

CPS Tri-State special project on harvest equipment:
A data-informed consensus of
“clean for the intended purpose” – Special Project

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Research Team

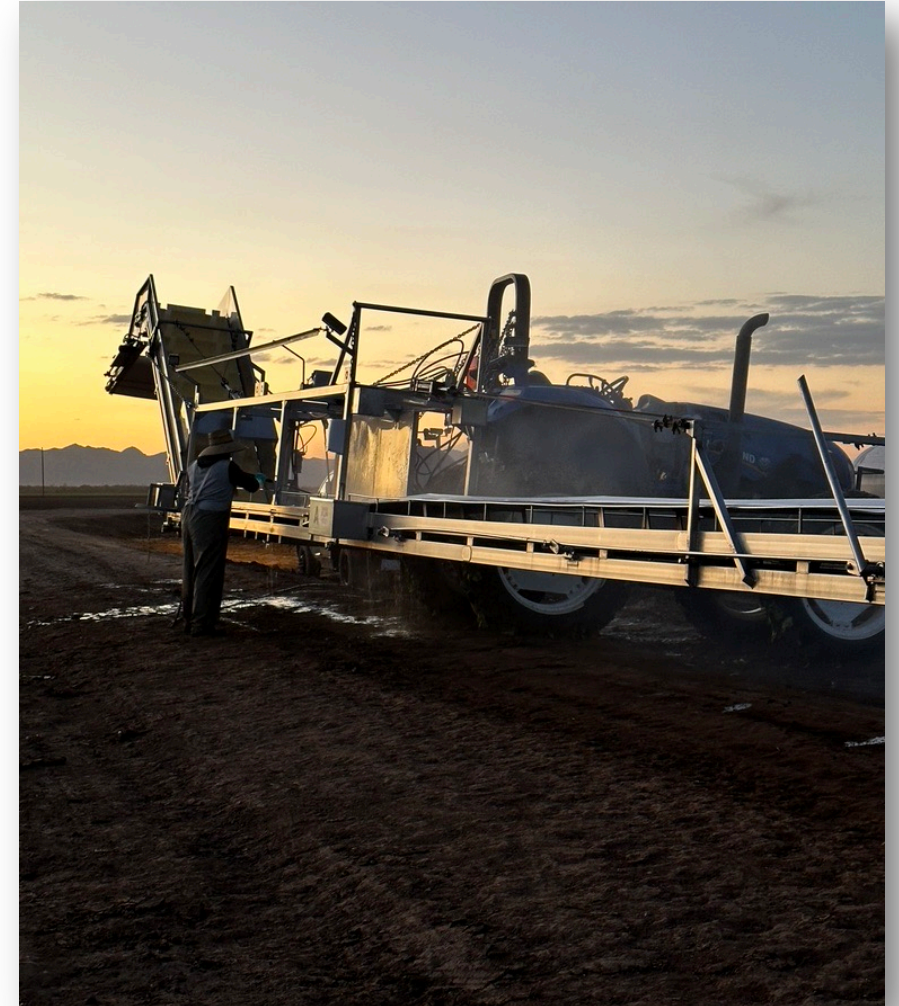
Channah Rock, University of Arizona

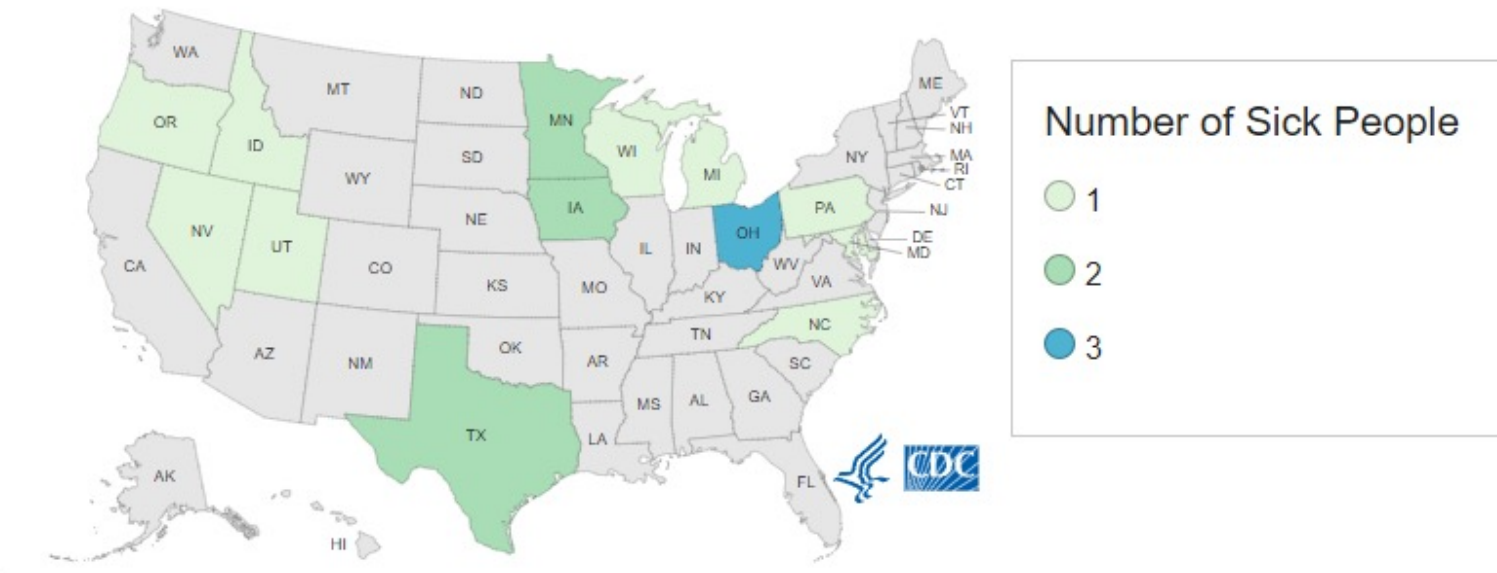
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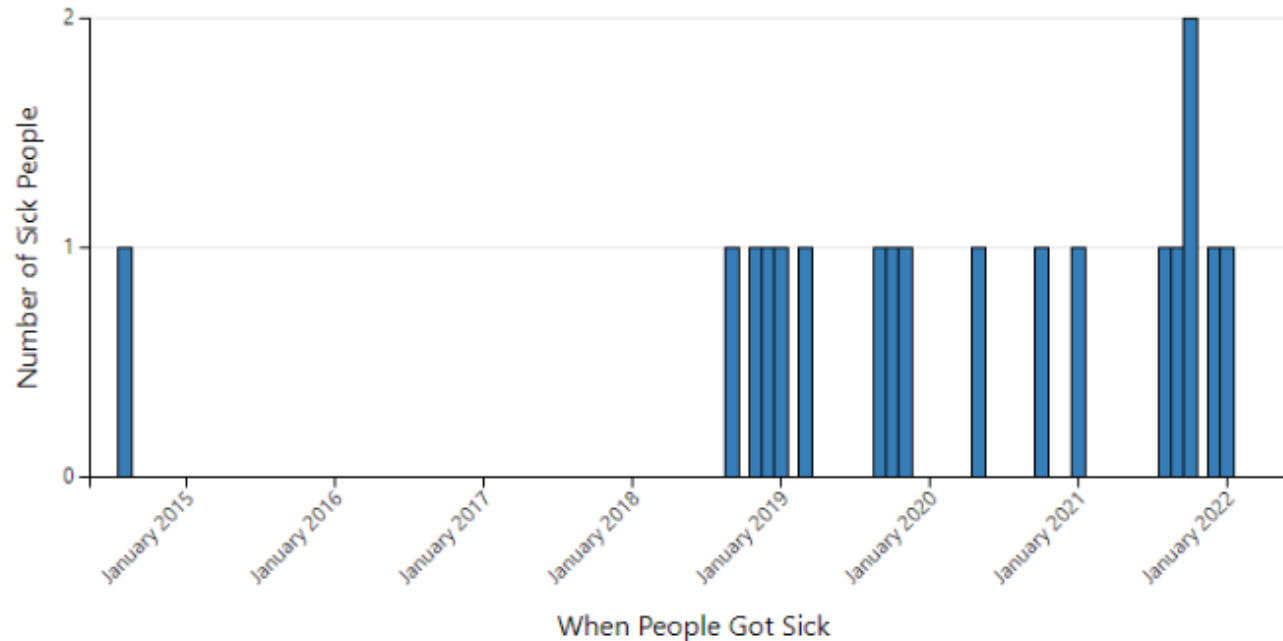


