



**Agriculture  
and Markets**

# **Regulatory Policies For Heavy Metals In Spices – A New York Approach**

*New York State Department of Agriculture and Markets  
Division of Food Safety and Inspection*

# Background

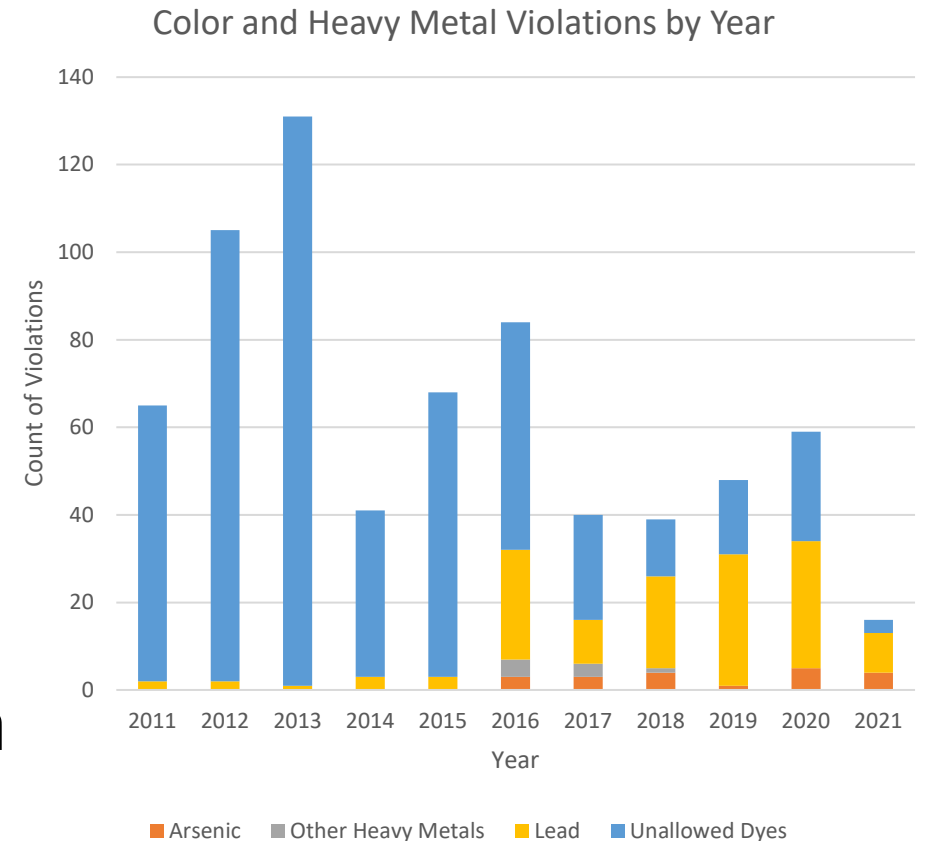
- The New York State Department of Agriculture and Markets (NYSAGM) Division of Food Safety and Inspection is responsible for the safety of food manufactured and sold in New York State.
- That responsibility covers the routine inspection of food, retail, storage and distribution food facilities, as well as the routine sampling of food to check for chemical, physical or biological contamination.
- If contamination or “adulterants” are found, the Department recalls, destroys and/or removes such products from commerce.



**Agriculture  
and Markets**

# Background

- Over the past 10 years, through the Department's routine food surveillance program, Food Laboratory analysts noticed an increase in the number of spices containing non-food-grade dyes.
- Such non-food-grade dyes were found to contain lead and chromium pigments.
- As a result of these findings, the Department began to target the collection and analysis of spice samples for heavy metals.



# Background

- There are no federal action levels for heavy metals in spices.
- In 2016, using results from a devised targeted sampling plan, the Department instituted a State Class II action level of 1 ppm for Inorganic Arsenic, Cadmium and Lead and a State Class I action level of 25 ppm for Lead in spices.

# Recall Classifications

- Class I Recall: Dangerous or defective products that predictably could cause serious health problems or death.
- Class II Recall: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.

# Background

Since 2016, over 1,000 spice samples analyzed resulted in the recall and removal of over 100 spices from the marketplace.

# Background

While the State action levels have resulted in the recall of over 100 spices, a health-based assessment of heavy metals in spices was needed to ensure the appropriate action levels were protecting the people of NY state from this potential source of heavy metal exposure.

# Background

In 2018, NYSAGM and the New York State Department of Health's Bureau of Toxic Substance Assessment (NYSDOH) formed an interagency collaboration to determine actionable limits of contaminants commonly found in spices, particularly heavy metals.



# AGM – DOH Interagency Collaboration

## Focus areas:

- Through this collaboration, we reviewed laboratory surveillance data, as well as toxicity data and spice consumption rates to identify which heavy metals were commonly found and, of those, which pose a risk to human health;
  - Inorganic Arsenic, Cadmium and Lead were determined to be the heavy metals of concern
- We also evaluated whether additional domestic and non-domestic spice samples should be collected.



