Using Simple Models to Direct Mitigation Choices in Leafy Green Production

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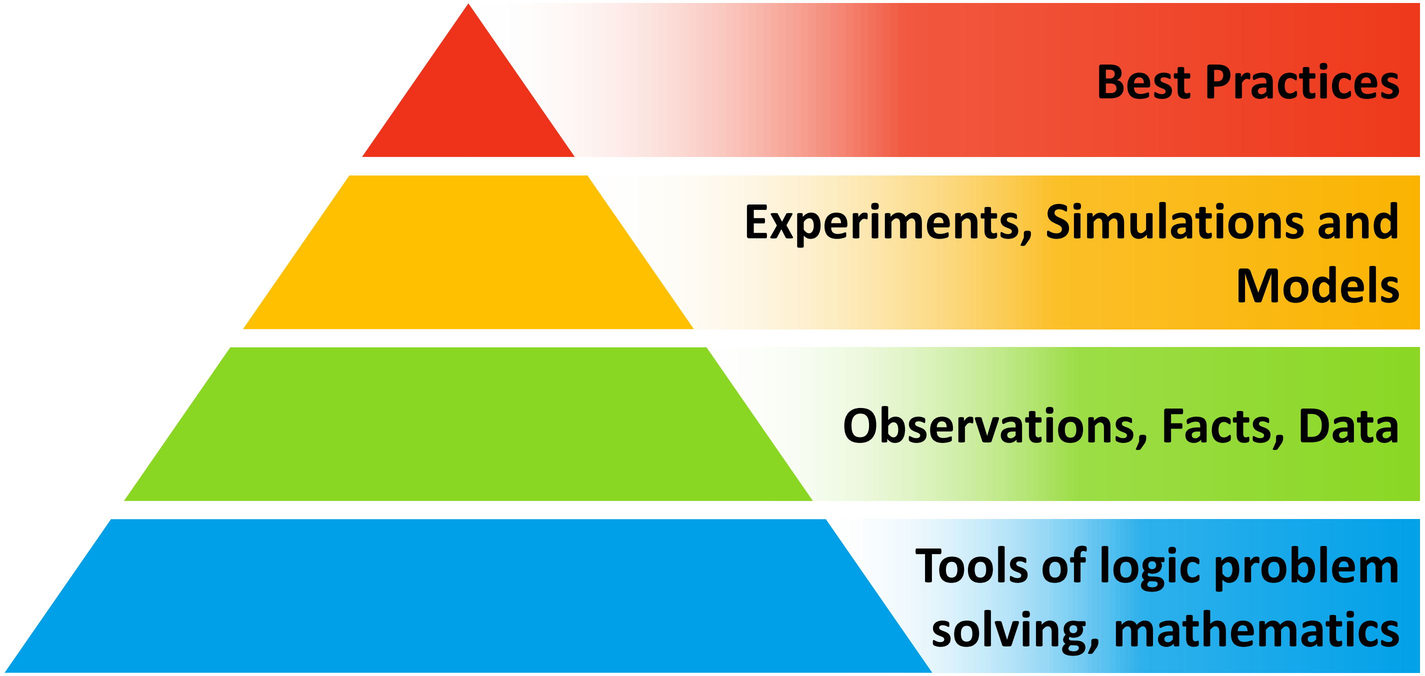
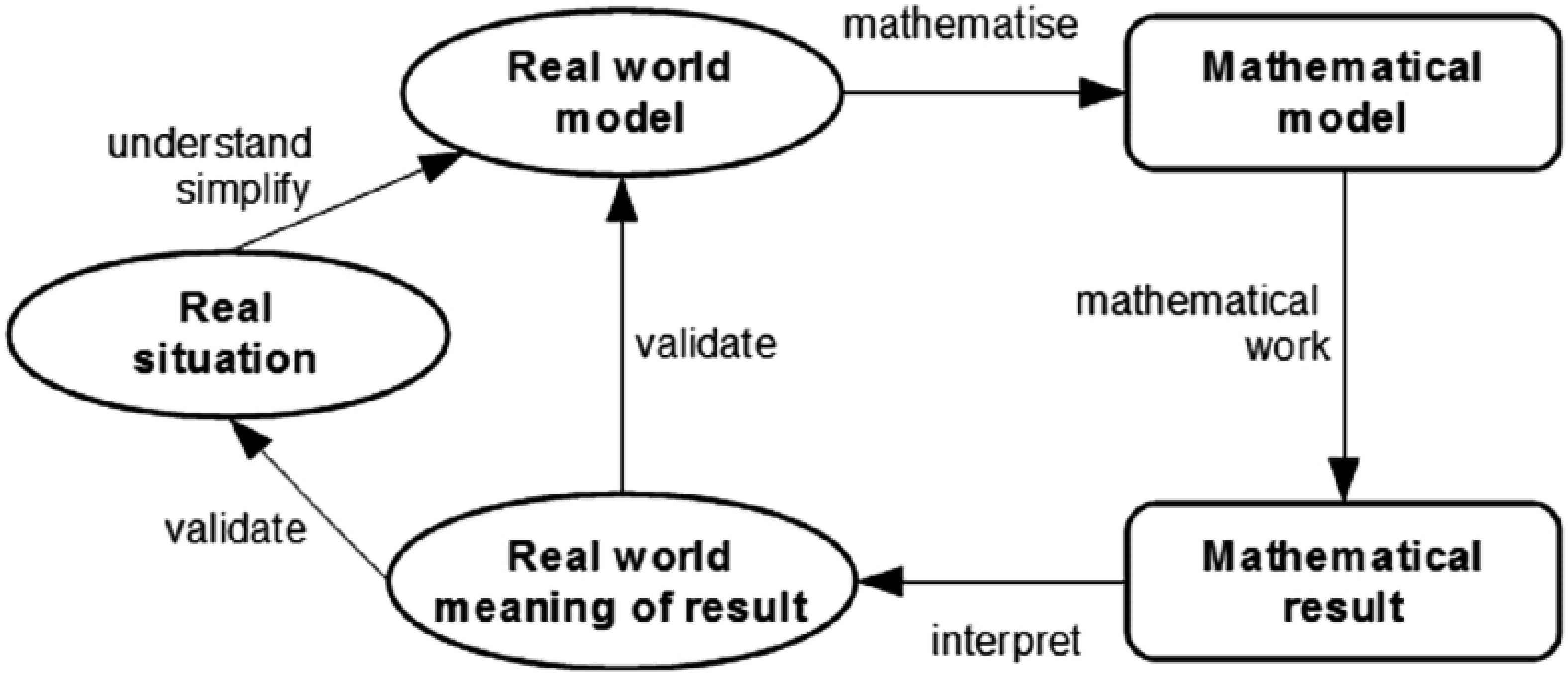
A look at the pathways to reducing illnesses related to produce contamination; a specific application of the scientific method



