Managing Risk in a Zero Tolerance World: International Impact of Risk Assessment

The Changing Landscape: Implications of New Regulations on Risk Assessment

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Presentation

- Historical approach to microbiological safety of foods
- Technological changes that are impacting risk assessment and risk management
- Regulatory changes that are impacting risk assessment and risk management
- A 21st Century approach to microbiological safety of foods

Historical Approach

- U.S. regulatory agencies have few quantitative microbiological standards
  - Most U.S. regulatory limits are for pathogens with a “zero tolerance” for a positive result
  - A non-transparent approach based on sample size and test method to define adulterated foods
- The quantitative regulatory limits are typically based on indicators of poor hygienic practices
- For most RTE foods, industry commonly tested a single 25 gm sample for pathogens such as *Salmonella*

Historical Approach

- Examples of current US regulatory limits:
  - USDA Extra Grade non-fat dry milk:
    - ✓ Not more than 10,000/gm SPC
    - ✓ Not more than 10/ gm coliforms
    - ✓ *Salmonella*: negative in a 400 gm composite (5 x 80gm)
  - FDA limits for powdered infant formula:
    - ✓ *Salmonella* negative in 60 x 25 gm sub-samples
  - FDA limits for cheese:
    - ✓ "Generic" *E. coli*: n=5; c=2; m=10; M=100
    - ✓ *Salmonella*: negative in 10 x 75 gm sub-samples

Technological Changes & Risk Management

- Culture and enumeration methods have steadily improved over the past 50 years
- Epidemiological investigative techniques have improved (e.g., food consumption database)
- PFGE typing made PulseNet and FoodNet possible
- Whole Genome Sequencing allowed for an even greater level of sub-typing to identify outbreak cases and link those cases to a food source
- Better outbreak investigation is revealing ”root causes” and providing insight into exposure, dose-response, and sub-population susceptibility

Regulatory Changes & Risk Management

- Implementation of HACCP regulations brought greater attention to hazard identification and risk management
- Expanded use of Quantitative Risk Assessment (QRA) by regulators caused us to think more about exposure assessments, dose-response relationships, risk management options, and sub-populations
- U.S. FSMA regulations integrated HACCP and risk management throughout the supply chain and mandated a comprehensive food safety plan
- Regulators now place greater emphasis on environmental pathogen testing (swab-a-thon) and regulatory action
- Industry has increased environmental pathogen testing and is using larger sample sizes for finished product pathogen testing (e.g., high resolution testing)

Field/Raw	POSITIVE	NEGATIVE	N	% Positive
Apple raw/core	560	8,557	9,117	6.14%
Leafy Greens	87	14,522	14,609	0.60%
Spinach	485	91,681	92,166	0.53%
Kale	38	9,556	9,594	0.40%
Chard	42	13,172	13,214	0.32%
Brussel Sprout	6	1,930	1,936	0.31%
Arugula	26	13,890	13,916	0.19%
Cilantro	10	9,298	9,308	0.11%
Lettuce	146	141,724	141,870	0.10%
Mustard	2	2,180	2,182	0.09%
Parsley	1	1,425	1,426	0.07%
Broccoli	2	3,900	3,902	0.05%
Carrot	4	10,044	10,048	0.04%
Cabbage	4	11,606	11,610	0.03%
iceberg	5	17,893	17,898	0.03%
Romaine	6	35,737	35,743	0.02%
Tomato	0	6,710	6,710	0.00%
Green Onion	0	3,992	3,992	0.00%
Cauliflower	0	1,294	1,294	0.00%
	1,424	**399,111**	**400,535**	0.36%

Produce: Field/Raw Pathogen* Prevalence 2014-2016

(Commodities with N>1,000)

