

ASTA 2020 Regulatory Workshop

web series

Welcome!



Prop 65 and Spices

Will Wagner | wagnerw@gtlaw.com | 916.868.0655

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www.gtlaw.com

The Basics

- Proposition 65 is a "right to know" law based on the idea that consumers should be warned before being exposed to carcinogens or reproductive toxicants
- Prop 65 requires businesses with 10 or more employees to provide “clear and reasonable warnings” for “exposures” above regulatory safe harbor levels to substances that are listed by California.
- Approximately 900 listed substances
- The warning requirement applies to all companies in the chain of distribution (manufacturers, packagers, distributors, and retailers)
- Manufacturers and/or packagers typically bear the ultimate burden on compliance

Warnings

- Old safe harbor warning

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

- New safe harbor warning

 **WARNING:** This product can expose you to Di(2-ethylhexyl)phthalate (DEHP), a chemical 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/

Warnings Cont.

- Foods Warning:

WARNING: Consuming 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.

- Short Form:

WARNING: Cancer and Reproductive Harm -
www.P65Warnings.ca.gov

- Online warning requirement

- Best option for spice companies?

- Likely foods warning referencing one listed substance that covers both end points (cancer and reproductive toxicity)

Enforcement

- California AG's Office, a district attorney, a city attorney (for cities whose population exceeds 750,000), a private entity, or a citizen can enforce Proposition 65
- Public enforcement is very rare
- Private enforcer must issue 60-Day Notice of Violation to alleged violator and public enforcers before proceeding with a lawsuit
- Over 2,500 Notices of Violation last year
- Penalties for violating Proposition 65 can be as high as \$2,500 per violation, plus plaintiff attorneys' fees

Exposures

- Prop 65 regulates EXPOSURES caused by foreseeable use of products, not the concentration of listed substances in a product
- How is exposure calculated?
 - Average dose X chemical concentration = exposure per dose/serving
- Average dose?
 - For foods with an on-label serving recommendation, it's normally a pretty easy calculation
 - For foods without an on-label serving recommendation, it's a much more difficult analysis

Safe Harbors

- Prop 65 safe harbors are set at extremely conservative levels
- Cancer safe harbor- **No Significant Risk Level:**
 - NSRL = The amount of a substance that will lead to a 1-in-100,000 increase in cancer risk, assuming lifetime exposure at that level
- Reproductive toxicity safe harbor- **Maximum Allowable Dose Level:**
 - MADL = amount of exposure that is less than 1/1000th of the level shown to have no observable reproductive effect

Primary Substances of Concern

- Lead
 - MADL of 0.5 ug/day – most significant issue
 - NSRL of 15 ug/day
- Arsenic (inorganic arsenic compounds)
 - NSRL of 10 ug/day
 - Not a listed reproductive toxicant
- Arsenic (inorganic oxides)
 - No promulgated MADL
 - Not a listed carcinogen
- Cadmium and Mercury?

Consent Judgment Reformulation Thresholds

- The Prop 65 bounty hunter Consumer Advocacy Group (“CAG”) has been actively targeting the spice industry for several years now
- Some levels agreed to with Defendants:
 - Ground cinnamon 550 ppb of lead
 - Ground turmeric 375 ppb of lead
 - Ground ginger 720 ppb of lead

Determine Your Compliance?

- Test product from various lots to get a sense for heavy metal content over time
- Determine a conservative daily dose of the spice at issue, multiply it by your highest test result, and see how it compares to the safe harbor
- Use the ASTA tool for further information
 - Uses average daily consumption based on arithmetic mean
- Hire an attorney specializing in Prop 65 and compare to consent judgment reformulation standards

Questions

- Contact Information

- Will Wagner
1201 K Street, Suite 1100
Sacramento, CA
(916) 868-0655
wagnerw@gtlaw.com





**Agriculture
and Markets**

Regulatory Policies for Heavy Metals in Spices - A New York Approach.