Modeling fits into this process to the extent it describes the real world



Modeling Cycle of Kaiser and Stender, 2013

We can walk one of these pathways with simple modeling if we have:

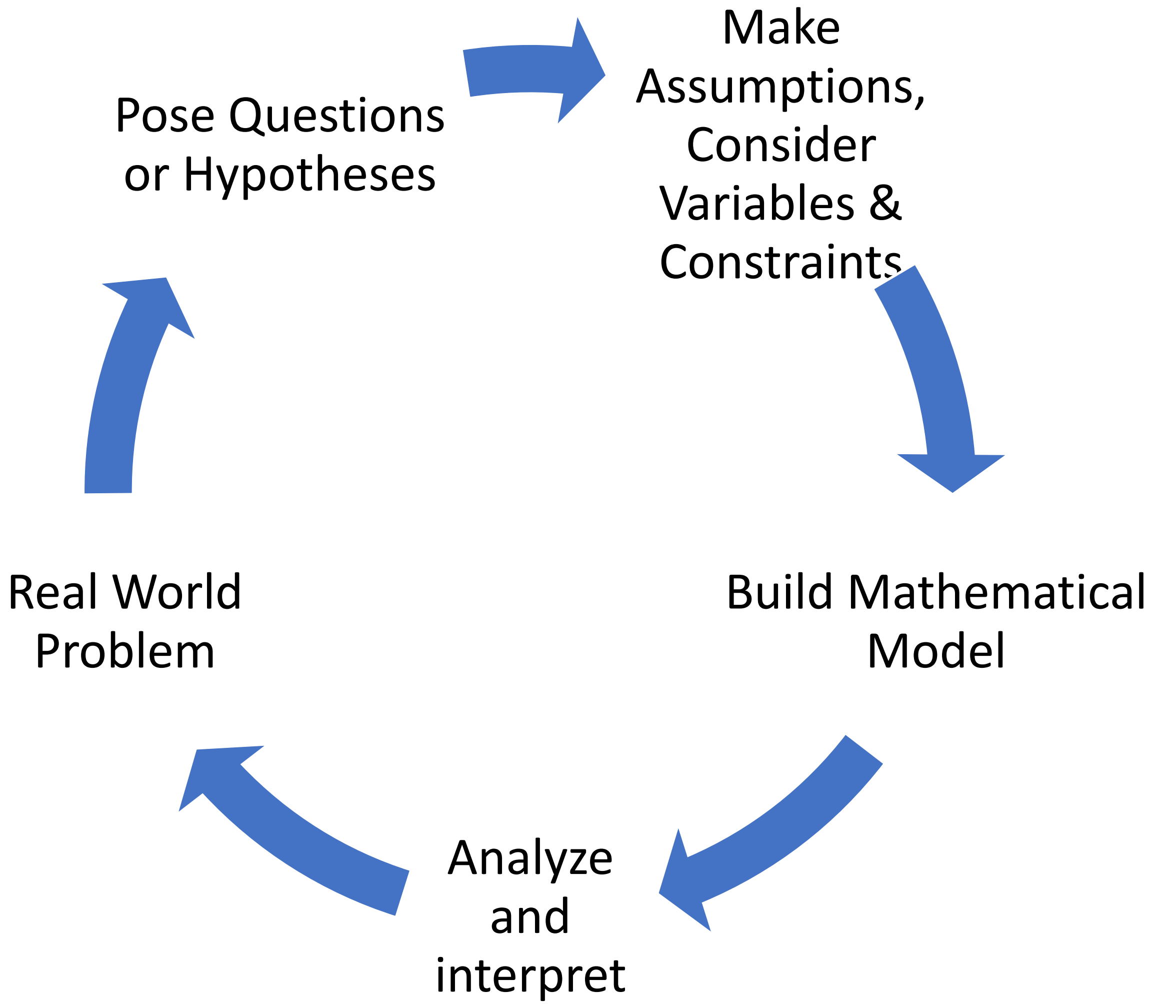
- A foundation of data and observations
- A few applicable scenarios
- A spreadsheet or calculator for Poisson distribution computations; mostly with zero defects

Probability of no defects = $e^{-(\text{average expected defects observed})}$

= Poisson.dist(0, Concentration * sample size, True)

Questions give modeling purpose

- When and how is testing an effective mitigation?
- What is the effect of a better wash process on illness?
- How would improved GAP impact illness?
- Can we realistically prevent outbreaks that shutdown the industry?



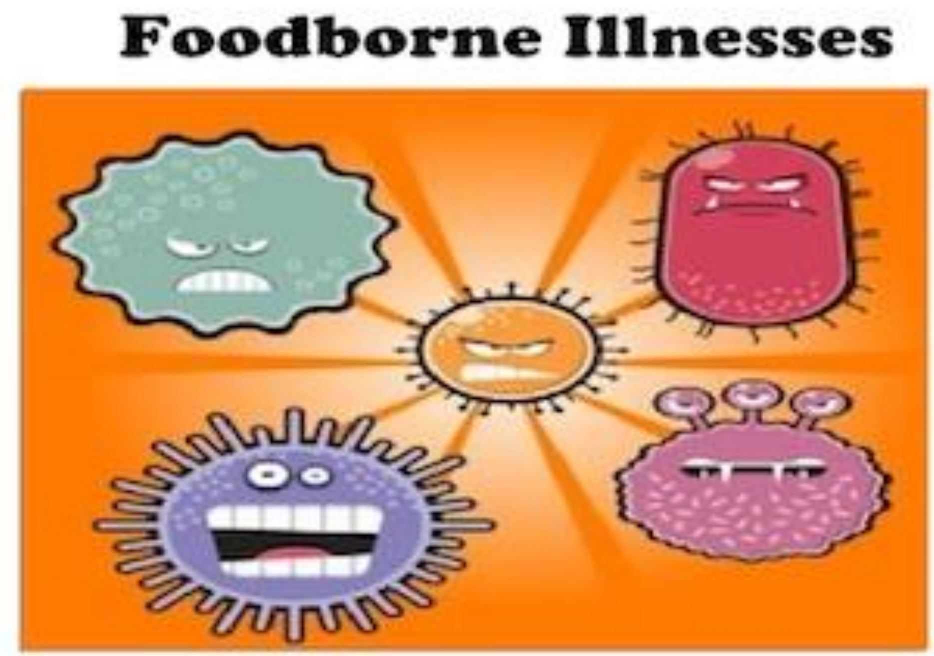
Four variables or attributes define scenarios or describe contamination events