* *Salmonella*, EHEC, *L. monocytogenes*

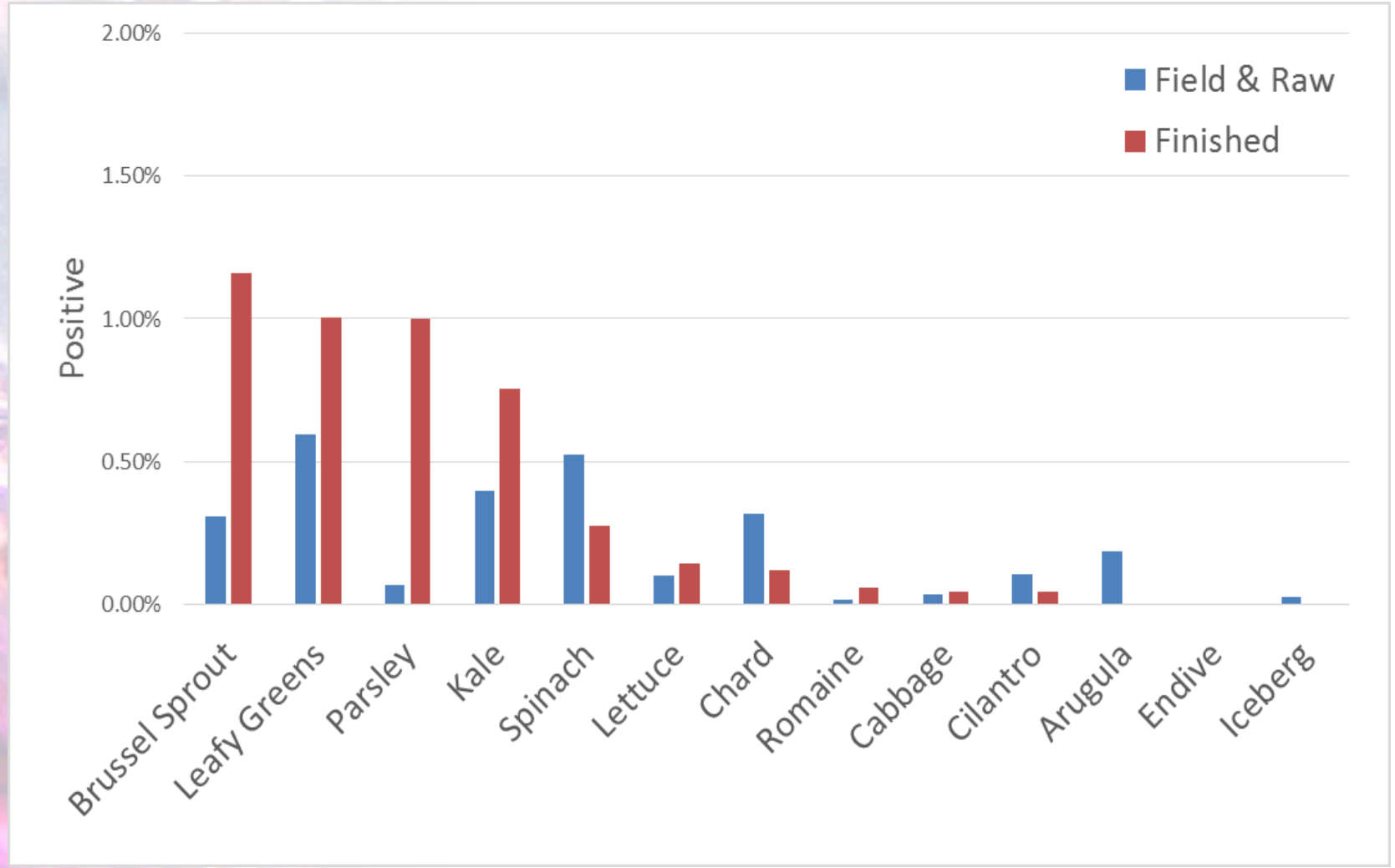
FINISHED	POSITIVE	NEGATIVE	N	% Positive
Brussel Sprout	29	2,503	2,532	1.16%
Leafy Greens	60	5,962	6,022	1.01%
Kale	100	13,276	13,376	0.75%
Broccoli	32	7,035	7,067	0.45%
IQF	88	19,846	19,934	0.44%
Apple Slices	155	47,355	47,510	0.33%
Spinach	53	19,326	19,379	0.27%
Cauliflower	11	5,051	5,062	0.22%
Lettuce	63	44,306	44,369	0.14%
Carrots	28	20,353	20,381	0.14%
Veggies Mixed	3	2,368	2,371	0.13%
Celery	15	11,883	11,898	0.13%
Mango	2	1,901	1,903	0.11%
Romaine	13	21,736	21,749	0.06%
Leafy Mix	10	17,509	17,519	0.06%
Cabbage	7	15,830	15,837	0.04%
Cilantro	4	9,291	9,295	0.04%
Peppers	6	14,579	14,585	0.04%
Green Onion	5	18,095	18,100	0.03%
Tomato	7	51,058	51,065	0.01%
Onion	1	21,005	21,006	0.00%
iceberg	0	9,466	9,466	0.00%
Slaw	0	6,600	6,600	0.00%
	692	**386,334**	**387,026**	0.18%

Produce: Finished Pathogen* Prevalence 2014-2016

(Commodities with N>1,500)

** Salmonella,* EHEC, *L. monocytogenes*

Leafy Greens Pathogen Prevalence 2014-2016



	N =	
	Field & Raw	Finished
Brussel Sprout	1,936	2,532
Leafy Greens	14,609	6,022
Parsley	1,426	101
Kale	9,594	13,376
Spinach	92,166	19,379
Lettuce	141,870	44,369
Chard	13,214	825
Romaine	35,743	21,749
Cabbage	11,610	15,837
Cilantro	9,308	9,295
Arugula	13,916	748
Endive	825	13
Iceberg	17,898	9,466

The Impact of Changes in Technology & Regulation

- We are finding pathogens in foods more frequently.
- We are learning more about routes of pathogen contamination during growing, harvesting and processing
- We are seeing more food recalls
- We are identifying smaller outbreaks of foodborne illness than were once thought to be “sporadic” cases
- We are learning more about the prevalence of pathogens in raw agricultural products and fresh produce
- We have yet to adapt our regulatory risk management strategies based on this new knowledge

21st Century Approach

- The idea that non-kill step RTE foods must be pathogen free for any reasonable sample size and test method **is doomed**
- Setting regulatory action limits for pathogens requires QRA using a non-threshold model considering each sub-population with a different susceptibility
- For some RTE foods that do not have kill step, a low level of pathogen contamination may be unavoidable or it may be too costly to make these foods pathogen-free
- We need to focus on food production practices and routes of contamination to reduce the prevalence of pathogens in non-kill step RTE foods to a level that is as low as reasonably possible.

21st Century Approach

- Fill data gaps on the effects of food production and harvesting practices on the prevalence of pathogens on RTE non-kill step foods.
  - Get more data on pathogen exposure at the time of consumption
  - Get more data on consumer food safety behaviors
- Use QRA to establish performance standards for RTE non-kill step foods.
- Use alternative risk management strategies for the most vulnerable sub-populations.
- Provide information that will encourage consumers to make sound food safety decisions.
- For processed foods, we need to know more about modes of failure and better educate food industry leadership