# AGM – DOH Interagency Outcome

- NYSDOH-BTSA performed oral exposure and toxicological assessments to derive health-based guidance values for Inorganic Arsenic, Cadmium, and Lead in spices used in food preparation.
- Informed by these assessments and sampling data on concentration of heavy metals in spices, NYSAGM lowered the State's Class II action levels for Inorganic Arsenic, Cadmium and Lead in spices by a factor of almost 5 times.

# Action Levels for Heavy Metals

New York is the first State in the nation to establish action levels for heavy metals in spices providing better protection to New York State consumers

Analyte	Class II Recall Action Level (ppm)
Lead (Pb)	>0.21
Cadmium (Cd)	>0.26
Inorganic Arsenic (As)	>0.21

New York State *Updated* Recall Policy for Heavy Metals in Spices (effective *TBD*)

# Class II Recall Action Levels

**Lead:** Class II recall action level selected is based on the NYSDOH derivation of a noncancer health-based guidance value for Lead in spices used in food preparation. It is important to recognize that this assessment differs from other noncancer assessments because of the absence of a threshold for the effects of Lead on the developing central nervous system of children. While the health-based guidance value is based on health protective methods and assumptions, the absence of a threshold means that we cannot assume that exposure below the health-based guidance value is without risk as we would for other noncancer health-based guidance values. Due to absence of a threshold for the noncancer health effects of Lead, and the presence of many other potential sources of exposure to Lead (e.g. soil, indoor dust, water), it is prudent to reduce risks for Lead exposure through consumption of spices by adopting screening or action levels as low as achievable.

# Class II Recall Action Levels

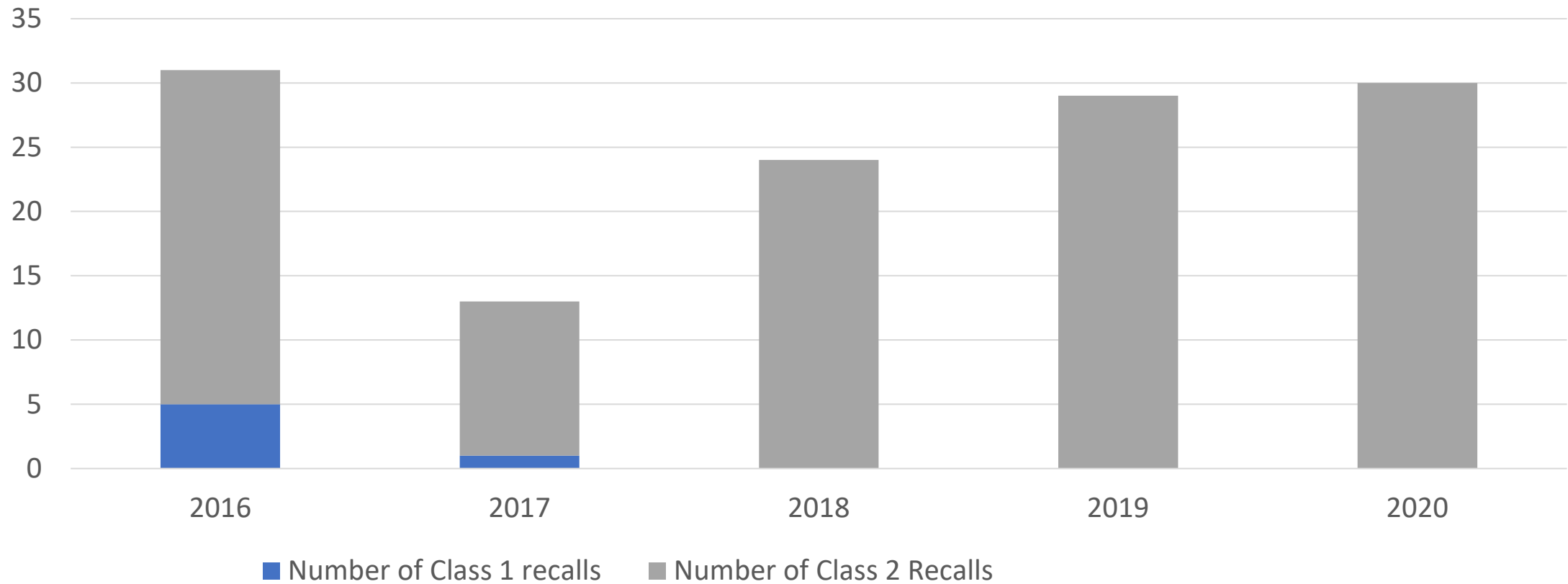
**Cadmium**: Class II recall action level is based on the 90th percentile of Cadmium concentrations detected in sampled spice products, which was used as a surrogate for background Cadmium concentrations found in spices and is also set as close as feasible to the health-based values for Cadmium in spices.

# Class II Recall Action Levels

**Inorganic Arsenic**: Class II recall action level is based on the 90th percentile of Inorganic Arsenic concentrations detected in sampled spice products, which was used as a surrogate for background inorganic arsenic concentrations found in spices, and is also set as close as feasible to the health-based values for Inorganic Arsenic in spices.