- **Pathogen**
- **Intensity**
- **Extent**
- **Distribution**

Four main bacterial pathogens cause illness in produce

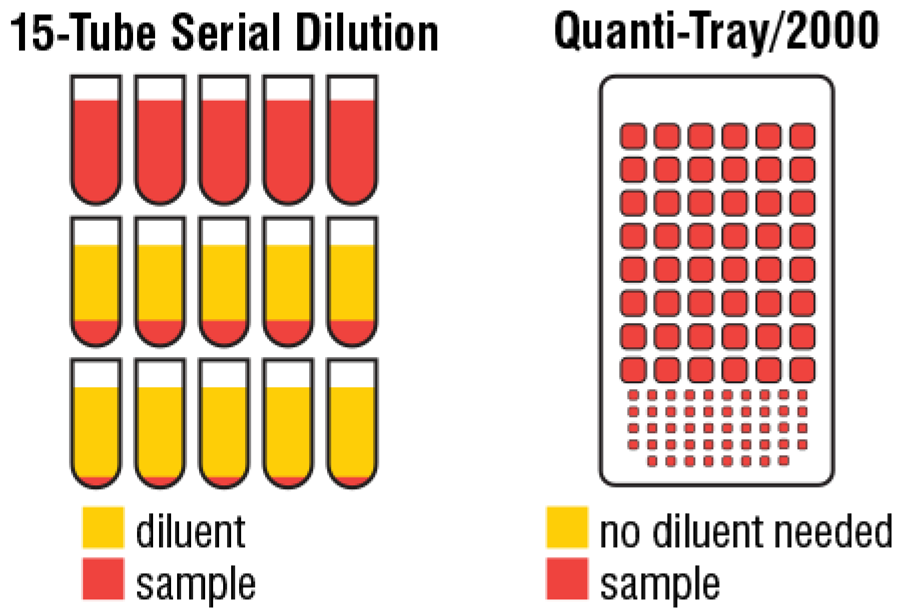
- O157
- Non-O157 EHEC
- *Salmonella*
- *Listeria*

- Noro virus is another player
- **The selection of a specific pathogen would not add to this discussion; use generic pathogen**



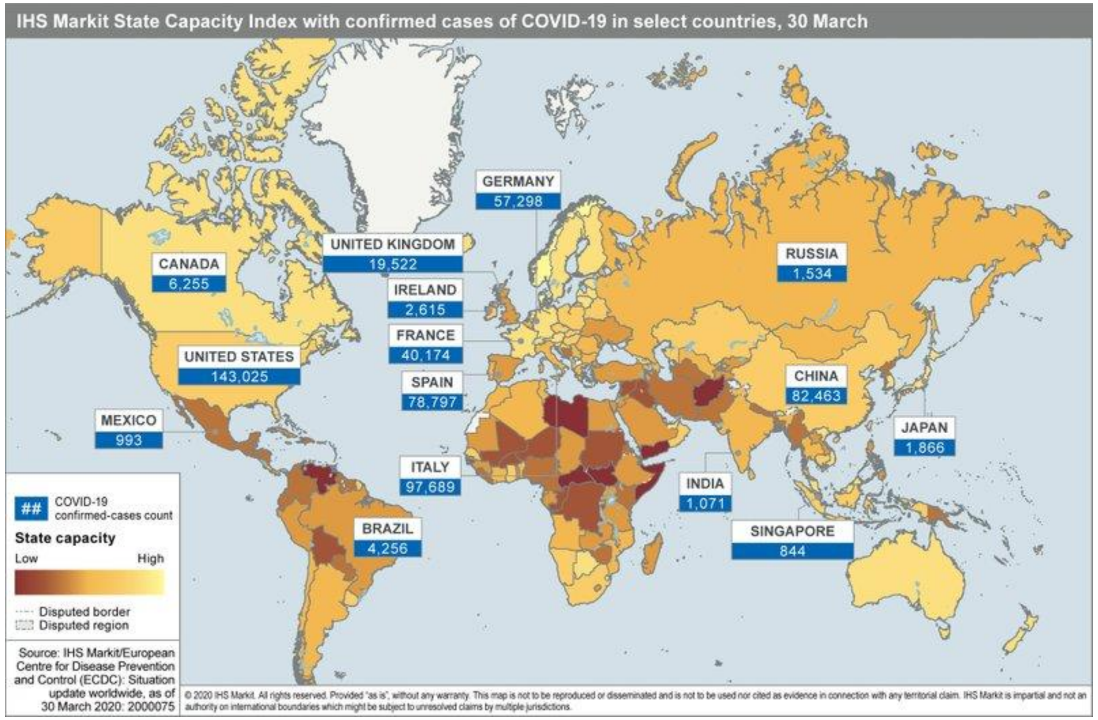
Intensity-the concentration of the pathogen

- Measured by testing
  - ✓Enumeration or counting
  - ✓Most Probable Number (MPN)
- Reported as CFU or MPN/volume or weight
- Detect/Non-detect databases can be used for MPN calculations
  - ✓Number of positives
  - ✓Number of samples
  - ✓Size of sample



Extent - the range of affected product

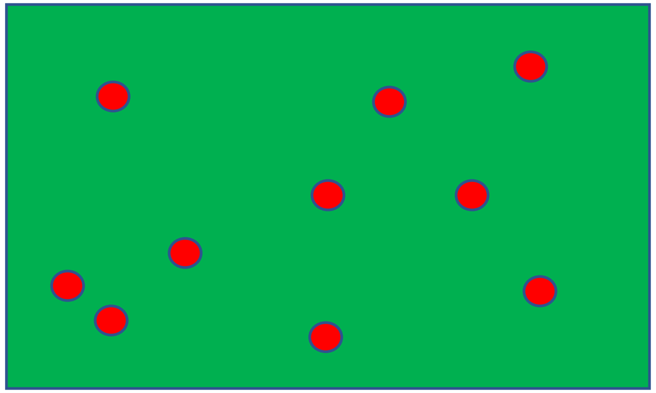
- Survey the potential range
  - Requires a test or metric
  - Resolution depends on the number of determinations
- Boundaries are usually fuzzy
  - Intensity is rarely uniform

