

Cheryl Deem, Executive Director

ASTA Update

- □ Lead in Turmeric
- □ Pesticide Residues
- □ Guidance Documents
- Other ASTA Activities



- Background
 - ASTA notified July by New York State lab or pending recalls of turmeric for excessive lead levels
 - Believed to be lead chromate economically motivated adulteration
 - Following initial recall in July there have been a number of subsequent recalls
 - Questions about allowable lead levels in turmeric prompt ASTA/FDA meeting



Past ASTA direction:

- FDA's lead in candy guidance 0.1ppm
- □ FDA's color additive regulation 10 ppm

FDA: well meaning but not accurate

- Candy guidance based on very small amount of ingredient containing lead (chilies)
- Color additive reg developed on 60s/70s
- Reflects available methodology at time not robust safety assessment

- FDA has not historically monitored spices for lead
 - Assumption that spice consumption levels low in general population and in children
- In 2013, turmeric from Bangladesh was recalled for excessive lead levels
- That recall prompted reconsideration because found turmeric consumption high enough in some instances to warrant monitoring



- Recent recalls are because of "gross contamination"
- □ Lead levels of 40 − 50ppm
- □ FDA has seen 100+ppm
- □ ASTA is in agreement that those levels are excessive



FDA's position on lead:

- Research shows there is no safe exposure level
- Lead is commonly found in agricultural products
 because of air/soil contamination
- □ They are not looking for zero
- □ FDA will not issue guidance to spice industry
- However.... FDA will share their "thinking" on a level that will not likely prompt enforcement action



- □ FDA wants to see spice industry data on lead in turmeric
- Compare levels from companies with good
 GAP/GMP practices to FDA monitoring data
- Will determine level based on that comparison
 - FDA wants the level to be something industry can meet
- Expect it will be between 10ppm and 0.1ppm



- □ How do we get there? With your help
- ASTA needs data on lead levels found in turmeric
- FDA wants to know is it possible to source turmeric with undetectable levels (won't impact result – they just want to know)
- What percentage of turmeric imported into U.S. is used as a spice? Color? Dietary supplement? Other?



- All information will be submitted through ASTA
 General Counsel, aggregated and blinded for FDA
 submission (FDA agrees they do not need to know companies)
- If you are willing to participate see me for data template
- Caution if we don't get data there will be no progress



Pesticide Residues

- Very few tolerances exist in the U.S. for spices
- Chemical companies seek tolerances for major crops when they introduce new chemicals because of cost and need to recoup investment: 2008 CropLife study: 10 years and \$270 million from product development to regulatory approval
- Minor crops, particularly imports, face challenges
- EPA is aware of this and is proposing pilot project to explore alternate ways of securing import tolerances for minor crops (using <u>field trials</u>)

Pesticide Residues

- ASTA is taking multi-pronged approach to a complex issue
 - Proposed pilot to secure import tolerance on metalaxyl for pepper
 - Cooperation with Vietnam on pesticide use
 - CropLife America membership and active participation in Food and Beverage Committee



Proposed Metalaxyl Pilot

- EPA not willing to include ASTA in their proposed pilot because we need to use monitoring data not field trial
- But they are willing to work with us
- Challenge: we need monitoring data to submit for safety assessment
- At this point we don't have data we can use



Efforts with Vietnam

- Meeting December 2015 in Vietnam
 - Joint representation ASTA/ESA/CSA
 - Stakeholder meeting with 150 people
 - Discussions on growers' needs to protect crops and importers' needs to meet regulations
 - Meeting with Ministry of Agriculture and Rural Development and Vietnam Pepper Association
 - Key accomplishment: acknowledgement of potential problem with residues and expressed willingness to work to address
 - Agreement to develop action plan and timeline



Efforts with Vietnam

- Meeting with VPA at ASTA Meeting in Scottsdale April 2016
 - Review of key issues
 - Update from VPA on progress
- Next meeting scheduled November 2016 in Vietnam
 - Will involve stakeholders
 - Overview of issues/progress/next steps



CropLife – Food and Beverage Comm.