2021 Outbreak of *Listeria* Linked to Dole Packaged Salads

Total Illnesses – 18

Hospitalizations – 16

Deaths – 3



<https://www.cdc.gov/listeria/outbreaks/packaged-salad-mix-12-21/details.html>

DOLE CONDUCTS AN RCA

- In October 2021, Georgia Department of Agriculture identified Listeria in a Dole brand garden salad as part of a routine sampling program of food at grocery stores.
 - WGS later showed that the Listeria in the garden salad was the outbreak strain.
 - The garden salad was produced at Dole's Bessemer City, North Carolina, facility.
- After CDC reopened this outbreak investigation, the Michigan Department of Agriculture and Rural Development collected samples of packaged salads from retail stores for testing
 - Identified the outbreak strain of Listeria in a Marketside brand package of shredded iceberg lettuce.
 - The shredded iceberg lettuce was produced at Dole's Yuma, Arizona, facility.

DOLE CONDUCTS AN RCA

- Dole collects samples from their facilities and equipment
 - **Listeria** found on harvest equipment matching outbreak strain
- Dec 22, 2021 recall of all products packed in NC and AZ
- Jan 7 of all products containing iceberg harvested on contaminated equipment.



For more information <https://contactproducesafety.ifas.ufl.edu> webinar with Natalie Dyenson and Justin Kerr on harvest sanitation.

INDUSTRY NEED

FDA U.S. FOOD & DRUG ADMINISTRATION Search Menu

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FY 23/24 Inspection and Environmental Sampling of Leafy Green Harvest Equipment for Listeria monocytogenes and E. coli O157:H7

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Sampling to Protect the Food Supply

[Environmental Sampling](#)

The U.S. Food and Drug Administration (FDA) is conducting inspections of harvest operations and collecting environmental samples from harvest equipment after an outbreak strain of *Listeria monocytogenes* was recovered from harvest equipment in 2022. The FDA is seeking to gain insights about the potential for human pathogens to persist on harvest equipment after routine cleaning and sanitizing and to be subsequently transmitted to produce. Accordingly, the agency has designed this assignment, which centers on the inspection and swabbing of harvest equipment. This assignment is a part of the FDA's [Leafy Greens STEC Action Plan](#), an ongoing preventative effort to help ensure the microbiological safety of leafy greens.

Content current as of:
06/13/2023

Regulated Product(s)
Food & Beverages

INDUSTRY QUESTIONS

- How does “visually clean” relate to daily ATP swabs?
- To periodic micro-testing (if done at all)?
- An audit checklist isn’t adequate unless linked to data
- How frequently should cleaning occur?
- How frequently should C&S occur? Deep cleaning?



GOAL

*The intent of this research project was to develop a **dynamic, aggregated, and confidential dataset** from which to offer leafy greens growers, shippers, handlers, harvest contractors, and processors to integrate outcomes into “real-time” opportunities for continual improvements and preparedness for audits and inspections.*



MEET THE TEAM!



Trevor Suslow
T&K Suslow Consulting, LLC.



Channah Rock
University of Arizona
Michelle Danyluk
University of Florida



Justin Kerr
Factor IV Solutions

OBJECTIVES

Harvesting Machine Types

3-Point Belt Harvester



Self Propelled Belt Harvester



METHODS

Sample Collection



- ATP (Charm Field Format)
- Aerobic Plate Count (APC)
- Total Coliform bacteria
- Generic *E. coli*

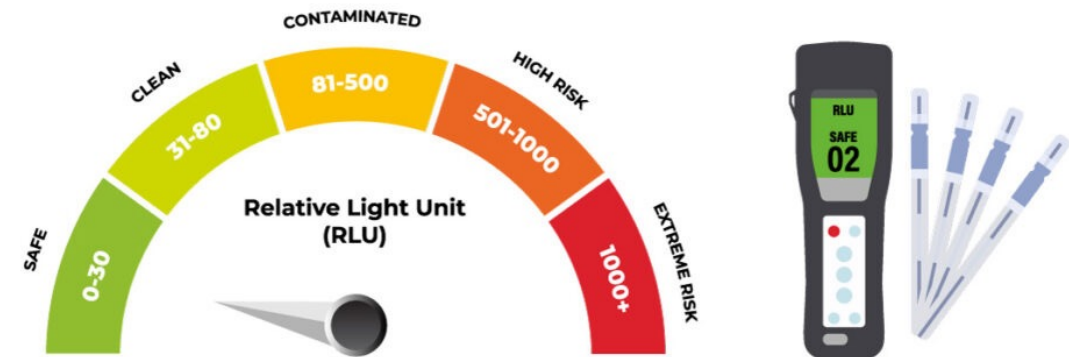
VERIFICATION OF CLEANING & SANITATION WITH TESTING

- Procedures to show the effectiveness of cleaning procedures or the entire sanitation program
- **NOT** a requirement of the Produce Safety Rule
 - May be a requirement of Audit Scheme or Buyers

Cleaning Verification	Sanitation Verification
ATP testing	Microbial testing

ATP TESTING

- Indication of cleanliness
 - Measure of ATP presence on a surface
- Monitoring Premise
 - Uses Firefly enzymes to measure amount of bioluminescence in Relative Light Units (RLUs)
 - Light generated is proportional to the amount of ATP present in the sample
 - Reaction is immediate – real time monitoring
- Limitations
 - Very little correlation with microbial load or presence of pathogens



MONITORING FOR APC

- Entry point – useful for first time swabbing, and continued use on food contact surfaces
- Look at hard to reach points, not easy to clean surfaces
- If higher counts are found:
 - develop new cleaning/sanitation methods
 - swab more frequently
 - add adjacent locations
- Update SSOPs to focus on these difficult areas

WHAT ABOUT MICRO TESTING?

Indicator Organisms

- Directly verify effectiveness of cleaning and sanitizing
- Serves as an early warning – if indicators can grow, pathogens may too
- Examples:
 - APC (Aerobic Plate Count, Total Count)
 - Coliforms
 - *Generic E. coli*
 - *Listeria* spp.

Pathogens

- Used to verify control Measures
- Serves in a “seek & destroy” program
- Examples
 - *Listeria monocytogenes*
 - *Salmonella*

Don't do this unless you are ready for the results



SUGGESTING SAMPLING IN VARIOUS ZONES













Zone	ATP	Indicators	Pathogens
1			
2			
3			
4			

Chart is just a suggestion for typical sampling.

