ASTA UPDATE

CHERYL DEEM

ASTA UPDATE

- Surrogate identification for validation
- Pesticide residues
- Risk Profile/FDA Retail Study
- New ASTA FSMA Inspection Program
- Codex – CCSCH

SURROGATE DEVELOPMENT

- FSMA requires validation of pathogen reduction processes
- FDA wants research to demonstrate appropriate surrogates in use
- ASTA sponsored research with ILSI North America to identify appropriate surrogates for validation of pathogen reduction
- Research concluded *E. facecium* is appropriate surrogate for:
  - Steam: peppercorns, cumin (?)
  - ETO: peppercorns, cumin
  - Irradiation: spices

SURROGATE DEVELOPMENT

FDA: research needed to confirm appropriate surrogate for **each** spice with **each** pathogen reduction technique

ASTA spice list has 50+ spices x three techniques…

SURROGATE IDENTIFICATION

- Met with FDA in December and they recognize challenges of cost/time to do research on every spice
- Agreed that grouping of spices is logical approach considering:
  - Physical type (leaf, root, seed, etc.)
  - Whole vs. ground
  - Concentration of essential oils
  - Moisture content
  - Density
- Concern about inhibitory characteristics of some spices (cloves, cinnamon, allspice, oregano) Asked for research

SURROGATE IDENTIFICATION

- Dr. James Dickson developed protocol and ASTA member labs submitted proposals to do research on whether those spices can easily be grouped
- Certified Laboratories selected to do research – *Salmonella* strains from FDA have been shipped
- Next steps: review research and finalize groupings
- Determine what additional research needs to be done to identify appropriate surrogate for each grouping

Caveat: FDA unlikely to formally approve – recommendations will be issued as guidance from ASTA

SURROGATE IDENTIFICATION

- FDA acknowledged they are challenged by their FSMA requirement for companies to validate every ingredient that undergoes microbial reduction
- Spices can be model for rest of the food industry
- ASTA is viewed by FDA as a leader in this effort

RISK PROFILE/RETAIL STUDY

- FDA issued Draft Risk Profile in 2013 – 6.6% of spices tested at import were positive for Salmonella – FDA concluded *Salmonella* is a problem in the spice supply chain and raised food safety issues
- ASTA submitted extensive comments to underscore that spices at import are not what consumers are typically exposed to
- FDA conducted 2-year retail study
- Published results in February and finalized risk profile

RISK PROFILE/RETAIL STUDY

- 7,250 retail samples collected – 16 positive for *Salmonella*
- FDA concluded that many imported spices are treated for pathogen after import and consumers do NOT need to change consumption or use of spices
- Findings do underscore need for companies to use validated microbial reduction processes
- RTE/NRTE – FDA recognizes NRTE of spices at border but may take time for that to trickle down with FSMA implementation

PESTICIDE RESIDUE TOLERANCES (MRLS)

- Has been an issue for many years, but FSMA has brought to forefront: should a hazard analysis include pesticide residues?
  - FDA has listed pesticides as a potential hazard
  - But some companies maintain that conflicts with FDA's stated standard for a potential hazard: would cause serious adverse health consequences or death
- Major challenge in US with no default tolerance
  - In the absence of a tolerance = zero
  - Very few tolerances for spices

PESTICIDE RESIDUE TOLERANCES (MRLS)

- EPA has recognized challenge for minor crops, particularly imports to secure tolerances because of
- EPA opened two new paths to secure import tolerances
  1. Use national reviews for MRLs as basis for EPA review
     - Eg.: Codex, EU, Japan, Canada
  2. Allow spice industry to submit monitoring data instead of field trials

NATIONAL REVIEWS

- European Spice Association asked IOSTA to add pepper to 2018 review of Metalaxyl to address EU issues on possible reduction in MRL
- ASTA consultant developed submission based on ESA data
- If accepted and Codex approves MRL, ASTA will ask EPA to consider US import tolerance – CCPR meeting in September
- 2 step process: Codex MRL than EPA tolerance

MONITORING DATA

- In the meantime, ASTA consultant secured commitment from IR-4 to develop petition to EPA using ESA data on Metalaxyl for separate EPA review
- ASTA applying for small business fee reduction in application fee ($63,816 per pesticide)
- Using same Metalaxyl data as Codex petition
- IR-4 looking for additional information on data to finalize petition (data is not robust)

PESTICIDE RESIDUES

- Challenge with both situations is data we have access to is not as robust as we need
- Codex route seems most promising:
  - **India has significant data and has already submitted requests to add spices to a number of pesticides slated for review in 2019**
  - Downside is that the two-step process takes longer - first Codex then EPA

Bottom line is there finally are options for ASTA to pursue – issue remains data, time and money

FSMA INSPECTION SHARE GROUP

- Modeled after program at Grocery Manufacturers Association
- Forum for companies to share their experiences with FDA inspections - Not results…process
  - How much notice did FDA give?
  - How many inspectors were there?
  - How long were they there?
  - Did they take swabs? How many?
  - Did they ask to take photographs and respect your policy on photos if you have one?

INSPECTION SHARE GROUP

- First call in May
- GR Committee developed series of questions to prompt discussion and have someone to begin sharing
- Focused on US inspections with the goal of helping members understand what to expect

CODEX - CCSCH

- First standards adopted July 2018
  - cumin; pepper (black, white, green); thyme
- Next set of standards in development
  - oregano, chili peppers/paprika, cloves, garlic, ginger, nutmeg, saffron
  - Next CCSCH Meeting January21 – 25, 2019

WE HOPE TO SEE YOU THERE!

2019 Annual Meeting

April 7 – 9

Omni Amelia Island Plantation Resort

THANK YOU

QUESTIONS?