A Multi-Hurdle Approach to Food Safety

COLLABORATIVE FOOD SAFETY FORUM
Role of Testing in FDA's Hazard Analysis and Risk-Based Preventive Controls Rule
March 22, 2013

Earthbound's History

- Fresh Cut and produce since 1984
  - Development of fresh cut processing
- Became national circa 2000
  - Shelf life challenge
- Summer of 2006
- What did we do?
  - Risk assessment lead to multi-hurdle approach with strong emphasis on testing

Testing Programs

- Input testing in the field
  - O0157-H7, EHEC, Salmonella
  - Water, fertilizer, transplants, seed?
- Environmental testing in our facility
  - Listeria zone program, weekly; 15 sites, zone 2 and 3
  - Air monitoring, monthly; TPC, Yeast and Mold
  - Water samples, weekly; TPC
  - Weekly zone 1; TPC
- Field tissue testing
  - O0157-H7, EHEC, Salmonella
  - Mostly for fields with dual purpose
- Raw and Finished Goods Tissue Testing

Development of the Tissue Sampling Plans

- Looked outside of produce
  - Beef industry trim sample program
  - ICMSF case 15
- Designed to catch a gross contamination event.
  - Paicines Ranch 2006: 500 pounds harvested from an acre (acre's harvest = approximately 7500 pounds)
  - We challenged our scientists to devise a plan that would catch this level of contamination and let us remove it from the stream of commerce.
- This precise sampling plan was developed with a confidence interval of 99.9% assuming uniform contamination.
  - Over time we have learned this is usually not the case

The Field Sampling Plan

- Field is broken down into 1 acre sample lots in fields used for commodity field pack and processing
- 60 grabs are taken from each acre, for a total sample of 150 grams. Grabs taken in z pattern.
- Other methods tried with no apparent improvement in detection
- Head lettuce vs baby greens
- Sampling has changed on head lettuce with greater efficacy
- PCR analysis: O0157-H7, EHEC, Salmonella

The Raw Product Sampling Plan

- 1 truckload = approx 24 pallets of greens, all harvested from the same part of the same field
- Truckload segregated into 6 production units, comprising 4 pallets each (approx 1500 pounds)
- 60 grabs are taken from each 4-pallet production unit, for a total sample of 150 grams. Grabs taken from all over.
- Will move to n=300 when in high risk situation
- PCR: O0157-H7, EHEC, Salmonella, Shigella

Finished Goods Sample Program

- Production day broken down into 2 hour manufacturing units
  - Each pack line is sampled from (15 lines)
  - 60 grabs, 150 g sample
  - Auto-sampling
  - PCR, O0157-H7, EHEC, Salmonella
- In the event of a positive:
  - Libraried water samples tested
  - Matrix developed
    - Like materials, test history
    - Like washlines
    - Other testing results during day
- Flanking units remain on hold

The Nature of Contamination Events

- Likely to be sporadic and localized, not widespread in a particular field
- Remember Paicines
  - Small amount of product involved
- Anything likely to cause widespread contamination would be cause to disc an entire block – such as a flood

Customer Testing Requirements

- Costco, YUM! Brands
- Costco: **Ready-to Eat Microbiological Finished Product Specifications**
  - TPC Target < 5,000,000 cfu/g Maximum 10,000,000 cfu/g
  - Generic E.coli Target < 10 Maximum 100 cfu/g
  - EHEC Negative
  - Salmonella: Negative
- Pesticide Residues PRODUCT IS REQUIRED TO HAVE RESIDUE LEVELS BELOW LEGAL LIMIT FOR ALLOWED PESTICIDES.
- ORGANIC PRODUCT must comply with NOP Regulations regarding pesticide residues.
- NO PRODUCT CAN BE DELIVERED UNTIL ALL TEST RESULTS ARE COMPLETED (TEST AND HOLD)