Jon Greenberg, Director
Division of Food Safety and Inspection

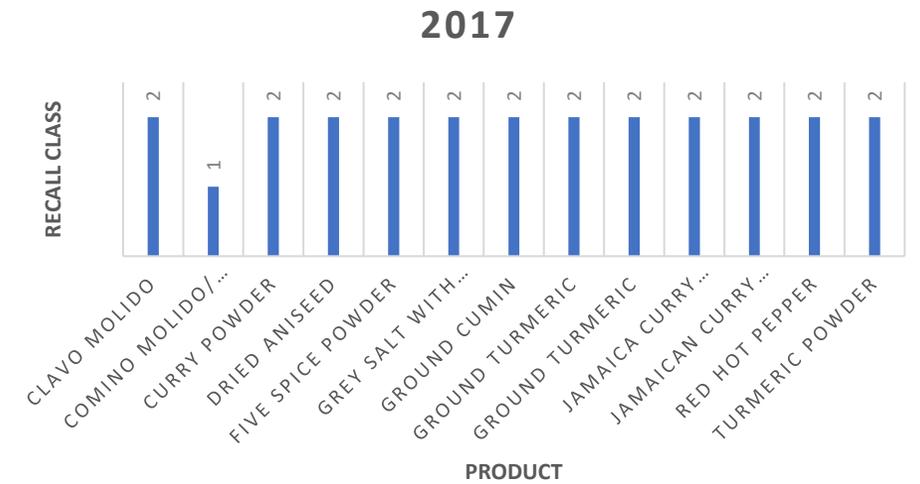
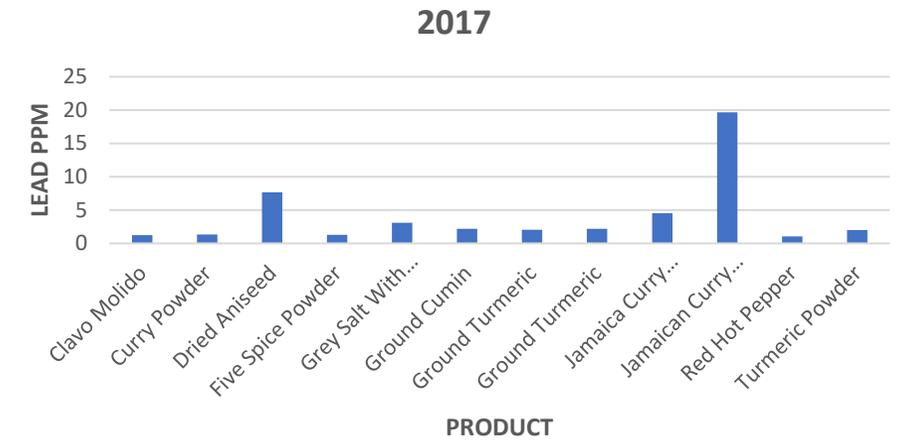
Regulatory Policies for Heavy Metals in Spices - A New York Approach

- Over the last decade, through its routine food surveillance program, the New York State Department of Agriculture and Markets (AGM) has seen a significant rise in the prevalence of heavy metal contamination of imported spices.
- However, no federal action limit for heavy metals in spices currently exists.
- In 2014, New York State created state action limits of 1 and 25 part per million (ppm), for Class 2 and 1 recalls for lead (Pb).

Regulatory Policies for Heavy Metals in Spices - A New York Approach

- AGM has been sampling products for the presence of adulterants in imported spices for decades.
- Initially, testing for adulterants primarily focused on testing for unallowable dyes and allergens.
- In 2014, the AGM Food Laboratory (FL) analysts noticed an increase in the number of spices containing Pb-based dyes, such as Pb chromate, and cadmium (Cd) pigments, causing NYSAGM to shift its focus to testing and analyzing such samples for heavy metals.

