

NRSL may also be established by industry and used in defense of bounty hunter action



Natural occurrence – Key Point

Classification of the listed substances as a “natural constituent” of food rather than a “natural contaminant.”

Natural constituents may be present at any level.

- Methyleugenol in basil

Natural contaminants must be reduced to the greatest extent possible.

- Lead and other heavy metals

Natural constituents allow the full application of the naturally occurring exemption.



Natural occurrence

These are natural constituents

- Acetaldehyde – many fruits, spices
- Estragole – basil, tarragon, fennel
- Methyleugenol – basil, tarragon
- *B*-Myrcene – thyme, bay, parsley, citrus
- Pulegone – mint
- Furfuryl alcohol – vanilla, cinnamon

Natural occurrence

Biggest challenge for the spice industry is natural contaminants.

- Lead!

Natural contaminants must be reduced to the lowest level possible.

Lead is ubiquitous as a result of human activity such as leaded gasoline and other industrial uses.



Lead

Naturally occurring exemption won't apply to lead in most cases because it is a natural contaminant not a natural constituent.

Safe harbor levels established by OEHHA.

- NSRL = 15 ug/day by ingestion
- MADL = 5 ug/day by ingestion

Enforcement actions against lead in ginger and crystallized ginger.

- Be aware of how spice is processed!



A recent lead enforcement action

Crystallized ginger

- A few hundred dollars worth was sold by one company in California.
- “Bounty hunter” enforcement action demanded several hundred thousand dollars in damages.
- Action will be settled for \$30-60,000.

Many other lead actions with very large awards.



Is some relief on the way?

OEHHA is reviewing some aspects of Prop 65

Proposed regulation attempts to limit “bounty hunter” enforcement

- Limit actions to those with a public health benefit
- Limit attorney fees
- Limit options for “buying the peace” settlements

There is interest in reforming the “lead issue.”

- But, a petition was filed to revoke the MADL for lead.

Prop 65

Interesting times ahead!

Watch the lead issue.

- This presents the most risk currently for the spice industry.

Watch for enforcement actions on the natural constituents – methyleugenol and others.

- One enforcement action on pulegone in supplements has been filed.



Noxious weed seed update

Met with USDA APHIS staff in North Carolina

- Obtained guidance on validation studies
- Discussed EtO, steam, irradiation
- Focus on EtO as currently used
- Discussed USDA Treatment Manual as goal for validated methods

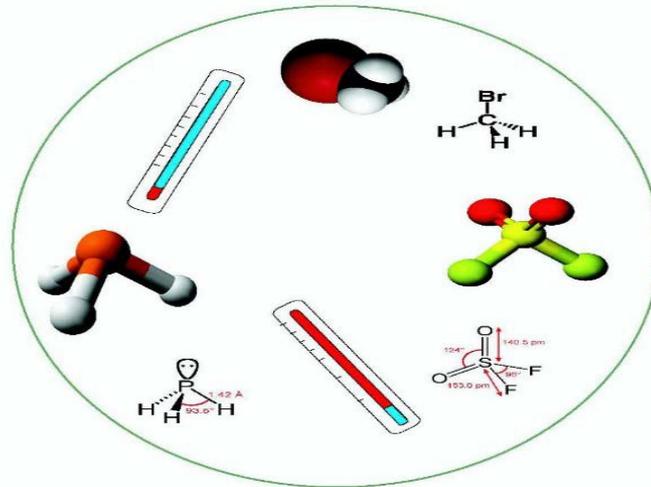
USDA Treatment Manual

Key document



United States Department of Agriculture

Treatment Manual



USDA Treatment Manual

Current treatments for devitalization of noxious weed seeds – *Cuscuta spp.* (Dodder)

Approved treatment – T412-b-2 (5-5-43)

- Dry or steam heat – heat to 212F for 15 minutes

Next steps

- Development of draft validation study protocols and cost estimates
- ASTA Board of Directors consideration
- If Board approves, final protocol development and APHIS review and approval
- Validation studies conducted
- Treatment protocols available for private sector through USDA Treatment Manual

Challenges

Identification of Dodder (*Cuscuta*) species to be tested

- There are 18 species, waiting for APHIS response to our inquiry.

Confusion on onionweed (*Asphodelus*)

- APHIS may have misidentified it at the port.

Where are we on noxious weed seeds?

As expected, this is a long-term, difficult project.

But we are keeping after it and making progress slowly but surely.



Questions?

Please contact me if you would like to discuss Prop 65 or noxious weed seeds.

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THANK YOU!