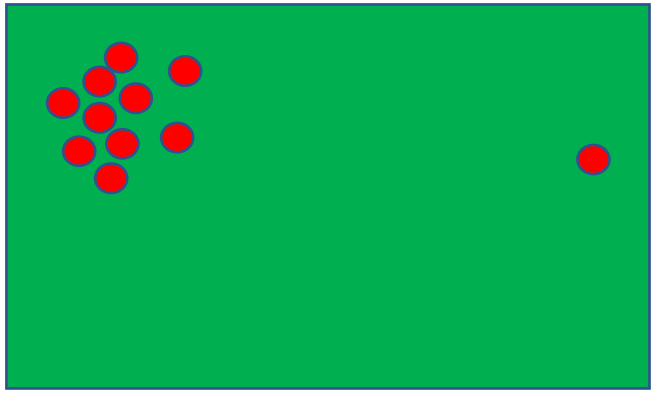


Distribution-the variation in intensity within an affected lot (Clustering)

- Requires intense surveys of affected lots
- Data is very sparse
- Follow-up testing of failed finished product shows clusters of 500-2000 pounds based on process line speeds.
- If we had *a priori* understanding of cluster positioning, the mitigation problem would be solved. <u>Unfortunately, the problem has not been solved.</u>

- Random versus Clustered





A non-O157 EHEC-positive field of Arugula

- Intensity, Extent, and Distribution are not obvious
- An investigation yielded some observations and data
- Such real-world observations allow creation of scenarios or case studies to drive modeling

Scenarios are an amalgam of real events with the blanks filled in.

- The postulated attributes must define intensity, extent and distribution.
- These attributes can easily be changed for other scenarios
- Varying one attribute while holding others constant allows testing hypotheses that would be difficult to test by direct experimentation.
- Scenarios at the extremes or boundary conditions often provide insights

What might an industry stopping contamination event look like?

Extent – 45 acres at 38,000 pounds each

- 1,710,000 pounds
- Largely arbitrary
  - ✓Multi-week duration
  - ✓Multi-state impact
  - ✓Not easily traced to source
- Other extents are easily considered

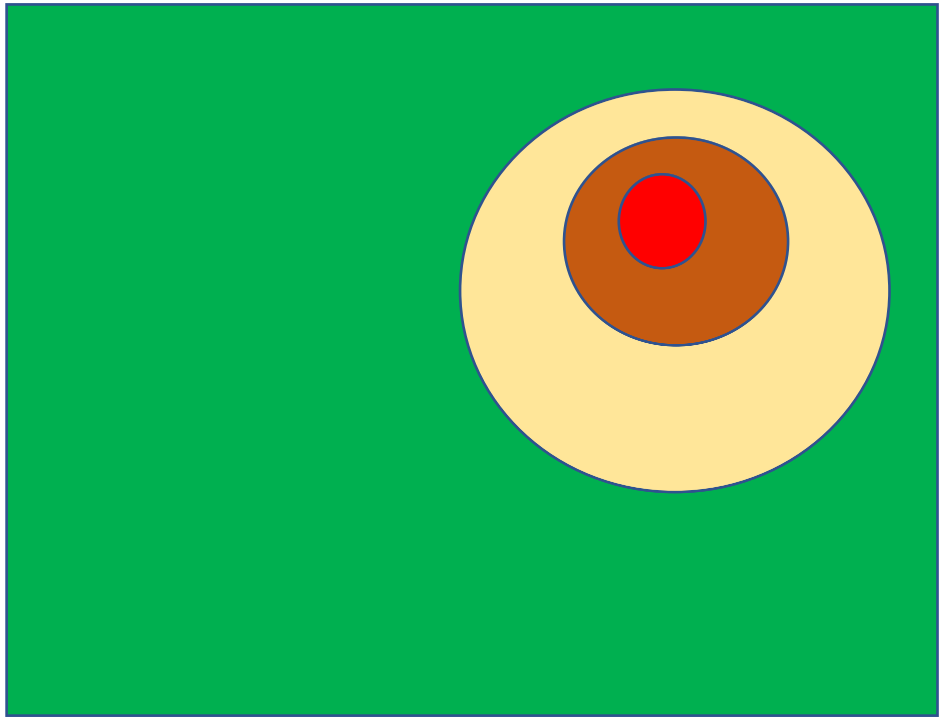
Intensity - average intensities of 0.84 CFU/pound or 0.084 CFU/pound will be considered

- Assume that this specific event would cause 60 reported illnesses to shut down industry
  - ✓We infer that 20-30 times as many people would be made ill
- Assume average dose is 800 CFU/illness
- The total number of CFU involved in the contamination is ~1.44×10^6

"60 reported illnesses X 30 unreported factor X 800 CFU/illness"

- The ratio of total CFU to extent is intensity
- A similar event causing 6 reported illness would have the lower intensity.

Consider 3 defined distributions to complete the scenarios



- Assume each acre contains a single cluster of 32000 CFU for the intense scenario and 3200 CFU at the lower level.
- The location of the clusters is unknown and is perhaps unknowable.
- Assume three sizes of cluster
  - ✓ 2000 pounds
  - ✓ 5000 pounds
  - ✓ 10000 pounds
- These distributions are almost arbitrary and are largely based on intuition.