Year 2017				
Product	Pb	Origin	Country of Origin	Recall Type
	concentration in ppm			(1 or 2)
Clavo Molido	1.2	Unknown	Not listed	2
Comino Molido/ Ground Cumin	10902	Imported	India	1
Curry Powder	1.33	Unknown	Not listed	2
Dried Aniseed	7.67	Imported	China	2
Five Spice Powder	1.26	Imported	Taiwan	2
Grey Salt With Black Summer Truffles	3.09	Imported	Italy	2
Ground Cumin	2.2	Unknown	Not listed	2
Ground Turmeric	2.03	Domestic	Not applicable	2
Ground Turmeric	2.19	Imported	Not listed	2
Jamaica Curry Powder	4.49	Unknown	Not listed	2
Jamaican Curry Powder	19.7	Unknown	Not listed	2
Red Hot Pepper	1.02	Imported	Turkey	2
Turmeric Powder	2	Imported	Thailand	2



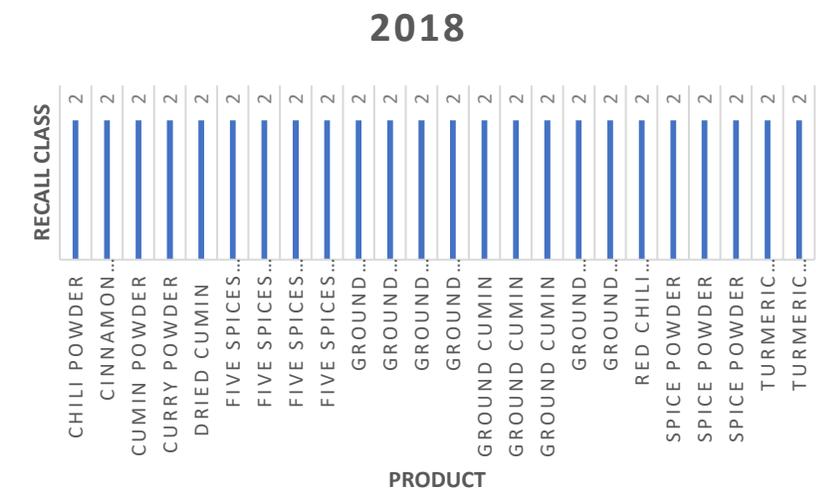
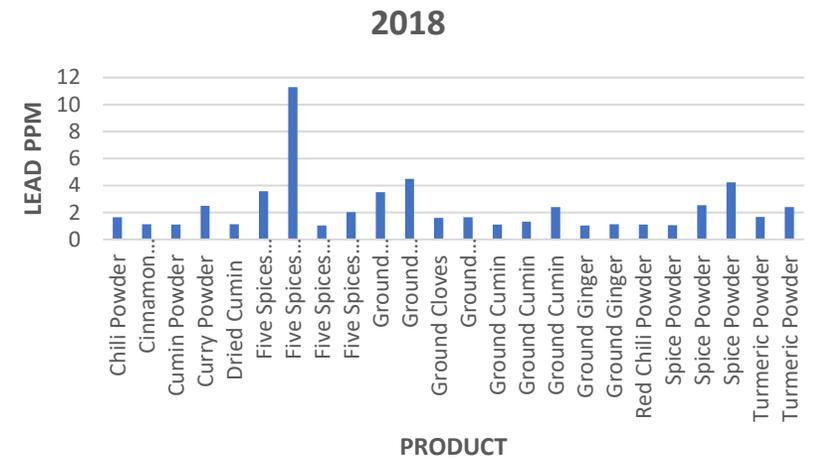
Average Class 2 Recall ppm: 4.02