Adjustments should be made based on results, or if you are investigating a problem

Please talk to SMEs (or someone) before you start sampling for pathogens

METHODS

Sample Collection Time-Points

- 25-point swab pre-cleaning (post-harvest) **PH**
- 25-point swab post-cleaning (wash down, detergent application, and rinse) **PD**
- 10-point swab post-cleaning and sanitizing (wash down, detergent application, rinse, and sanitizer). **PS**



METHODS

Section Routine Verification Swab Location Descriptions

- **Section A:** Includes the drive roller, Top of conveyance, Inside conveyance
- **Section B:** Belt Guides, Side walls, Support Rollers on bottom
- **Section C:** Spray Tunnel inside, Spray tunnel Flaps, Spray tunnel Mounts to harvester (weld/bolts)
- **Section D:** Incline Drive Roller, Top of conveyance, Inside Conveyance
- **Section E:** Collar Structure, Collar Belt or Cute, Collar Mounts (weld/bolts)



METHODS

Field Report Out Information Per Event

iAuditor Software used to track events in “real time”

Type of detergent , mix ratio (example 4oz. To 1 gallon of water)	Wind speed at time of swab collection
Type of sanitizer, ppm's of (chlorine, quat, PAA, etc.)	Belt type(s) monolithic, vinyl cloth backed, stainless belt bar & chain
Type of brush and surface assignment	Access to collar (can it be lowered or is platform or ladder used for cleaning high points
Method of application detergent and sanitizer (pump sprayer, venturi or batch foamer)	Number of employees completing the wash
Time of day	Total time to collect ATP and micro swabs
Temperature at time of wash	Belt speed , total time per rotation during wash
Product harvested	List of specialty tools or chemicals used
Location of wash (in-field, adjacent road, shop, etc.)	Total gallons of water used in wash
ATP results (Charm NOVALUM IIX w/ 20,000 RLU pass setting	Micro results for all 60+ locations



Event Data	
What is the CPS Harvester ID #?	AZ1
What time did the sanitation event start?	15:30 MST
What was the crop harvested for the sanitation event?	Romaine
Name(s) of observer of sanitation event?	CMR, DZ, Geo
Sanitation Utilities	
	0 / 1 (0%)
Is sanitation using a Truck or Trailer?	Truck
Total water volume in gallons at start of wash?	325
Total water volume at completion of wash?	150
Did sanitation need to refill water tank during event?	No
If water was added how many gallons?	0
How many pressure washers are used for sanitation?	1
Is there heated pressure washing available?	No
How many employees are used for sanitation?	1
Does the sanitation vehicle have lighting for event?	N/A

Is detergent applied with pump sprayer?

Yes



Photo 3

How many gallons are used from pump sprayer

1

Is detergent applied with buckets and brushes?

No

If detergent is manually mixed what is the oz./gallons?

Premade

What is the sanitizer type? (Review SDS)

Chlorine

200ppm

Are disposable scrub pads used?

Yes



Photo 4

Are brushes used?

No

Are color codes applied to use of brushes?

N/A

Are brushes of hygienic design? (bristles, handles)

N/A

FDA SAMPLING

- FDA called growers weeks in advance to notify.
- Told growers to clean the harvester like “normal” the day before FDA visit.
- Day of FDA Visit
 - Harvest minimum 1 hr.
 - Observed full cleaning and sanitation protocol.
 - Collected post-sanitation swabs
- Sampling Events
 - 64 swabs/event - tested exclusively for *L. monocytogenes* and STEC
 - Focused on food contact and not food contact surfaces, but not decided in advance
 - 12 in CA, 10 in AZ, and 6 in FL.
- No positives found (to the best of our knowledge)



FIND THE SOLUTIONS

Sampling



30 Visits



23 Harvesters



4 Crop Types

	Visits	Harvesters	Crop Types
Arizona	11	9	Romaine, Cabbage
California	9	9	Romaine, Green Leaf, Iceberg
Florida	10	8	Iceberg, Cabbage

Total number of swabs = 6,196

Total number of data points = 557,444



Sample Settings

- AZ, CA, and FL
- October 12th – May 14th
 - Afternoon - Evening
- 23 Harvesters
 - Self-propelled
 - Three-point
 - Top and Tail box

Wind and temperatures at the beginning of cleaning and sanitizing

	Wind (MPH)	Temperature (° F)
Min	1	58
Median	8	73.5
Mean	9.5	72.7
Max	27	87

FIND THE SOLUTIONS

Cleaning and Sanitation Events

	Total (min)*	Cleaning (min)	Sanitizing (min)	Water (Gal)	Dedicated Staff
Min	22	22	8	65	1
Median	104	85.5	13.5	200	2
Mean	105.2	90.5	20.1	198.5	2.8
Max	225	203	89	500	7

*Some cleaning and sanitation steps were completed in one step

FIND THE SOLUTIONS

Cleaning and Sanitation Chemicals

Detergents	Sanitizers	Sanitizer Concentration (ppm)
Non-chlorinated alkaline	Chlorine	50-200
Non-chlorinated alkaline	Quat	200
Non-chlorinated alkaline	Silver ion/chlorine	200
Sodium hydroxide	Chlorine	100-200
Sodium hydroxide	Quat	-
Chlorinated caustic blend	Chlorine	100-200
Chlorinated sodium hydroxide	Chlorine	200
Chlorinated sodium hydroxide	Quat	50-400
Chlorinated sodium hydroxide	Silver ion/chlorine	200
Chlorinated potassium hydroxide	Chlorine	4-200
Acid blend (proprietary)	Chlorine	150
Acid blend (proprietary)	Quat	200



Cleaning and Sanitation Tools

	Frequency (n=30)
Hygienically Designed Brush Use	88.0%
Brushes Color Coded (n=25)	56.0%
Platform/Ladder	69.2%
Dedicated Trucks	53.3%
Sanitation Trailers	33.3%
ATP Machine	43.3%

*Other tools include belt scrub pads, scrub pads, sponges, and steel wool

Cleaning and Sanitation Tools

BELT/IN-LINE SCRUBBER

- Can reduce labor while increasing cleaning frequency.
- Requires monitoring and may require additional cleaning of the surface.

FIND THE SOLUTIONS



Adenosine triphosphate (ATP)

ATP Swabs above $\geq 20,000$ RLU (%)

Total	PH (n=660) 96.9%	PD (n=489) 62.0%	PS (n=382) 41.3%
A (n=155)	97%	59%	53%
B (n=150)	99%	61%	47%
C (n=151)	95%	56%	39%
D (n=105)	98%	72%	35%
E (n=105)	94% →	62% →	32%



FIND THE SOLUTIONS

E. coli



Swabs where *E. coli* was detected ≥ 10 CFU (%)

	PH (n=659)	PD (n=492)	PS (n=382)
Total:	6.2%	5.3%	1.1%
A (n=155)	5.2%	2.6%	0.6%
B (n=146)	7.1%	6.4%	1.4%
C (n=148)	4.0%	5.3%	0.7%
D (n=105)	11.4%	3.8%	1.9%
E (n=105)	3.8%	8.6%	1.0%



FIND THE SOLUTIONS

Total Coliforms (TC)



TC changes between swab time points (log CFU/swab)

	PH TO PD (n=493)	PD TO PS (n=208)	PH TO PS (n=381)
Min	-4.25	-2.34	-3.54
Median	0.00	0.00	0.00
Mean	0.09	0.36	0.32
Max	6.71	3.99	6.13

(-) means it got worse (+) means it got better

FREQUENCY OF INCREASES BY ZONE



Zone	APC Post Harvest to Post Detergent N = 487	TC Post Harvest to Post Detergent N = 493	ATP Post Harvest to Post Detergent N = 489
A	27.2%	30.9%	17.2%
B	19.8%	29.5%	11.4%
C	30.20%	41.7%	17.6%
D	28.2%	40.0%	15.3%
E	34.1%	40.0%	12.3%

Zone	APC Post Detergent to Post Sanitation N = 208	TC Post Detergent to Post Sanitation N = 208	ATP Post Detergent to Post Sanitation N = 195
A	56.0%	12.0%	58.3%
B	41.7%	18.8%	41.3%
C	35.7%	19.0%	55.0%
D	35.3%	26.5%	35.5%
E	35.3%	17.6%	33.3%



HOW TO LOOK AT THE DATA

The vertical Axis is a log reduction – the different in the number of organisms or ATP between the two swabbing points

