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Microbial Safety in Spices & Microbial Reduction Regulatory Update

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Background

- Spices used for centuries for flavor and the preservation of some foods
- Generally viewed by consumers as "Ready-to-eat"
- Agricultural-based food ingredients may be contaminated with pathogens
- Drying or dehydration may prevent pathogen growth, but is not a kill step
- Sampling and Testing plays a key role in a comprehensive food safety system
- Microbial reduction/kill steps are routinely utilized to ensure food safety

Selected Spice Recalls

YEAR	PRODUCT	PATHOGEN	NUMBER OF ILLNESSES	
2001	Paprika	Salmonella Ohio	0	
2002	Oregano	Salmonella Bispebjerg	0	
2002	Sesame Seeds	Salmonella Senftenberg	0	
2002	Basil Leaves	Salmonella Haifa	0	
2003	Cumin, Ground	Salmonella Onderstepoort	0	
2003	Paprika	Salmonella Karlshamn	0	
2003	Sage, Ground	Salmonella Gaminara	0	
2003	Cumin, Ground	Salmonella Salford	0	
2004	Red Pepper, Powdered	Salmonella Derby	0	
2004	Paprika	Salmonella spp.	0	
2004	Sesame Seeds, White	Salmonella spp.	0	
2005	Basil, Ground	Salmonella spp.	0	
2005	Basil, Extra Fancy	Salmonella Blockley	0	
2006	Veggie Booty (Seasoning)	Salmonella Wadsworth Salmonella Typhimurium	60 (mostly toddlers)	
2007	Peppercorns ^b	Salmonella spp.	0	
2007	Sesame Seeds ^b	Salmonella spp.	0	
2007	Mojito Cocktail Garnish (Parsley Powder)	Salmonella spp.	0	

^b Recalls that occurred in Canada, all other recalls listed in table occurred in the U.S.

Case Scenario: Salmonella in Paprika April – September 1993 Outbreak

- ~ 1,000 cases of salmonellosis in Germany
- Traced to paprika and paprika-powdered potato chips
- Majority of cases were in children aged 14 years or less
- Salmonella enumeration revealed levels of 0.04-0.45 organisms per gram
- Infective dose estimated at 4-45 organisms
- Attack rate of 1 in 10,000 exposed persons

Case Scenario: Salmonella in Paprika April – September 1993 Outbreak: Key Learnings

- Salmonella present in low numbers in spices can present a human health hazard when no kill step is applied prior to consumption.
- Salmonella is very stable in dry environments and can survive through production, distribution, and eventually consumption.
- A person does not need to consume a large amount of contaminated spices or seasonings to become ill.

2009 Spice Recall

- Salmonellosis outbreak linked to black & white pepper from California-based spice importer
- Recall expanded all spices and oils
- Company ceased production/distribution of affected products while FDA and CDPH continue investigation
- Details regarding root cause have not been released

2009 Spice Recall Impact

- As of April 2nd, over 1380 retailers and restaurants impacted
- Illnesses reported for 60 people in four states, including 45 in California, in 18 Central and Northern California counties
- No deaths have been reported
- Green Cardamom Salmonella
 - Alert issued by CFIA April 8th
 - Importer voluntarily recalling bulk/retail; no illnesses have been reported

Government & Regulatory Changes

US Government Focus

- United States Congress increased their food safety focus via hearings in 2007, 2008 and 2009
 - CEOs from several U.S. food companies, food industry organization representatives, and regulatory representatives from the FDA and USDA testified
 - Several Food Safety bills pending in congress

US Government Changes

- New FDA Leadership
 - Dr. Margaret Hamburg FDA Commissioner

- Food Safety Working Group Formed
 - Advise the President on improving coordination throughout the government
 - Examining and upgrading food safety laws
 - Enforcing laws that will keep the American people safe

- Good Agricultural Practices (GAPs)
- Good Manufacturing Practices (GMPs)
 - including pest management
- Third-party audits
 - GFSI (Global Food Safety Initiative)
 Food Safety Programs
 - SQF, BRC, Dutch HACCP, IFS

HACCP GUIDE FOR SPICES & SEASONINGS



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February 2006



CONTROL OF SALMONELLA IN LOW-MOISTURE FOODS

February 4, 2009 (Minor corrections March 16, 2009)

- Grocery Manufacturers Association Guidance Document
- "Control of Salmonella in Low Moisture Foods"
- Emphasizes processing environment

Micro Reduction Treatment Options

Micro Reduction Treatment Options

In order to provide a greater assurance of food safety, a variety of microbial reduction techniques are employed within the spice industry