# Spice Samples Violative for Lead

Number of Recalls per year by Class



# Historical Samples for Lead and Cadmium

2016 Policy for both Lead and Cadmium: Class 2 = > 1 ppm                      Class 1 = 25 ppm								
			Class 2	Class 1			Class 2	Class 1
		# of tests	> 1 ppm	> 25 ppm		# of tests	> 1 ppm	> 25 ppm
2014	Cadmium	12	0	0	Lead	38	5 (13%)	2 (5.3%)
2015	Cadmium	37	1 (2.7%)	0	Lead	59	7 (12%)	0
2016	Cadmium	226	0	0	Lead	239	28 (12%)	3 (1.3%)
2017	Cadmium	166	2 (1.2%)	0	Lead	167	12 (1%)	1 (0.6%)
2018	Cadmium	284	2 (0.7%)	0	Lead	284	24 (9%)	0
2019	Cadmium	309	0	0	Lead	309	33 (11%)	2* (0.6%)
2020	Cadmium	173	0	0	Lead	173	29 (17%)	0
<b>Totals</b>	<b>Totals</b>	1207	5 (0.4%)	0	<b>Totals</b>	1269	138 (11%)	8 (0.6%)

\*Both 2019 samples > 25 ppm were from a health investigation into elevated blood lead levels linked with a non-commercially available product.

\*\*Arsenic was not included in the table because the metal was not detected for every sample or speciated as inorganic As (toxic form). Inorganic As is speciated only if total As is 1 ppm or higher.



# Updated Recall Policy Implementation

- Public health and the protection of New York's consumers is our top priority and effective implementation of its public health mission is vital.
- In order to successfully implement the State's update recall policy and subsequent enforcement activities, NYSAGM will use a phased approach over the span of an 18-month period.
- Currently, NYSAGM has a Class II recall action level of 1 ppm for Pb, that was put into place in 2016. As part of the State's implementation strategy NYSAGM will monitor and document violations of the new Class II recall action level policy (e.g.  $>0.21$  ppm Pb) by sending warning letters to those responsible for the violation (unless actionable under the current Class II recall action level, i.e.  $Pb \geq 1$  ppm).
- This approach will afford importers, distributors, co-packers, manufacturers of spices and retailers the opportunity to implement additional controls that may be needed to comply with the new Class II recall action levels in the future.

# Stakeholder Input

- NYSAGM also intends to work closely with retailers, importers, wholesalers, manufacturers (spice manufacturers and those using spices as ingredients in their finished products), and any other relevant industry partners during the 18-month implementation period.
- It will engage in various forms of comprehensive outreach and education sessions by 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.

# Protecting Public Health

- NYSAGM's goal is to ensure that all stakeholders affected by this updated policy are adequately prepared once the change becomes effective, while ensuring that the implementation of this updated recall policy efficaciously protects public health.
- For this project to have a broad impact, NYSAGM will share this information with state departments of health and agriculture, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to serve as a national model for appropriate action concerning spices contaminated with heavy metals.

# Publication: Journal of Regulatory Science

- A copy of the manuscript prepared for this project is currently going through scientific-peer review
- We will share the final copy of this manuscript once it is published

## Regulatory policies for heavy metals in spices – a New York approach

Maria L. Ishida<sup>a\*</sup>, Virginia Greene<sup>a</sup>, Thomas King<sup>a</sup>, Jon Greenberg<sup>b</sup>, John Luker<sup>b</sup>, Debra Oglesby<sup>a</sup>, Robert Sheridan<sup>a</sup>, Jennifer Trodden<sup>c</sup>

<sup>a</sup>*Division of Food Laboratory, New York Department of Agriculture and Markets, 1220 Washington Avenue Building 6, Albany, NY 12206*

<sup>b</sup>*Division of Food Safety and Inspection, New York Department of Agriculture and Markets, 10B Airline Drive, Albany, NY 12235*

<sup>c</sup>*Executive Office, New York Department of Agriculture and Markets, 10B Airline Drive, Albany, NY 12235*

\*Corresponding author: Maria L. Ishida, Phone: 518-457-4477, Fax: 518-485-8097, Email: [Maria.Ishida@agriculture.ny.gov](mailto:Maria.Ishida@agriculture.ny.gov).

## Abstract

The New York State Department of Agriculture and Markets (NYSAGM) Division of Food Safety and Inspection (NYSAGM-FSI), observed high levels of heavy metals in spices through its routine food surveillance program. There are no federal action levels for heavy metals in spices. In consultation with the NYSAGM Food Laboratory (NYSAGM-FL) and using results from a devised targeted sampling plan, NYSAGM-FSI instituted a State Class II action level of 1 ppm for Pb, arsenic (As) and cadmium (Cd) and a State Class I action level of 25 ppm for Pb in spices. In 2018, NYSAGM and the New York State Department of Health's Bureau of Toxic Substance Assessment (NYSDOH-BTSA) formed an interagency collaboration to determine actionable limits of contaminants commonly found in spices, particularly heavy metals. NYSDOH-BTSA



**Agriculture  
and Markets**

# Questions?

**Website:** <https://agriculture.ny.gov/food-safety>

**Email:** [FSIWebInquiries@agriculture.ny.gov](mailto:FSIWebInquiries@agriculture.ny.gov)