Some of the data is split between different surface types

Food Contact (**FC**) Zone 1

Non Food Contact (**NFC**) Zone 2 & 3

Above the green line is **good!** It means more reduction

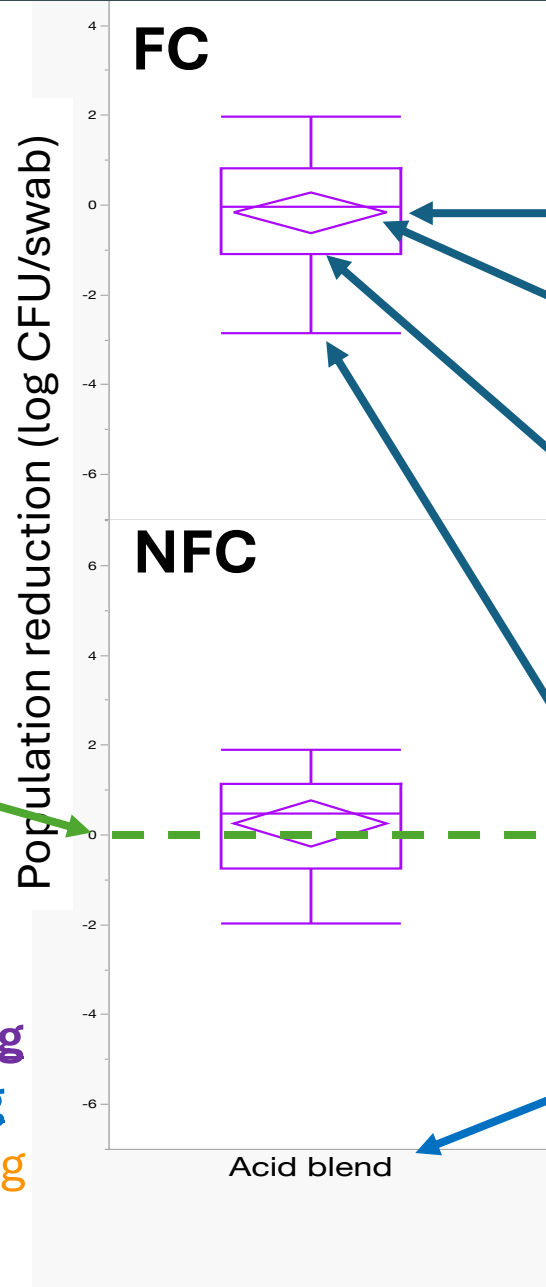
The green **line** means **no change**

Below the green is **not good!** It means more bacteria than how it started

Purple data are reductions during cleaning

Blue data are reductions during sanitizing

Orange data are the total reductions during cleaning AND sanitizing



This type of a graph is called a box and whisker plot, or just a box plot

The line in the middle is the median

The diamond is the mean

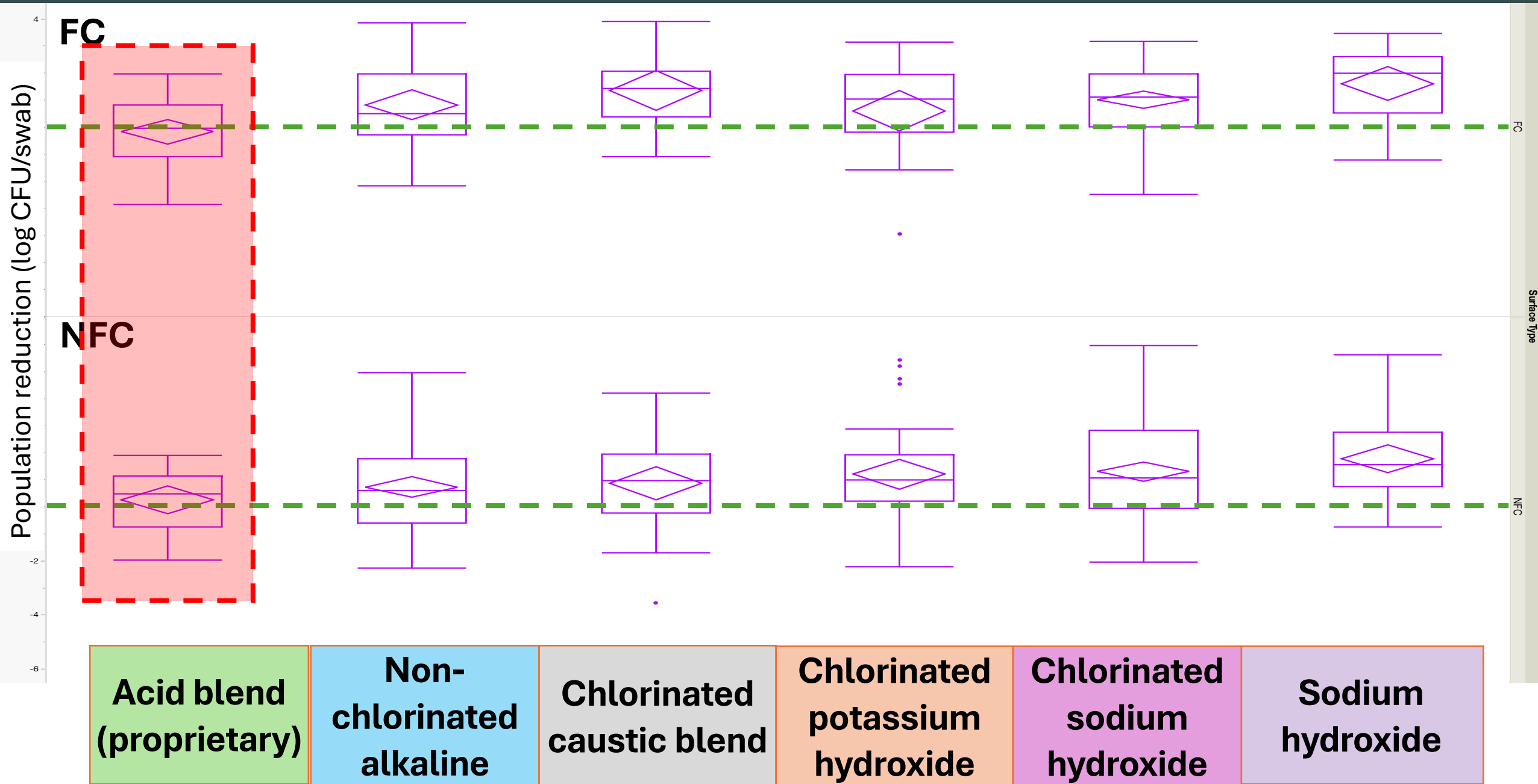
The box represent where 50% of the data is found, 25% above the median and 25% below the median

The whiskers are 1.5 times the 25% range of the box.