- Steam
- Irradiation
- Fumigants
 - Propylene oxide
 - Ethylene oxide

Microbiological Testing Role & Sampling

Microbiological Testing Role

- Routine microbiological testing often used to determine purchased ingredients, raw materials, and finished products acceptance...
- Microbiological contamination test protocols need to be based on sound handling methods and statistically-guided sampling plans
- Spice pathogen testing may be useful to screen for high contamination rates entering a plant, but cannot completely eliminate risk.
- Due to a typically low contamination rate testing as the lone measure of food safety may be misleading - negative results do not always ensure safety.⁽⁶⁾

Microbiological Testing Role: Sampling

A fundamental principle of lot acceptance sampling plans is that the samples collected will reflect the lot as a whole

- Critical that samples be collected at various points throughout the entire lot
- Be aware of instances where the microbial population is not homogenous – one "lot" of imported raw spices may be comprised of many batches or sub-lots
- For non-homogenous lots, an increased number of samples may be required to properly evaluate the lot

Microbiological Testing Role: Sampling

- Sampling plan effectiveness factors
 - Whether random samples can be collected from a lot
 - Sample preparation
 - Analytical method sensitivity and specificity⁽⁶⁾
- Lot acceptance sampling plans assume microbial population random distribution throughout the lot
 - This is often not true, especially for foods that are not liquids
 - Better estimation of the true microbiological population estimation within a lot can be obtained by analyzing more than one sample
- Sample number per lot is a balance between risk, accuracy, available resources, time, and cost

Microbiological Testing Role: Treated vs Untreated Spices

 Untreated spices typically require a more stringent sampling plan than those that have undergone microbial reduction

- For treated spices, extensive testing post-treatment
 - adds little to ensure food safety
 - increases cost
 - and may be unnecessary

Microbiological Testing Role: Sample Collection

- Sample collection technique is key to ensure accurate results
 - Scoops and bags must be sterile to prevent crosscontamination
 - Proper hand washing techniques and glove use to prevent cross-contamination

 Potential cross-contamination in processing/packaging equipment if product samples collected prior to final processing and packaging

Microbiological Testing Role: Sample Result Evaluation

- When more than one sample is analyzed for a microbiological attribute, a two- or three-class sampling plan may be applied to evaluate results.
 - Two-class sampling plan when zero positives are permitted
 - Three-class sampling plan when a proportion of sample units may yield test values in a marginally acceptable range without causing consequent problems.⁽⁶⁾
 - Consult a statistician
- Additional information on sampling plans is available from ICMSF ⁽⁷⁾ and the FDA.

Microbiological Testing Role: Sampling Two-Class Plan Probability of Acceptance

Table 2. Probability of acceptance (P_a) of defective product using a two-class sampling plan

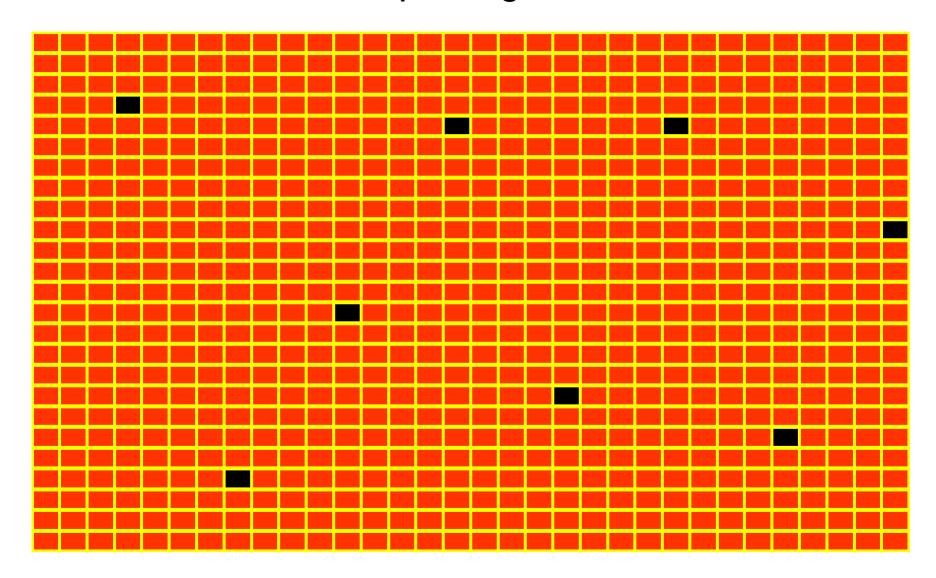
PERCENT _	NUMBER OF SAMPLES							
DEFECTS	1	5	10	15	20	30	60	
1	0.99	0.95	0.90	0.86	0.82	0.74	0.55	
2	0.98	0.90	0.82	0.74	0.67	0.55	0.30	
5	0.95	0.77	0.60	0.46	0.36	0.21	0.05	
10	0.90	0.59	0.35	0.21	0.12	0.04	< 0.005	
20	0.80	0.33	0.11	0.04	0.01	< 0.005	< 0.005	

10 samples collected, lot with *Salmonella* in 1% of samples, 90% probability that *Salmonella* will not be detected and the lot will be accepted.