Average Class 1 Recall ppm: 10902

Number Class 2 Recalls - 12

Number Class 1 Recalls - 1

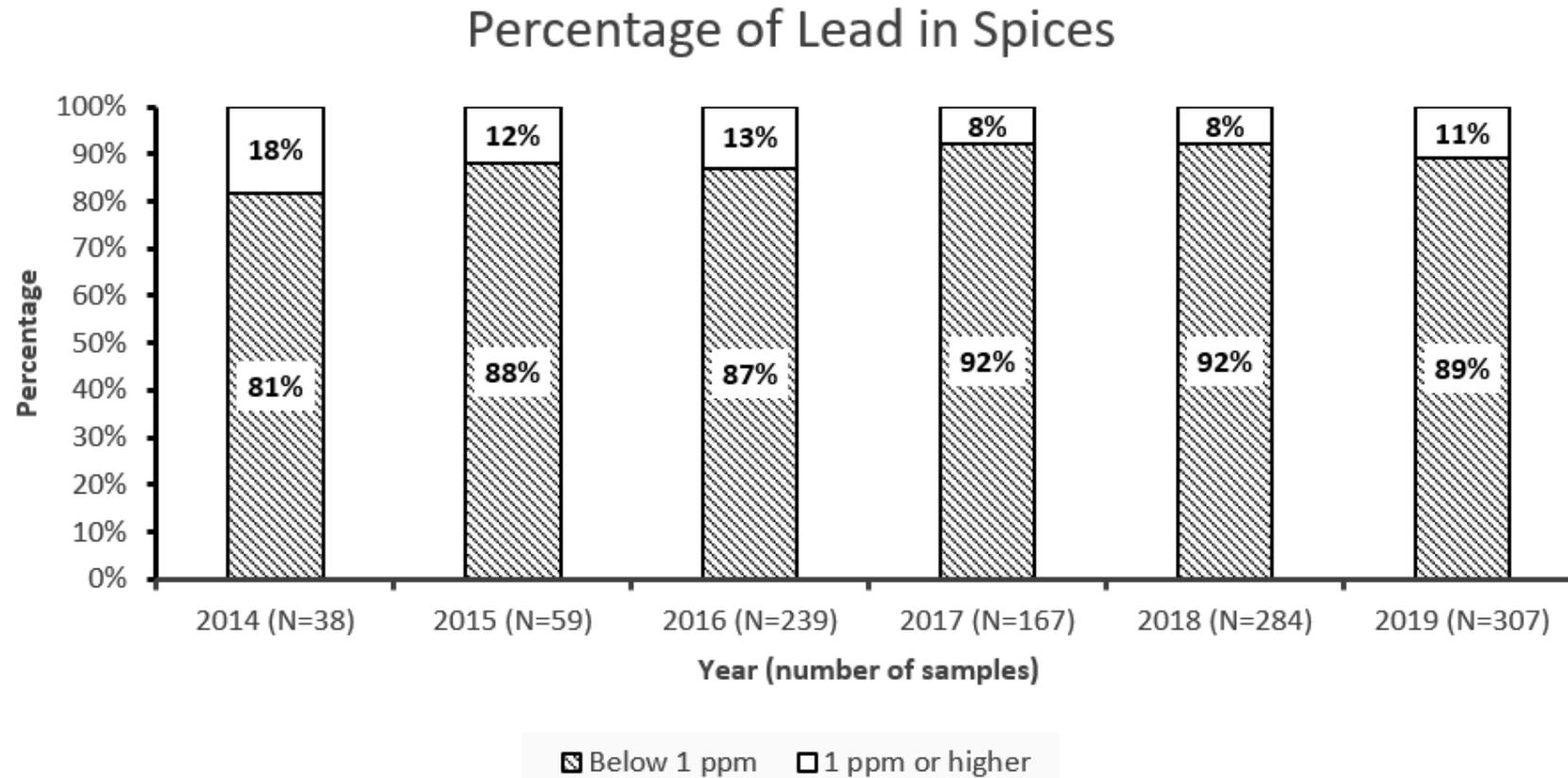
Year 2018					Year 2018				
Product	Pb	Origin	Country of Origin	Recall Type	Product	Pb	Origin	Country of Origin	Recall Type
	concentration in ppm			(1 or 2)		concentration in ppm			(1 or 2)
Chili Powder	1.66	Domestic	Not applicable	2	Ground Coriander	1.66	Unknown	Not listed	2
Cinnamon Powder	1.13	Imported	India	2	Ground Cumin	1.12	Domestic	Not applicable	2
Cumin Powder	1.12	Imported	Hong Kong	2	Ground Cumin	1.33	Unknown	Not listed	2
Curry Powder	2.5	Domestic	Not applicable	2	Ground Cumin	2.41	Imported	Mexico	2
Dried Cumin	1.13	Imported	China	2	Ground Ginger	1.05	Unknown	Not listed	2
Five Spices Powder	3.59	Imported	China	2	Ground Ginger	1.14	Domestic	Not applicable	2
Five Spices Powder	11.3	Imported	China	2	Red Chili Powder	1.11	Imported	Pakistan	2
Five Spices Powder	1.05	Imported	Not listed	2	Spice Powder	1.06	Imported	China	2
Five Spices Powder	2.02	Imported	Hong Kong	2	Spice Powder	2.54	Imported	China	2
Ground Cinnamon	3.5	Unknown	Not listed	2	Spice Powder	4.24	Imported	China	2
Ground Cinnamon	4.49	Domestic	Not applicable	2	Turmeric Powder	1.67	Imported	Not listed	2
Ground Cloves	1.6	Unknown	Not listed	2	Turmeric Powder	2.4	Imported	India	2