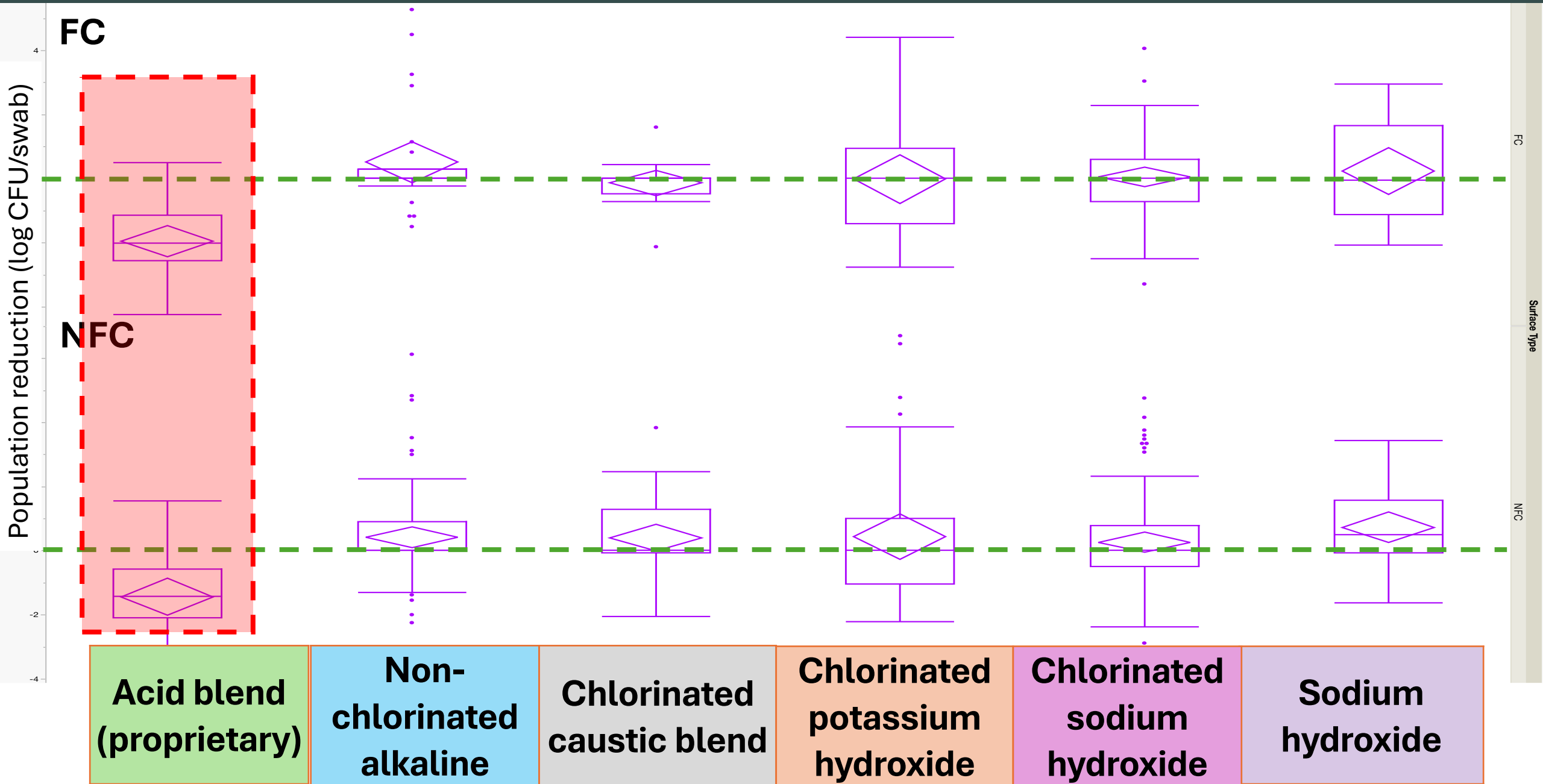
Any datapoints that fall beyond this whiskers are considered outliers

Along the bottom is the variable we're looking at: zones; sanitizers; detergents; time; etc.