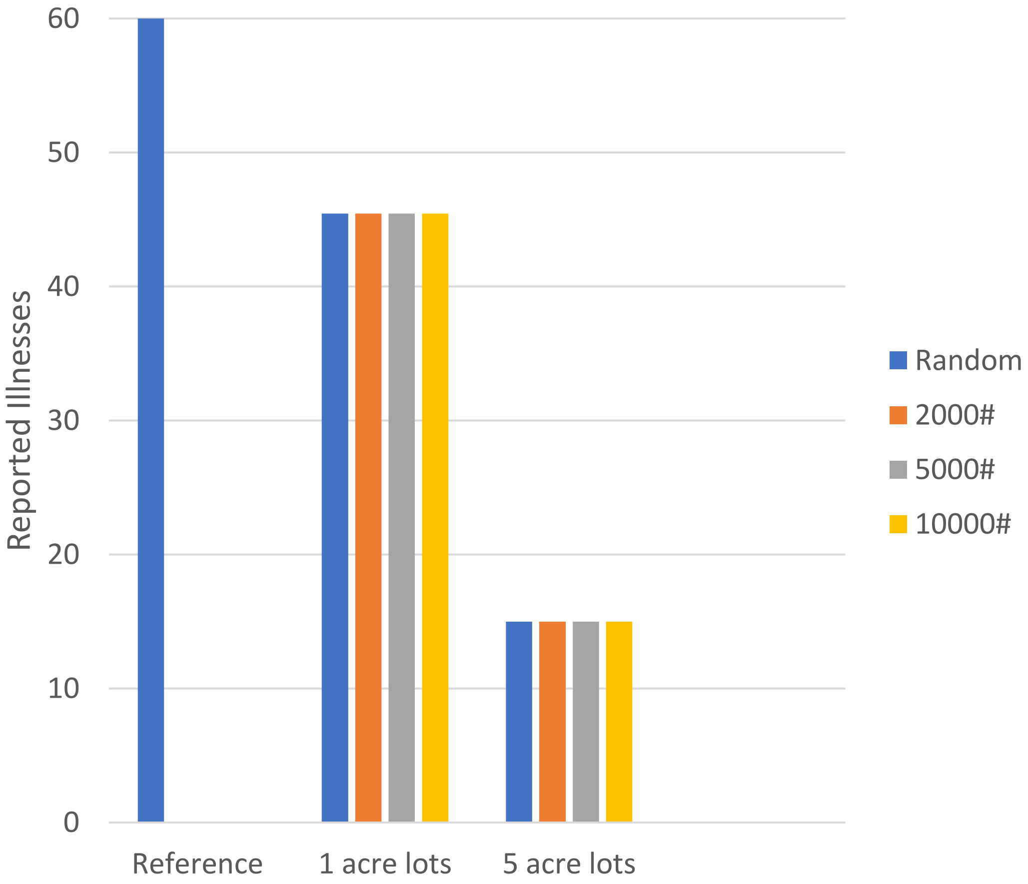
We can vary these attributes to model various mitigations approaches

When and how is testing an effective mitigation?

Flavors of testing and decision making

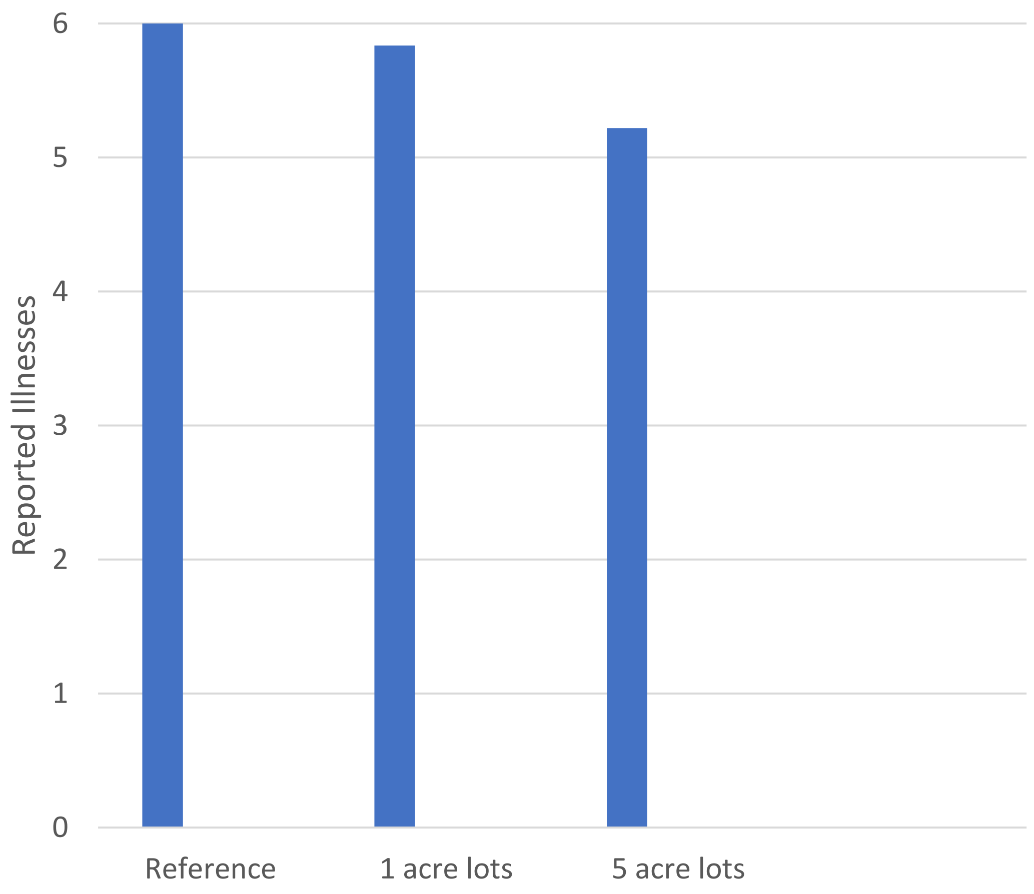
- Pre-harvest testing - 150g composited test per acre
  - ✓ Decisions can be made by acre with 1 test or by lot with 5 tests per lot
- In-harvest testing –aggregated surface sampling with an effective sample weight of 2000g per acre
  - ✓Decisions can be made by acre with 1 test or by lot with 5 tests per lot
- Finished Product testing – 150g composited test per hour at 12,600 pounds processed per hour
  - ✓ Decisions can be made for the just the hour testing positive or can be extended to the flanking hours (before and after)