Test & Hold
Molecular Confirmation Incident Rate - Data

Field MC	Yuma 07/08	SJB 2008	Yuma 08/09	SJB 2009	Yuma 09/10	SJB 2010	Yuma 10/11	SJB 2011	Yuma 11/12	SJB 2012	Total
# of MCs	1	15	1	20	6	10	26	4	35	30	148
Samples	500	2458	1074	2017	904	2351	2191	2295	1622	1649	17061
% of Field MCs	0.200%	0.610%	0.093%	0.992%	0.664%	0.425%	1.187%	0.174%	2.158%	1.819%	0.867%

Raw MC	Yuma 07/08	SJB 2008	Yuma 08/09	SJB 2009	Yuma 09/10	SJB 2010	Yuma 10/11	SJB 2011	Yuma 11/12	SJB 2012	Total
# of MCs	19	152	82	373	158	455	198	103	397	872	2925
Samples	47547	33547	40157	39340	42761	32521	37774	31920	39127	30677	375371
% of Raw MCs	0.040%	0.453%	0.204%	0.948%	0.369%	1.399%	0.524%	0.686%	1.015%	2.843%	0.779%

FGS MC	Yuma 07/08	SJB 2008	Yuma 08/09	SJB 2009	Yuma 09/10	SJB 2010	Yuma 10/11	SJB 2011	Yuma 11/12	SJB 2012	Total
# of MCs	0	8	0	9	9	1	2	7	20	26	82
Samples	32920	35420	28834	36572	34029	42699	34019	45206	38605	34966	363270
% of FGS MCs	0.000%	0.023%	0.000%	0.025%	0.026%	0.002%	0.006%	0.015%	0.052%	0.074%	0.023%


Earthbound Farm
ORGANIC
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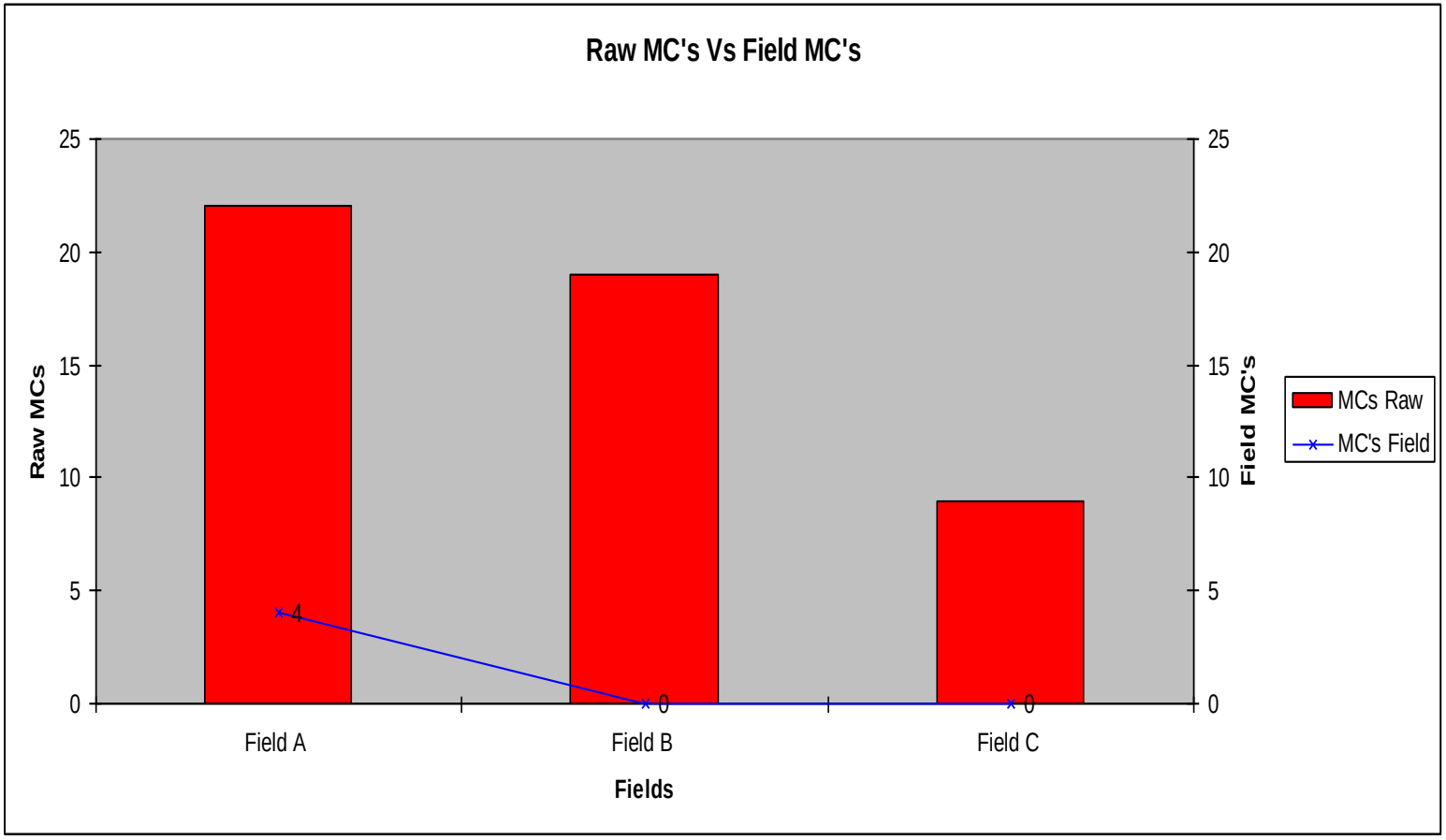
Raw MC's Vs Field MC's
25
20
15
10
5
0
Raw MCs
Field MC's
4
0
0
Field A
Field B
Field C
Fields
MCs Raw
MC's Field