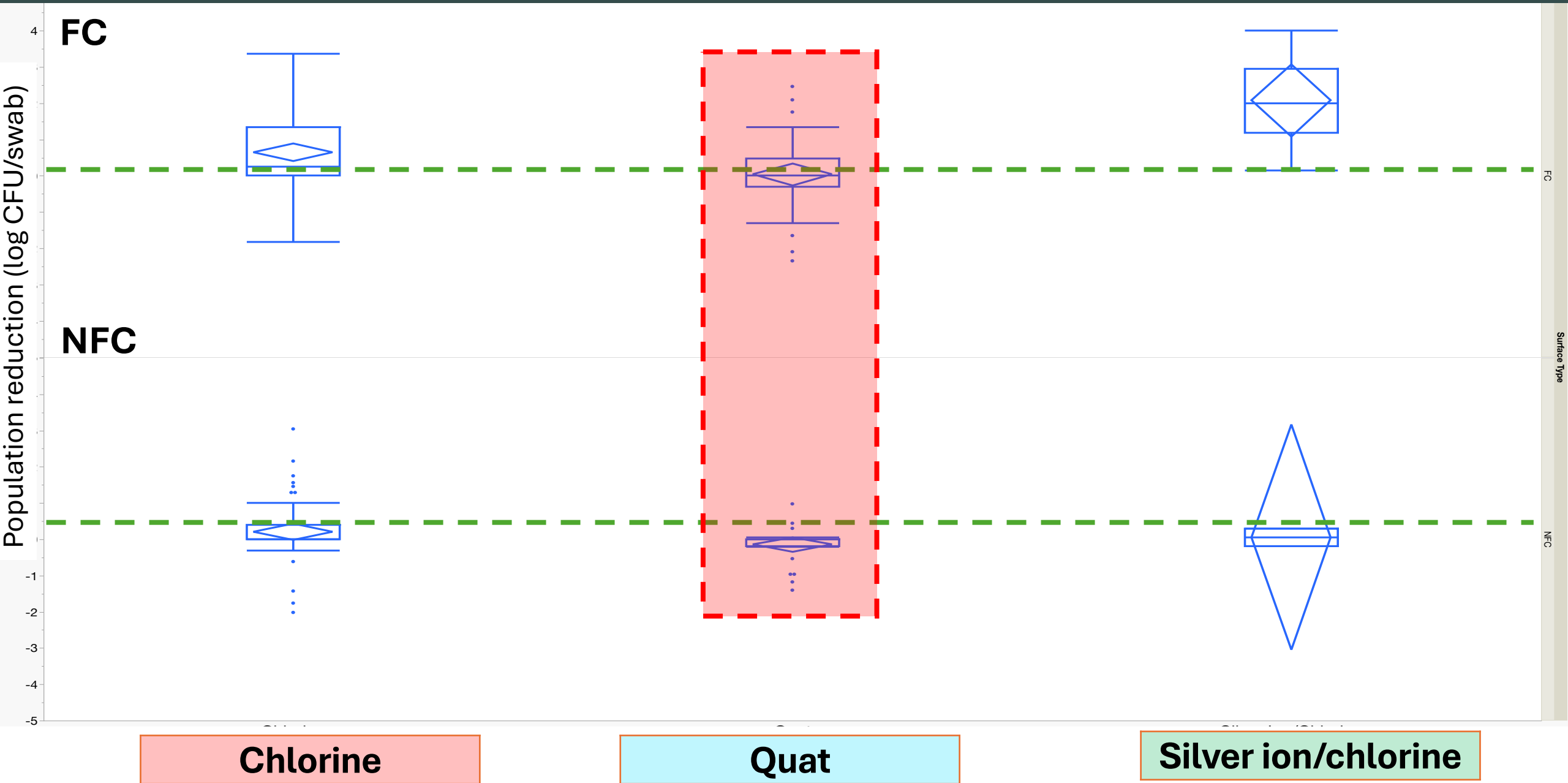
APC POPULATION REDUCTIONS BY DETERGENT



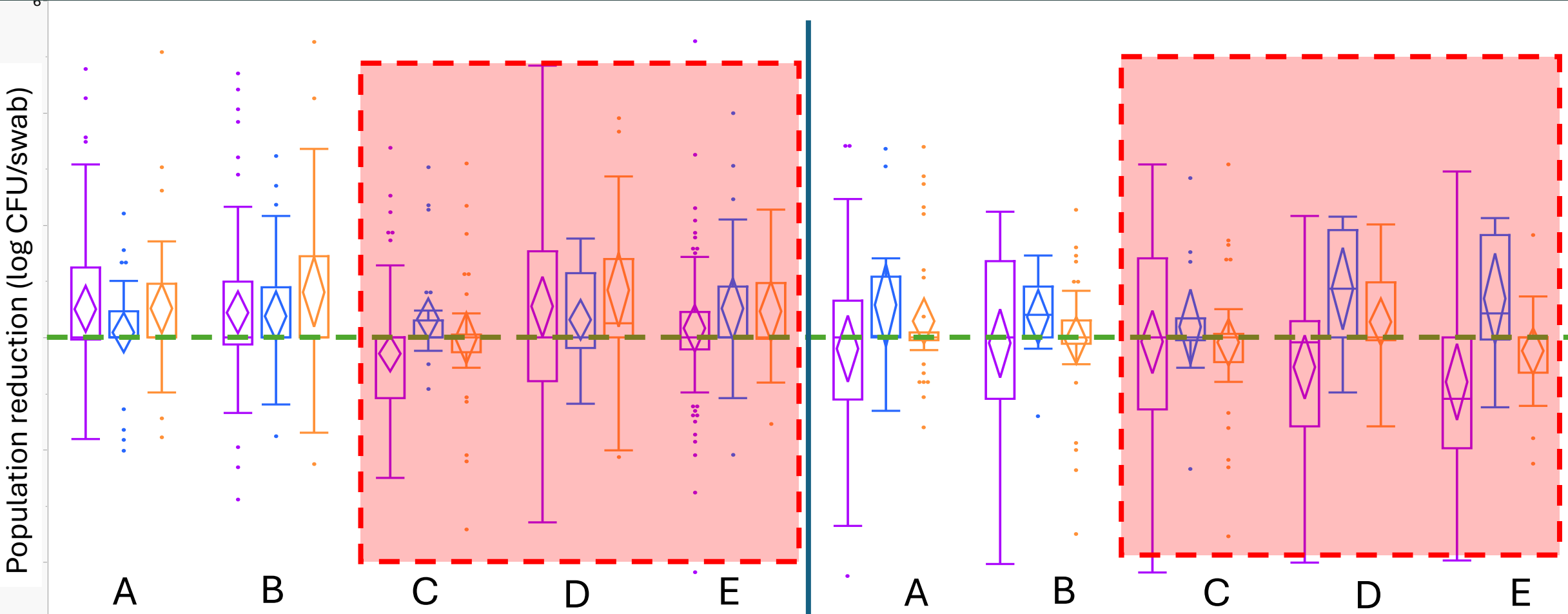
TC POPULATION REDUCTIONS BY DETERGENT



TC POPULATION REDUCTIONS BY SANITIZER



TC POPULATION REDUCTIONS BY ZONE AND MACHINE



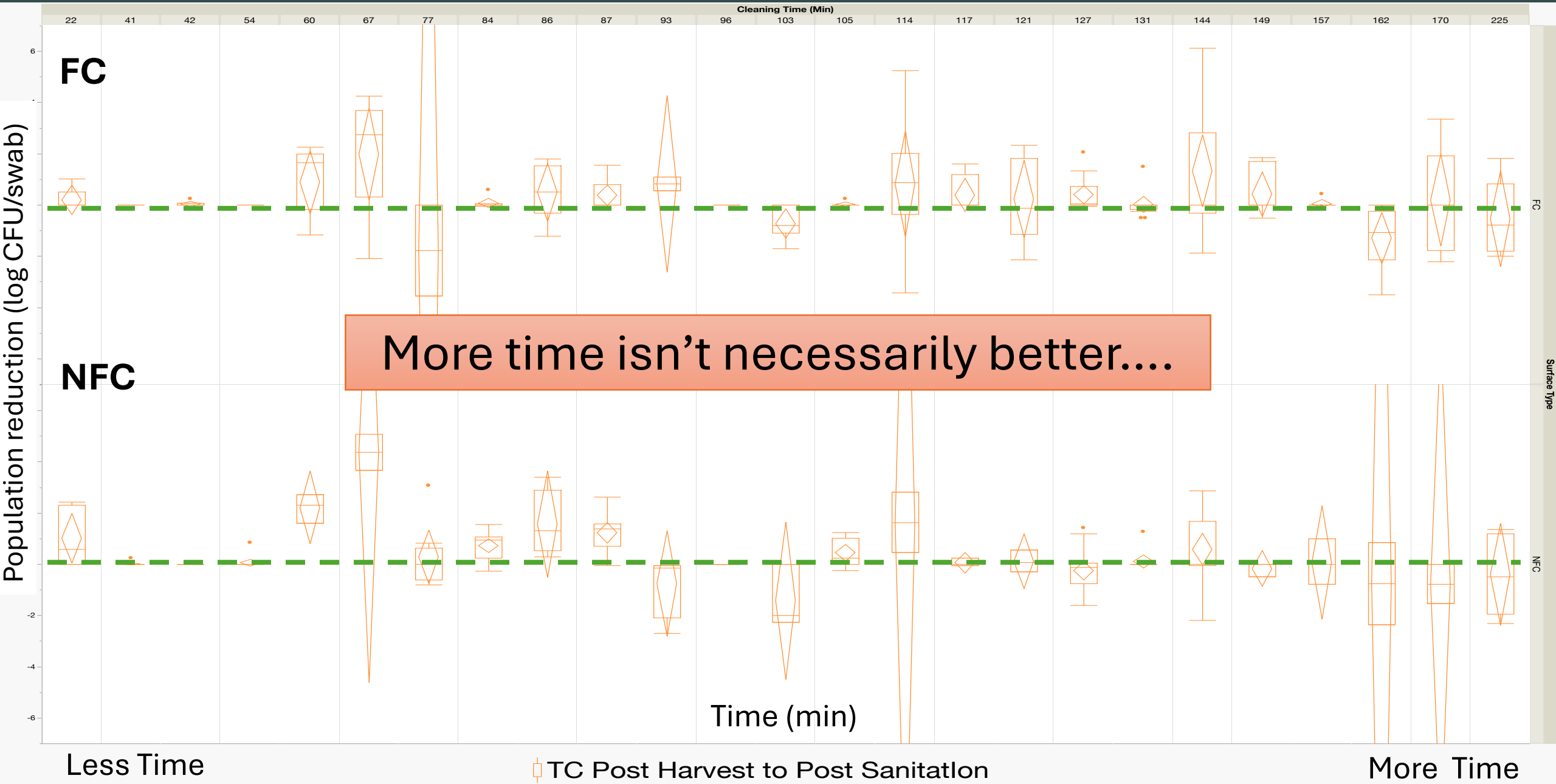
E



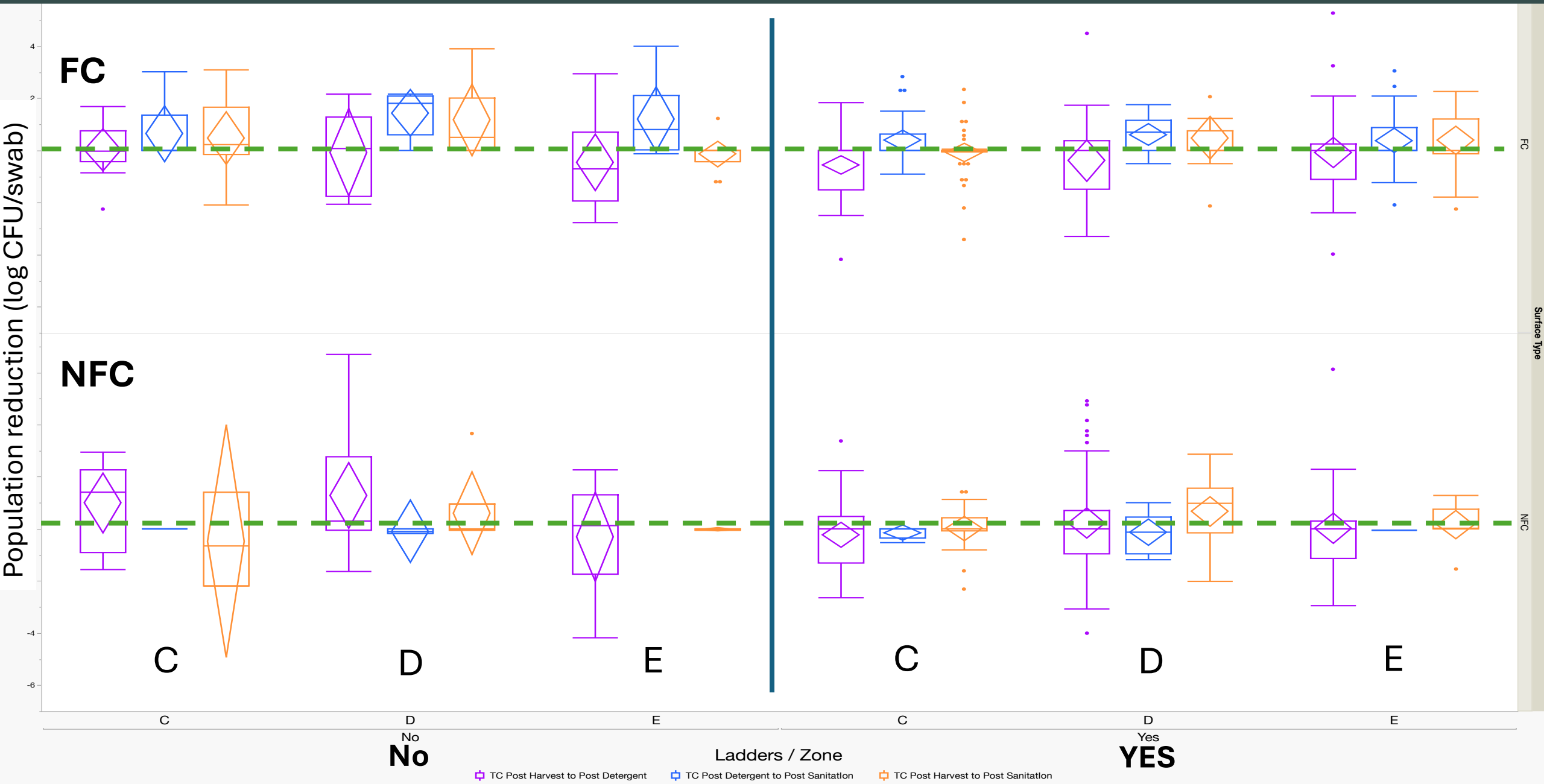
A

E

TC POPULATION REDUCTIONS BY CLEANING TIME



TC POPULATION REDUCTIONS BY PRESENCE OF LADDER/PLATFORM



FINDINGS

Current trends, correlations, and significance in data analysis:

- APC values correlate the most strongly with ATP values and have smaller standard deviations than Total Coliforms or *E. coli* data
- The **cleaning step had the most significant impact** on Total Coliform reductions