At intensity 0.84 CFU/pound, pre-harvest testing reduces illness



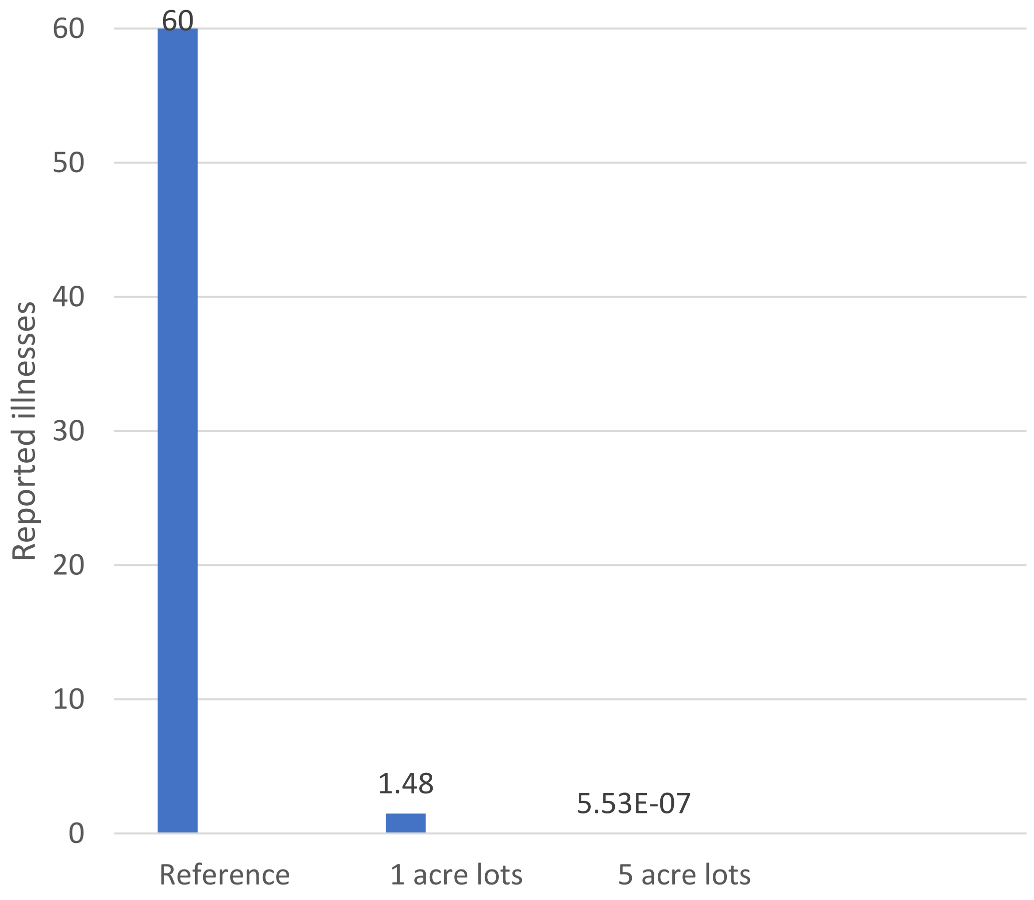
- Increased lot size or more tests per lot increases illness mitigation
- The cluster size (distribution) has no impact on illness mitigation

At intensity 0.084 CFU/pound, pre-harvest testing would have less impact on illness



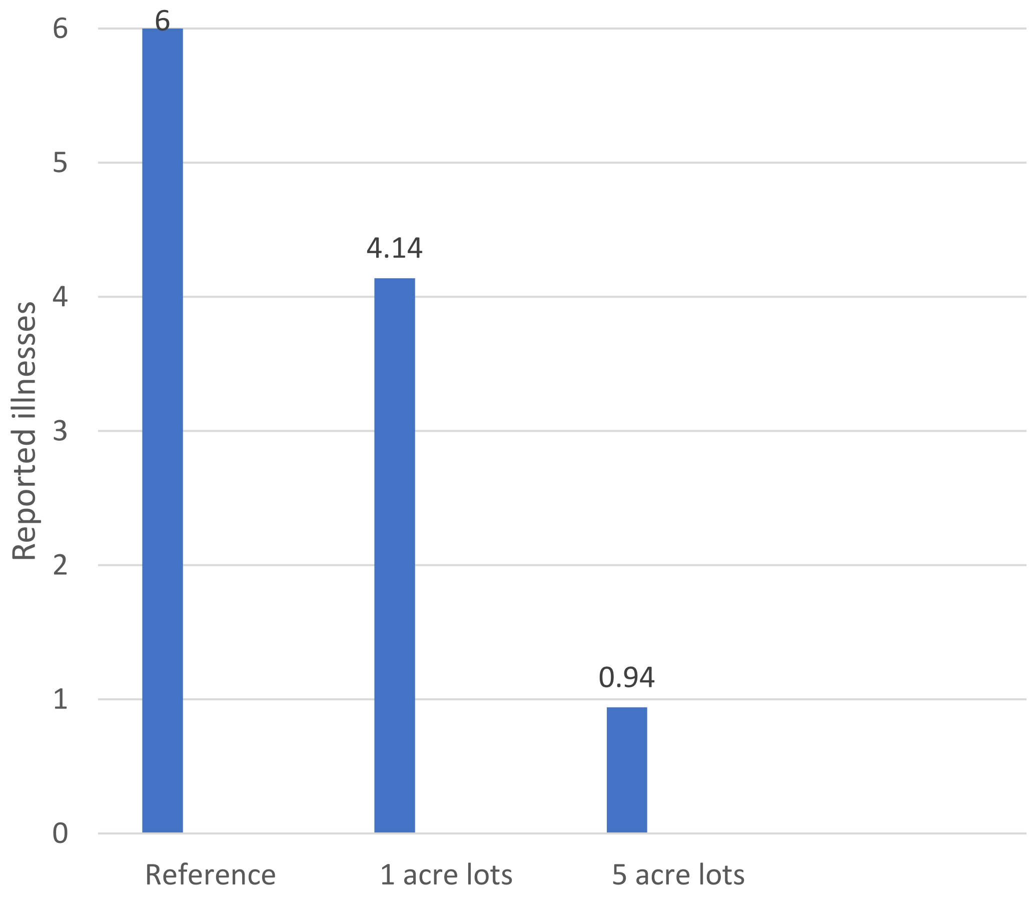
- Again, increased lot size or more tests per lot increases illness mitigation
- The clustering (distribution) has no impact on detection rates based on contingent probabilities. (Results not shown).

At intensity 0.84CFU/pound, aggregated in-harvest testing would greatly reduce illness



- Again, increased lot size or more tests per lot increases illness mitigation
- Equivalent to about 13 conventional (N=60) pre-harvest tests

At intensity 0.084 CFU/pound, aggregated in-harvest testing loses some effectiveness

