

2014 ASTA Regulatory Workshop

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ASTA Update

- Draft Risk Profile: FDA Retail Study
- Crop Protection Chemical Strategy
- Surrogate Development Research



Draft Risk Profile – Retail Study

- ◎ DRP published October 2013
- ◎ Key findings:
 - 6.6% spices sampled contaminated with *Salmonella*
 - 12% exceeded allowable levels for filth
- ◎ ASTA position
 - Spices sampled at import are not representative of what consumers eat
 - Fill identified data gap: retail study



Draft Risk Profile – Retail Study

- April 9, 2014 – recall whole black pepper
- April 9, 2014 – recall basil
- April 23, 2014 – recall annato

- All for *Salmonella* found during testing by FDA

Draft Risk Profile – Retail Study

- April 2014 – ASTA Contacted FDA to learn details
- May 2014 – FDA agreed to meeting with ASTA to provide preliminary results
 - 1100 samples complete
 - **0.5% positive**
 - **“pleasantly surprised”** results were much lower than typically see in foods with prior *Salmonella* issues

Draft Risk Profile – Retail Study

◎ FDA Plans

- 3,300 samples FY 2014 (Sept. 30)
- 3,300 samples FY 2015 (pending funding)
- Publish results in peer-reviewed scientific journals



Draft Risk Profile – Retail Study

- FY 14 complete – FDA has received summary from contractor
- Agreed to review and will provide more information after they see all data
- Provided update yesterday

Draft Risk Profile – Retail Study

- Goal – get a sense of what is available to consumers through broad range of suppliers
- Target 3,300 samples: 1,100 black pepper and 550 each red pepper, paprika, basil & oregano
- Ground, whole, flakes, etc.

Draft Risk Profile - Retail Study

- Gathered 175 grams for each sample
- If multiple containers needed, all were from the same lot number to ensure single, unique traceable source
- No one brand had more than 100 samples

Draft Risk Profile – Retail Study

- National assignment – 8 regional collection sites:

419 CA

423 CO

173 CT (area)

668 GA

729 MD

311 MN

362 TX

306 WA

557 on line purchases



Draft Risk Profile – Retail Study

Broad range retail venues

- Major chain supermarkets – traditional and large ethnic markets eg. Giant, Trader Joe's H-Mart, Walmart
- Smaller ethnic/national food markets (independent or small chains – less than 10)
- Small discount/variety (eg. CVS, Walgreens)
- Internet suppliers

Draft Risk Profile – Retail Study

| <u>Spice</u> | <u>#</u> | <u>±</u> | <u>APC</u> |
|--------------|----------|----------|--------------------------------|
| Basil | 500 | 1 | 1 million |
| Black Pepper | 1300 | 4 | 20, 80, 600K, 10 million |
| Oregano | 700 | 1 | 1,000 |
| Paprika | 800 | 2 | 80K, 300K |
| Red Pepper | 650 | 4 | 25, 75K, 1.5 & 1.6 million |

Draft Risk Profile – Retail Study

- FDA is most alarmed by high APC
- Did not expect positives with low APC
- Looking to industry to explain range of APC with positive (treated vs. untreated)
- FY 15 funding unclear – not sure if second phase of study will be done

Draft Risk Profile – Retail Study

- ⦿ Disappointing – 0.5% positive for 1,100 was “pleasant surprise” and would be very good news if continued
- ⦿ Final 0.3% is “still of concern”
- ⦿ Believe that is assessment based on FDA representatives on the call
- ⦿ Unknown if they will publish – will likely add as appendix to final risk profile

Draft Risk Profile – Retail Study

- Next steps for ASTA include:
 - Written response to FDA with scientific assessment from Dr. Jim Dickson on APC
 - Review of raw data, if possible and further comment
 - Continued emphasis of need for FDA to focus on RTE at border – alleviate sampling/testing delays of RAC
 - Follow up with membership on results and emphasize need for validation/GMPs
 - (FDA views education as positive steps to address problem)

Surrogate Development Research

- Partnering with International Life Sciences Institute (ILSI) North America
- Virginia Tech, Texas A&M, Iowa State
- Completion October 2015
- Goals:
 - Identify surrogates for spice process validation for ETO, steam & irradiation
 - Provide procedures for in-plant validation and demonstrated log reduction



Crop Protection Chemical Strategy

- ⦿ EPA sets tolerances/FDA enforces
- ⦿ FDA has indicated some flexibility in enforcement (orange juice/carbendazim)
- ⦿ EPA strictly adheres to safety standard in Federal Food, Drug and Cosmetic Act: “a reasonable certainty of no harm from exposure to the pesticide residue.”

Crop Protection Chemical Strategy

- ◎ Import tolerances require less data to meet the safety standard:
 - Name and product chemistry
 - Amount, frequency & timing of application including copies of product labels (must be in use legally in source country)
 - Toxicology data
 - Residue chemistry data
 - Proposed tolerance based on maximum residues identified in field trials – some flexibility to use monitoring data

Crop Protection Chemical Strategy

- ◎ ASTA recognizes importance of addressing:
 - FSMA
 - Customers
 - Consumers
- ◎ Challenge:
 - Data
 - Time
 - Money



Crop Protection Chemical Strategy

- 2014: ASTA joins CropLife America
- Food and Beverage Committee works to address issue of lack of import tolerances
- F&B Comm develops pilot project to fine tune process for tolerance approval
- F&B Comm expertise can be leveraged
- EPA willing to support effort



Crop Protection Chemical Strategy

- ① Develop list of chemicals
- ① F&B Comm and/or EPA review
 - Not permitted for use on food in US
 - Can't pursue because of risk cup problems
 - Potential candidate for pilot project
- ① Select chemical for pilot
- ① Work with F&B Comm on pilot submissions

Crop Protection Chemical Strategy

- ◎ Following completion of pilot will know:
 - What it takes to obtain import tolerance
 - Data
 - Cost
 - Time
 - Prioritize needed tolerances and determine next steps: data, funding, etc.

Crop Protection Chemical Strategy

- ◎ First step: list of chemicals
 - Product
 - Commodity(s) used on
 - Existing US tolerance (yes/no)
 - Priority (high/medium)
 - Country(s) of origin of commodity
- Template in handouts – available electronically
- Submit to ASTA office or through legal counsel

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THANK YOU!