 - Suggest that **detergent type, detergent application, and equipment used** during cleaning has a **greater impact** on reductions than the sanitizers
 - Cleaning vehicle presence and type has an impact on reductions achieved
- **Type of detergent** also significantly **impacts APC/ ATP reductions** over time
 - ATP reductions are significantly increased by chlorination detergents

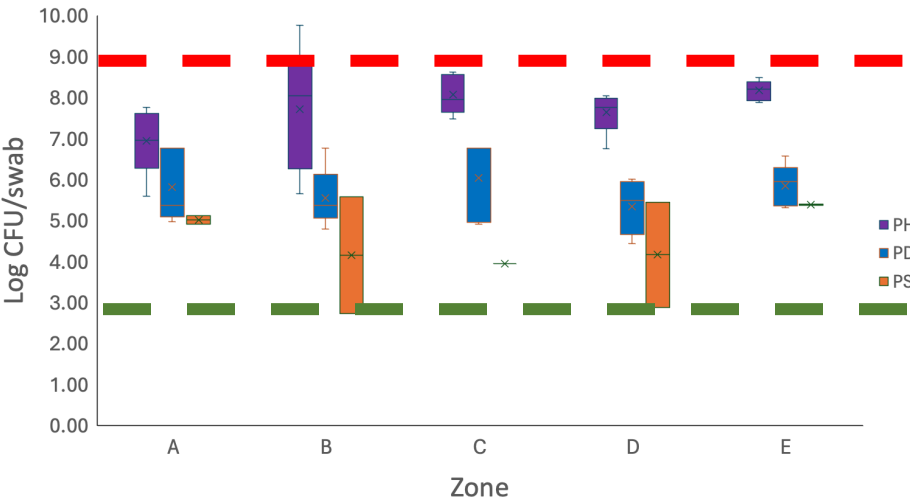
CHANGE OVER TIME



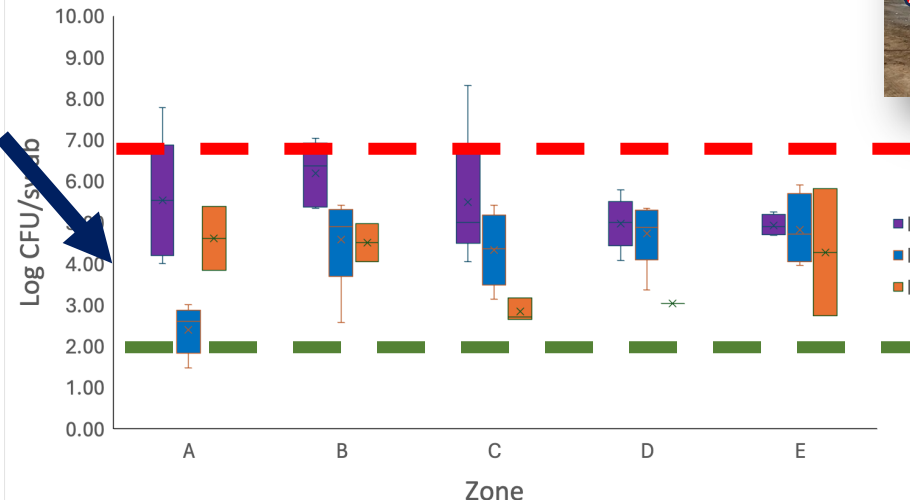
Changes between two visits:

- Moved harvester out of the field
- Added second employee
- Increased cleaning time/detergent coverage
- Cleaned from top down
- Added brushes
- Kept pressure washer nozzle off the ground
- Changed sanitizers
- Increased sanitizer application time/coverage
- Deep cleaning had occurred to remove caked on plant debris