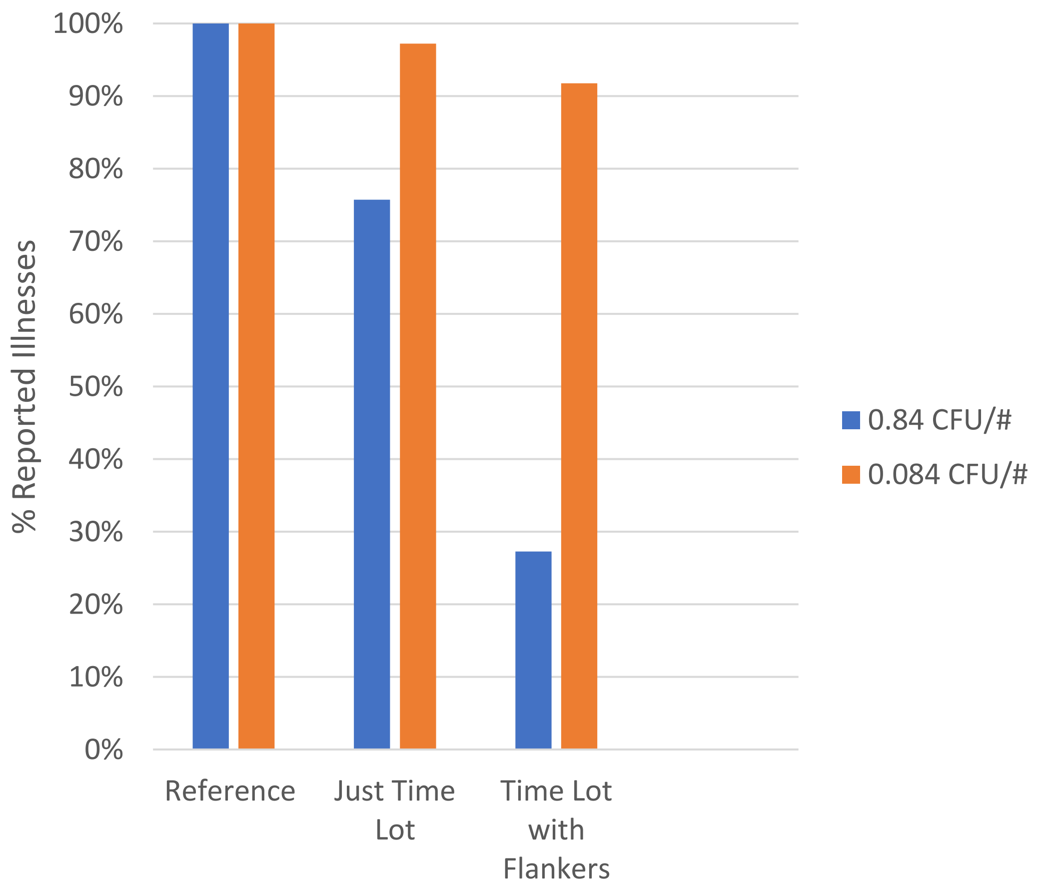


- Again, increased lot size or more tests per lot increases illness reduction
- Still equivalent to about 13 conventional (N=60) pre-harvest tests

Aggregated in-harvest sampling is under evaluation

- Pilot plant simulations indicate effective sample masses of >2000g are possible.
- Saturation still needs to be researched. Sampling a whole acre may require more than one swab.
- Commercialization is not just around the corner and may require an analysis procedure with < 2 hour turn around.

At both intensities, illness reduction by finished product testing is like pre-harvest testing



- The effect of the rejection of flankers maybe overstated because the flankers are assumed to have equivalent contamination.

Testing is most effective at directly mitigating illness when:

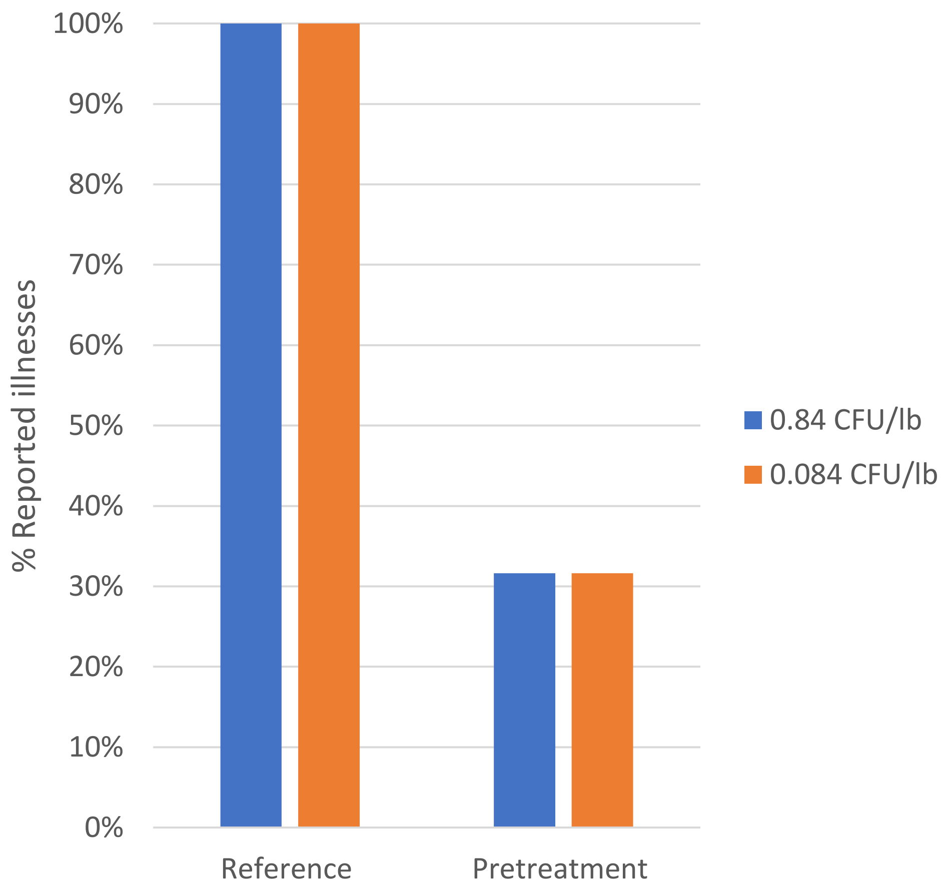
- Intensity is high
- Multiple tests are used for making decisions
- Sample or effective sample size increases

Additionally, as mentioned above, when large amounts of testing data are aggregated, it can be used to assess the average pathogen intensity for all or portions of a FSQA system.

What is the effect of a better wash process on illness?

Specifically, what is the impact of a 0.5 log increase in lethality?