Average Class 2 Recall ppm: 2.37

Number Class 2 Recalls - 24

Percentage of lead (Pb) in spices found by the NYSAGM from 2014 to 2019 in two level ranges: 0-1 ppm and 1 ppm or higher.



Regulatory Policies for Heavy Metals in Spices - A New York Approach

In 2018, NYSAGM began a Mutual Reliance Pilot Project with The Food and Drug Administration (FDA). NYSAGM resources are used to sample and analyze FDA regulated imported products at the retail level. When samples are determined to be violative and result in NYSAGM recall, this is communicated to the FDA to trigger, as appropriate, domestic import recalls (outside NY), domestic follow-up inspections, foreign inspections, imported bulleting surveillance, additions to an existent Import Alert, or a new one.

Regulatory Policies for Heavy Metals in Spices - A New York Approach

Protecting New York's consumers is the State's top priority and effective implementation of its public health mission is vital.

In his State of the State Message in 2018, Governor Cuomo launched an initiative, whereby NYSAGM and the New York State Department of Health (NYSDOH) created a Center of Excellence on Food Research to further study heavy metals in spice. This collaborative effort charged NYSDOH with quantitatively evaluating the health effects of heavy metals in spices and developing health-based guidance values to address this adulteration. Based on the results of this study, NYSDAM will lower the state's recall action limits for heavy metals in spices and update its recall policy.

Regulatory Policies for Heavy Metals in Spices - A New York Approach

According to the US Department of Agriculture (USDA), the US is the world's largest importer of more than 40 distinct spices from more than 50 countries. The increase in spice ingestion trends is partly due to:

- General enjoyment of food, while at the same time thought to be used to reduce fat and salt intake in the US diet (Peters et al., 2014, Anderson et al., 2015).
 - Others are adding spices to their daily routine because of their apparent natural anti-microbial and anti-inflammatory properties.
- In order to successfully implement the State's new recall policy and subsequent enforcement activities, NYSAGM will take a phased approach to educate its stakeholders.

Regulatory Policies for Heavy Metals in Spices - A New York Approach

NYSAGM recognizes that it will take time for the industry to fully implement the new recall action limits. There is currently product that is acceptable by today's limits that is:

- In the retail stores
- In the blenders and packers possession
- Harvested

New areas of lower contamination may have to be found.

The new limits will be implemented within 18 months of the public announcement of the NYSAGM updated recall policy.

Regulatory Policies for Heavy Metals in Spices - A New York Approach

During the implementation phase, NYSAGM intends to work with:

- Importers
- Wholesalers
- Retailers
- Manufacturers (spice manufacturers and those using spices as ingredients in their finished products), and any other relevant industry partners.

NYSAGM will engage in a comprehensive outreach and education strategy:

- Speaking at national and regional food safety conferences
- Hosting in-person meetings and
- Providing those affected by this change various forms of written communication to ensure they are aware of this change.

Questions

Jon Greenberg

Director | Division of Food Safety & Inspection

NYS Department of Agriculture and Markets

10B Airline Drive, Albany, NY 12235

(518) 457-4492 jon.greenberg@agriculture.ny.gov

www.agriculture.ny.gov

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