- Membership consists of trade associations and a number of companies, including Coca-Cola, PepsiCo, Unilever
- Provided educational background on regulations and process for establishment of tolerances
- Exploring how to increase awareness of minor
 crop/imported crop issues with chemical companies
- □ Exploring options for minor crops



Guidance Documents

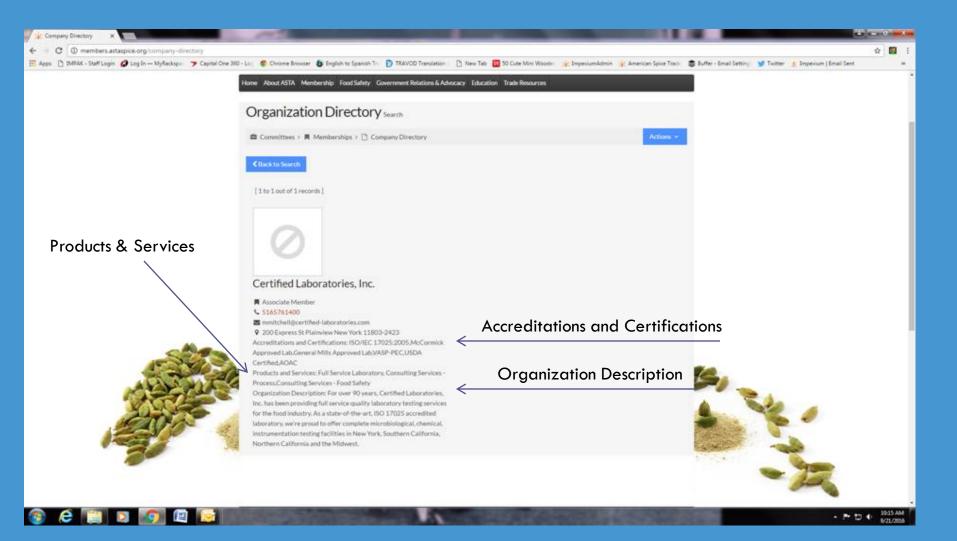
- □ Clean, Safe Spices update
 - **■** FSMA/RFR information
 - No changes to recommendations
- □ Allergens − new
 - □ Pre-Conference Workshop April 2017
- □ Economically Motivated Adulteration new
 - Food Safety Committee Working Group developing
 - Combines ASTA White Paper on Adulteration with Guidance on Authenticity of Herbs and Spices (UK)

Additional ASTA Resources

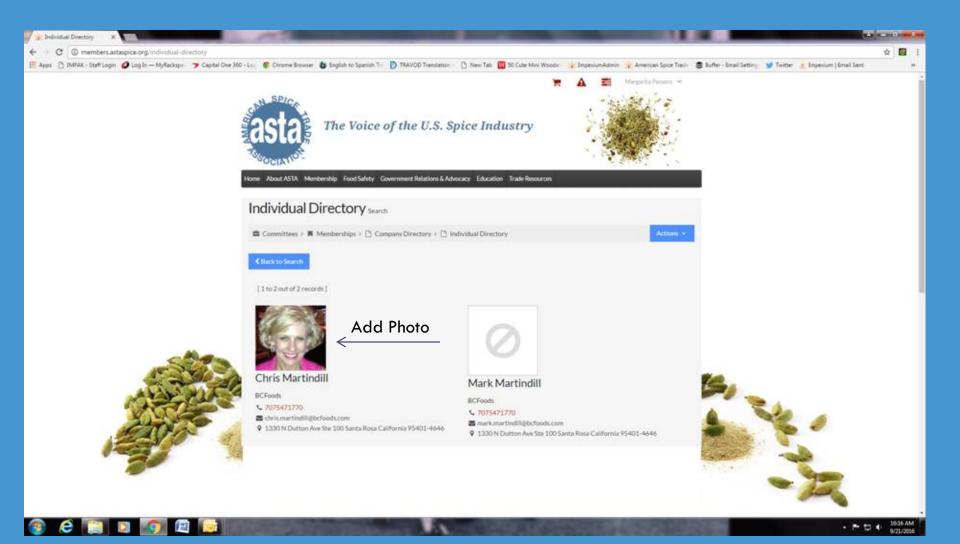
- Government Relations and Advocacy Committee
 - FSMA Decision Tree
- Food Safety Committee
 - Risk Assessment Considerations for FSMA
 - On-demand webinar series on process validation
- Membership Committee
 - Database Resources



ASTA Database Resources



ASTA Database Resources



ASTA Annual Meetings

- □ April 23 25, 2017 Austin Hilton, Austin, TX
- April 15 18, 2018 Ritz-Carlton Golf Resort,
 Naples, FL
- April 7 10, 2019 Omni Amelia Island Plantation,
 Amelia Island, FL