At both intensities, an incremental 0.5 log increase in lethality reduces illness

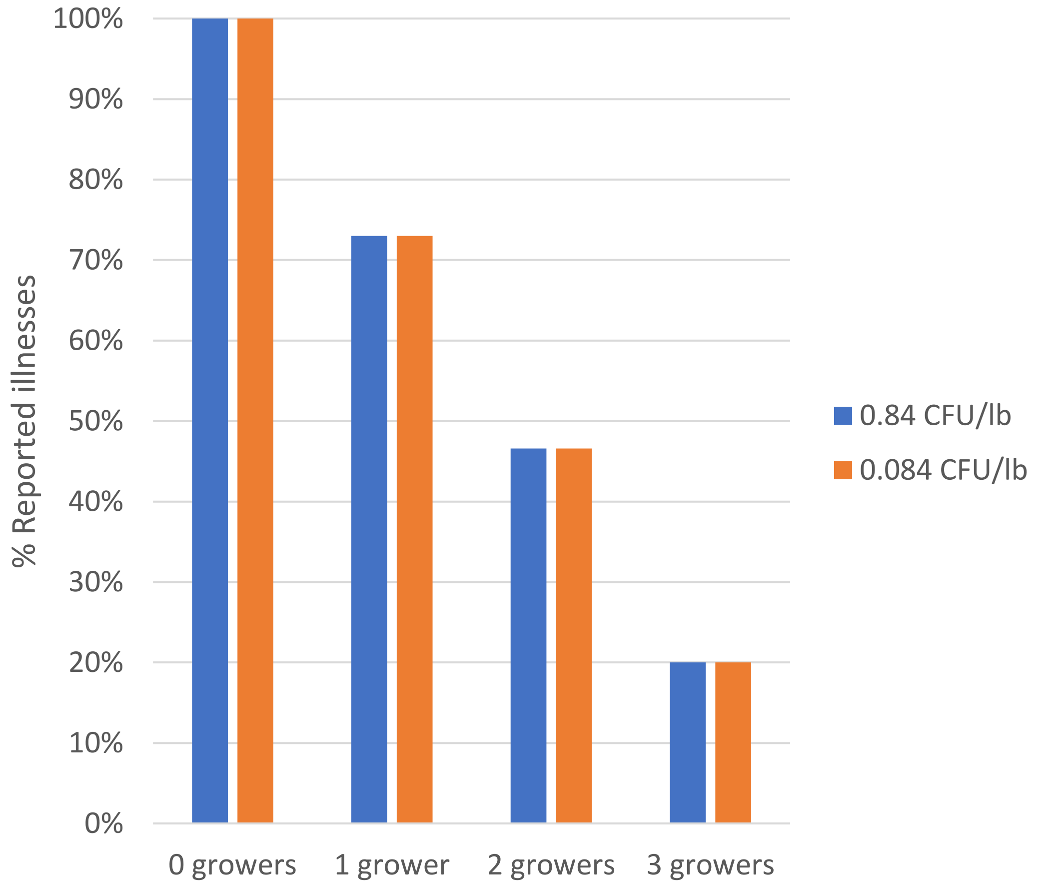


- Equal to or up to 300% more effective than finished product testing
- Pilot plant inoculated studies indicate that a silver ion based pretreatment can provide this level of increased lethality.

How would improved GAP impact illness?

Specifically, how would a 5-fold reduction in pathogens impact illness?

At both intensities, the hypothesized GAP reduces illnesses



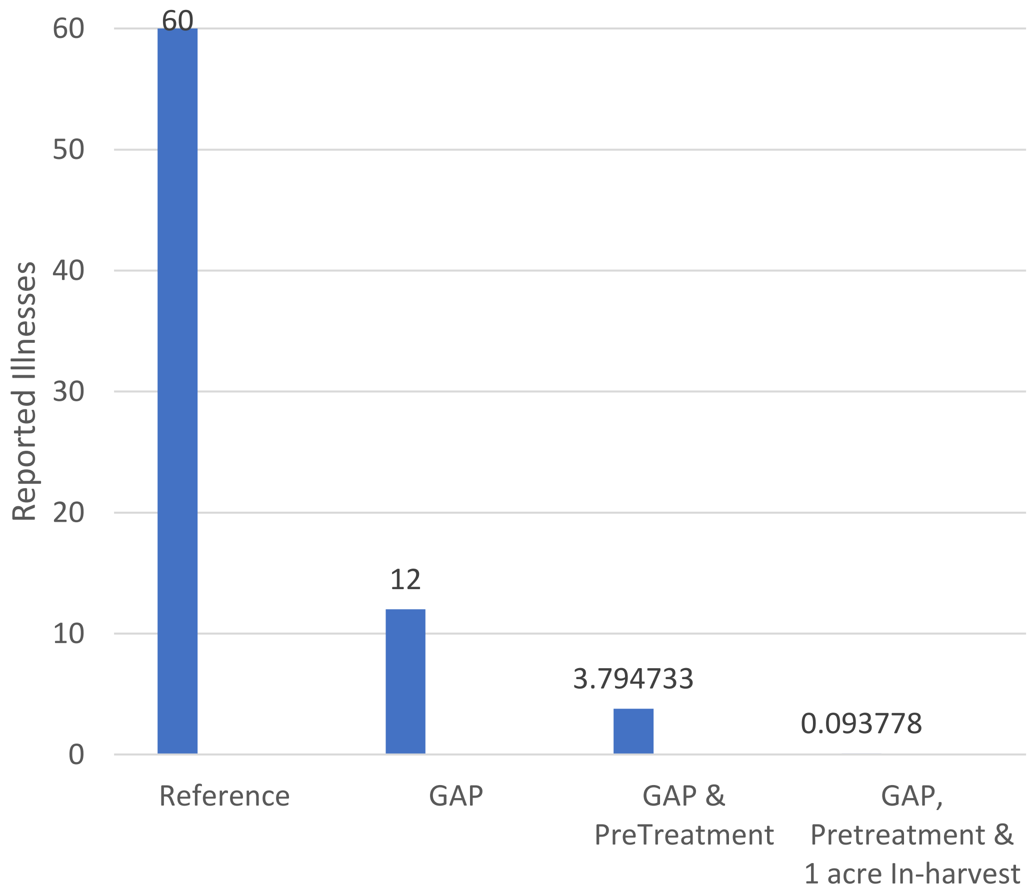
- Clearly as more growers adopt the better practices, greater reductions are observed

Is a 5-fold reduction a reasonable goal?

- The observed differences in average MPN/pound between systems are very encouraging
- Observed improvements are confounded with other factors
- Aggregated testing data and comparative analysis of many mitigation programs would add power to the analysis
- Understanding the drivers of the variation in performance will be key to establishing Best Practices.

Can we realistically prevent outbreaks that shutdown the industry?

At intensity 0.84 CFU/pound, three mitigations in concert would virtually eliminate illness



Perhaps, if all the players keep working to develop and improve mitigation strategies and these become accepted Best Practices, a 0.84 CFU/pound intensity event could be prevented from reaching the marketplace.

Points illustrated by these models

- Simple modeling can be used to direct research and experimentation on the path to Best Practices in selecting mitigations to implement.
- Process mitigations such as GAP or the pretreatment are effective even when the contamination is less severe.
- Detect/Non-detect databases will be an important source of information for comparing the effectiveness of various programs.
- The cumulative impact of small improvements in mitigation will reduce risk.

Acknowledgments

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