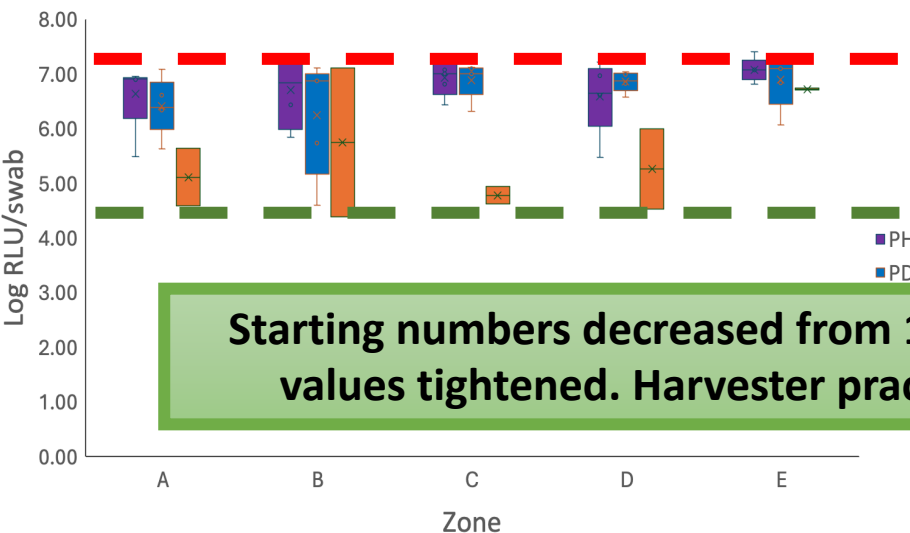
APC - visit 1



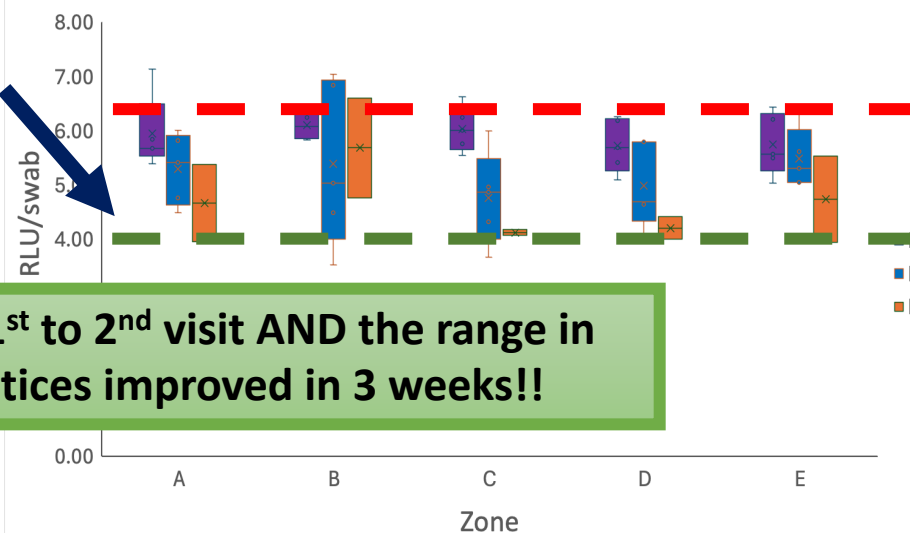
APC - visit 2



ATP - visit 1



ATP - visit 2



Starting numbers decreased from 1st to 2nd visit AND the range in values tightened. Harvester practices improved in 3 weeks!!

FUEL THE CHANGE

- Practices, and challenges, were similar across all states
- Sanitation crews work hard, alone, and sometimes with little support
- This represented best case scenario
 - Equipment cleaned immediately following harvest day (i.e. did not sit overnight)
 - Prepping for FDA visit
- Programs improved between our visits
- Opportunities exist for improvement
 - Some very simple (e.g. ladder/platform, brushes, verification tools, dedicated employees, time, training, chemicals (foamers/coverage/contact times), pointing out areas of concern)
- Volunteers to participate exceeded capacity in current project



WHAT ARE WE COMMUNICATING TO INDUSTRY?



How clean is clean for your harvesting equipment?



When was the last time you went to watch cleaning and sanitation?



How does your SOP verify clean? Does it include a preharvest inspection of the equipment?

Practice based or Records Based?



Does you/your audit scheme just check SOP and records of harvest equipment cleaning and sanitizing?



Are you confident in your cleaning and sanitation step being a “clean break”?



AREAS TO IMPROVE...

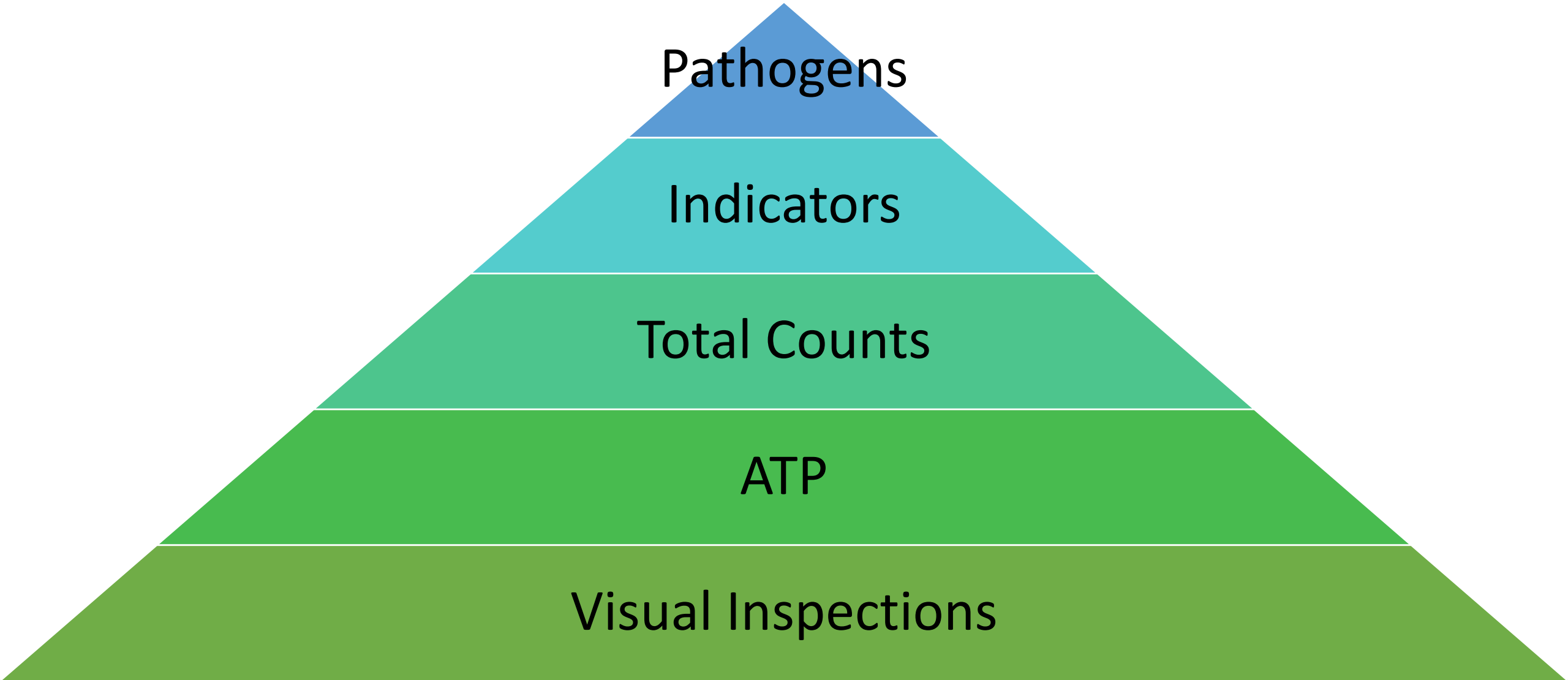
- Detergent and Sanitizer Application
- Training of Crews
- Adequate time
- Proper tools
- Verification activities
- Visually clean?

CORRECTIVE ACTIONS & CORRECTIONS

- Corrective actions will depend on the unique situation
- Corrections should be written down & employees trained on proper implementation
- Corrections could include short and long-term activities
 - Re-clean
 - Re-train
 - Implementing new policies
 - Making Repairs or replacements to equipment or tools
 - Changing flow of cleaning and timing of sanitation



VERIFICATION OF CLEANING & SANITATION PRACTICES



SAMPLING FREQUENCY

“Look once, look twice, and keep looking for it.”

Sampling frequency of sites should be based on the results of appropriately designed and executed swabbing surveys of the process and sanitation effectiveness.



IMPORTANT CONSIDERATIONS

- Verification measures include assuring proper cleaning and sanitation procedures for food contact surfaces and a broad sanitation program for non-food contact surfaces
- Records review of all monitoring and verification activities provides assurance that the sanitation measures are working effectively
- Corrections/Corrective Actions must be timely and will likely include re-cleaning and re-sanitizing surfaces
- Training may be your most important investment rather than more swabbing.
- Training, time, and correct equipment is essential for an effective program!



WHAT DID IT TAKE TO GET THE WORK DONE?

- Its not as easy as it sounds...! TRUST
- Team calibration across three states
- Small teams managing large sample numbers
- Multiple hours on the road in the middle of nowhere
- Afternoon/Evening swabbing events
- 3rd Party laboratory coordination in three states (same methods, detection limits, hold times, etc.)
- Nimble... *“Harvest ends at 6pm, oh wait, they have increased our orders, harvest now ends at 9pm.”*



ACKNOWLEDGEMENTS

Industry Collaborators!!

Center for Produce Safety

University of Florida

- LaTaunya Tillman
- Lorrie Friedrich
- Clara Diekman
- Luis Martinez

University of Arizona

- Dalton Zingali
- Jose Partida
- Hannah Crean
- Ban Saber
- Natalie Brassill

Factor IV

- Geovanny Espinoza
- Dolores Aceves

Eurofins

- Rafael Davila
- Chantale Mays



Questions?