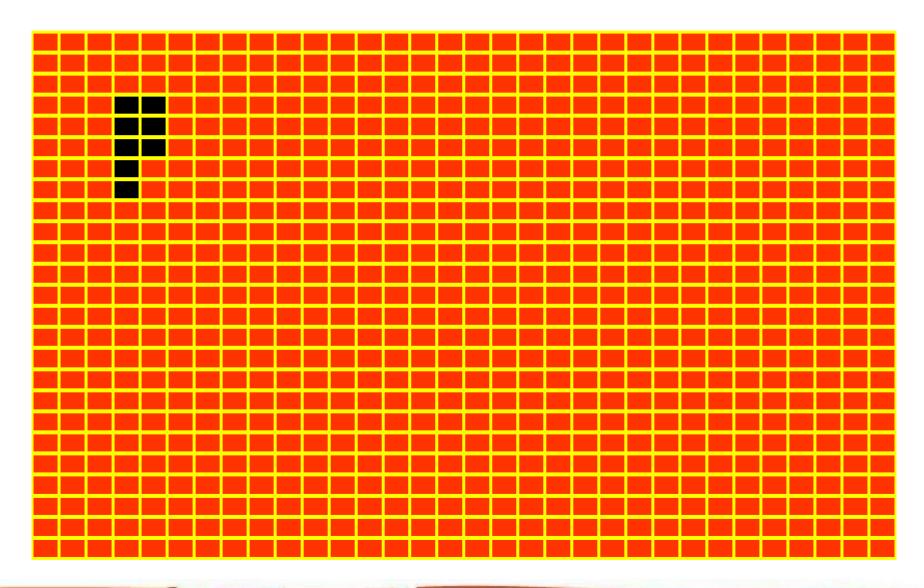
10 samples collected, lot with *Salmonella* in 10% of samples, 35% probability that *Salmonella* will not be detected and the lot will be accepted.

15 samples collected, lot with *Salmonella* in 5% of samples, 46% probability that *Salmonella* will not be detected and the lot will be accepted.

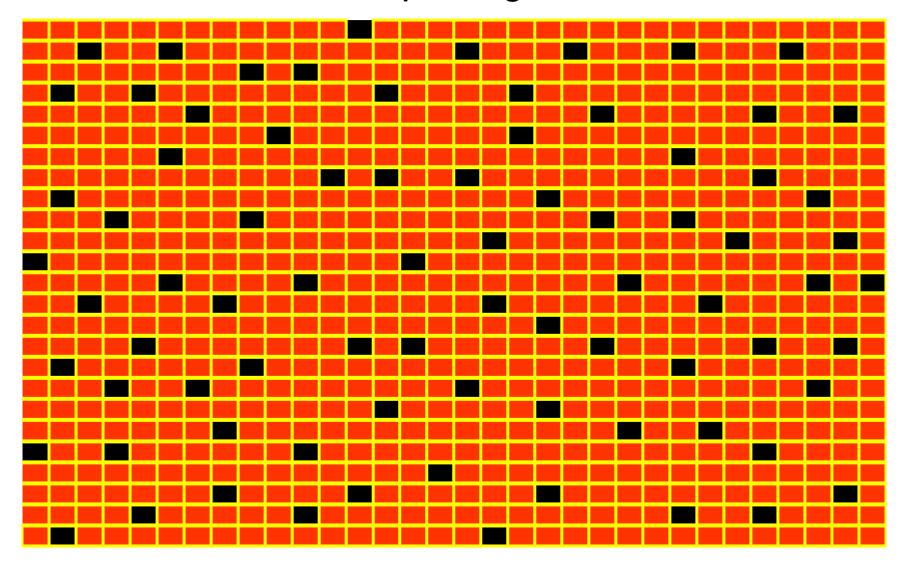
Microbiological Testing Role: Sampling 1% Failure Rate in 800 packages