Lot 84, Total acreage = 27 Acres. Second planting rotation = 24.65 acres, plantings A2 to D2, 88 beds
Sample 21 Negative Result
Sample 11 Negative Result
Sample 1 Negative Result
Sample 31 Negative Result
Sample 41 Negative Result
Sample 22 Negative Result
Sample 12 Negative Result
Sample 2 Positive Result - EHEC
Sample 32 Negative Result
Sample 42 Negative Result
Sample 23 Negative Result
Sample 13 Negative Result
Sample 3 Negative Result
Sample 33 Negative Result
Sample 43 Negative Result
Sample 24 Negative Result
Sample 14 Negative Result
Sample 4 Negative Result
Sample 34 Negative Result
Sample 44 Negative Result
Sample 25 Negative Result
Sample 15 Negative Result
Sample 5 Negative Result
Sample 35 Negative Result
Sample 45 Negative Result
Sample 26 Negative Result
Sample 16 Negative Result
Sample 6 Negative Result
Sample 36 Negative Result
Sample 46 Negative Result
Sample 27 Negative Result
Sample 17 Negative Result
Sample 7 Negative Result
Sample 37 Negative Result
Sample 47 Negative Result
Sample 28 Negative Result
Sample 18 Negative Result
Sample 8 Negative Result
Sample 38 Negative Result
Sample 48 Negative Result
Sample 29 Negative Result
Sample 19 Negative Result
Sample 9 Negative Result
Sample 39 Negative Result
Sample 40 Negative Result
Sample 30 Negative Result
Sample 20 Negative Result
Sample 10 Negative Result

Sporadic Contamination Requires a Precise Sampling Plan

- If all contamination were widespread, then we wouldn't need to do so much sampling – fewer samples would tell the tale and the whole field block would be indicted.
- But because contamination is likely to be localized and sporadic, we had to develop a sampling plan that touches every row of every field and lets us isolate those areas affected by the contamination.


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Q & A
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