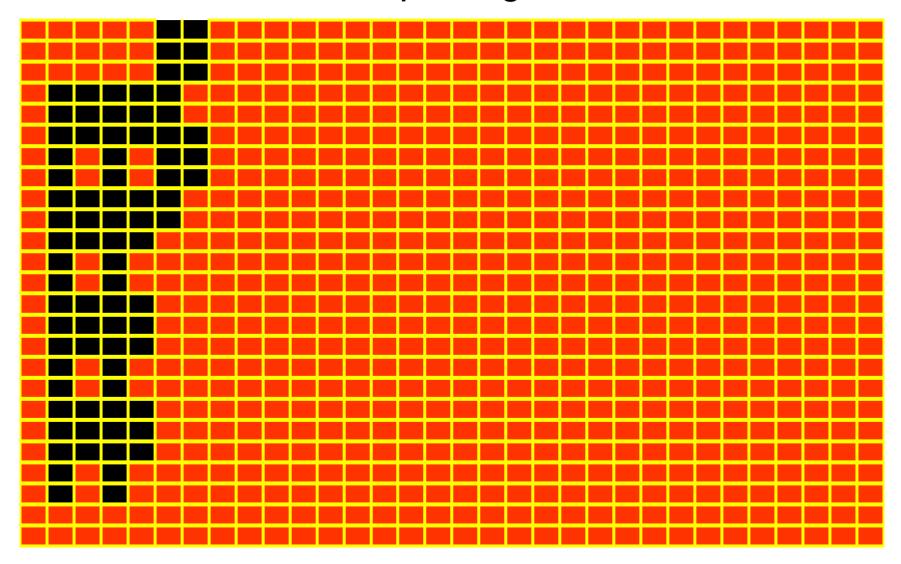
Microbiological Testing Role: Sampling 1% Failure Rate in 800 packages



Microbiological Testing Role: Sampling 10% Failure Rate in 800 packages



Microbiological Testing Role: Sampling 10% Failure Rate in 800 packages



Microbial Safety in Spices Conclusions

- Although it is clear that raw spices may be contaminated with microbial pathogens
- There are treatment and testing options available to ensure food safety and minimize risk.
- Comprehensive food safety plans must always include knowledge of ingredients, controlling the supply chain, auditing suppliers, and planning for supply chain interruptions.⁽¹¹⁾
- Food manufacturers must then consider these programs when determining use of treated versus untreated spice.

Microbial Reduction Regulatory Update

Microbial Reduction Regulatory Update

- Steam Treatment
- Irradiation
- Propylene Oxide
- Ethylene Oxide

Microbial Reduction Regulatory Update Steam Treatment

- Usage
 - No regulatory restrictions world-wide
- Labeling
 - No special labeling requirements

Microbial Reduction Regulatory Update Irradiation Usage on Spices

- US
 - 30 kGy max
- Canada
 - 10 kGy max
- EU
 - only permitted in EU approved irradiation plants
 - New UK Regulations responses due Apr. 27 '09
 - Aligns "spices and condiments" to "dried aromatic herbs, spices and vegetable seasonings" per 1999/2/EC

Microbial Reduction Regulatory Update Irradiation Labeling

- US
 - Wholesale whole product or component
 - Retail whole product
- Canada
 - Wholesale whole product or components
 - Retail whole or if irrad. components ≥10% of final product
- EU
 - Always wholesale & retail, whole product or component
- Verify local regulations, labeling and customer requirements

Microbial Reduction Regulatory Update Propylene Oxide

- Usage
 - US 300 ppm residue limit
 - EU not permitted
 - Japan 300 ppm residue limit
- Labeling
 - No special labeling required
- Verify local regulations, labeling and customer requirements

Microbial Reduction Regulatory Update Ethylene Oxide

- Usage
 - US, Canada, India, China, Mexico
 - Banned in many countries EU countries,
 Japan
- Labeling
 - Labeling is currently not required for EtO treated spices where treatment is permitted

Microbial Reduction Regulatory Update Ethylene Oxide Re-registration Status

- Dec. 31, 2008 EPA published proposed residue tolerances in Federal Register, comments due Mar. 2, 2009
 - EtO: 7 ppm in Crop Group 19
 - ECH: 940 ppm Crop Group 19 and dried vegetables
 - Basil not included as EtO treatment no longer permitted as of August 2007
- Crop Group 19 does not include all spices on ASTA spice list, expansion to full list requested
- Comments are under review by EPA
- Date of final ruling is not yet known

Spice Microbiological Safety & Microbial Reduction Regulatory Update

- Spice Micro Safety
 - Pathogen risk in untreated spices
 - Measured via sound sampling and testing
 - Mitigated via comprehensive food safety programs and validated treatment processes
- Treatment Regulatory Status
 - Acceptance and use varies by treatment type and country
 - Verify acceptance of treatment with customer to ensure meets expectations and local regulations