



AgriPhage™



**OMNILYTICS™**  
THE PHAGE COMPANY

# OmniLytics- The Phage Company

- ▶ World's Largest provider of commercial bacteriophage products for agricultural use.
- ▶ Bacteriophage?
  - ▶ Bacteria-eater
  - ▶ Naturally occurring bacterial virus
    - ▶ Cannot infect mammalian, fungal, yeasts or molds
    - ▶ 100 times smaller than bacterial cells
    - ▶ It is estimated there are more than  $10^{31}$  bacteriophages on the planet, more than every other organism on Earth, including bacteria, **combined**.



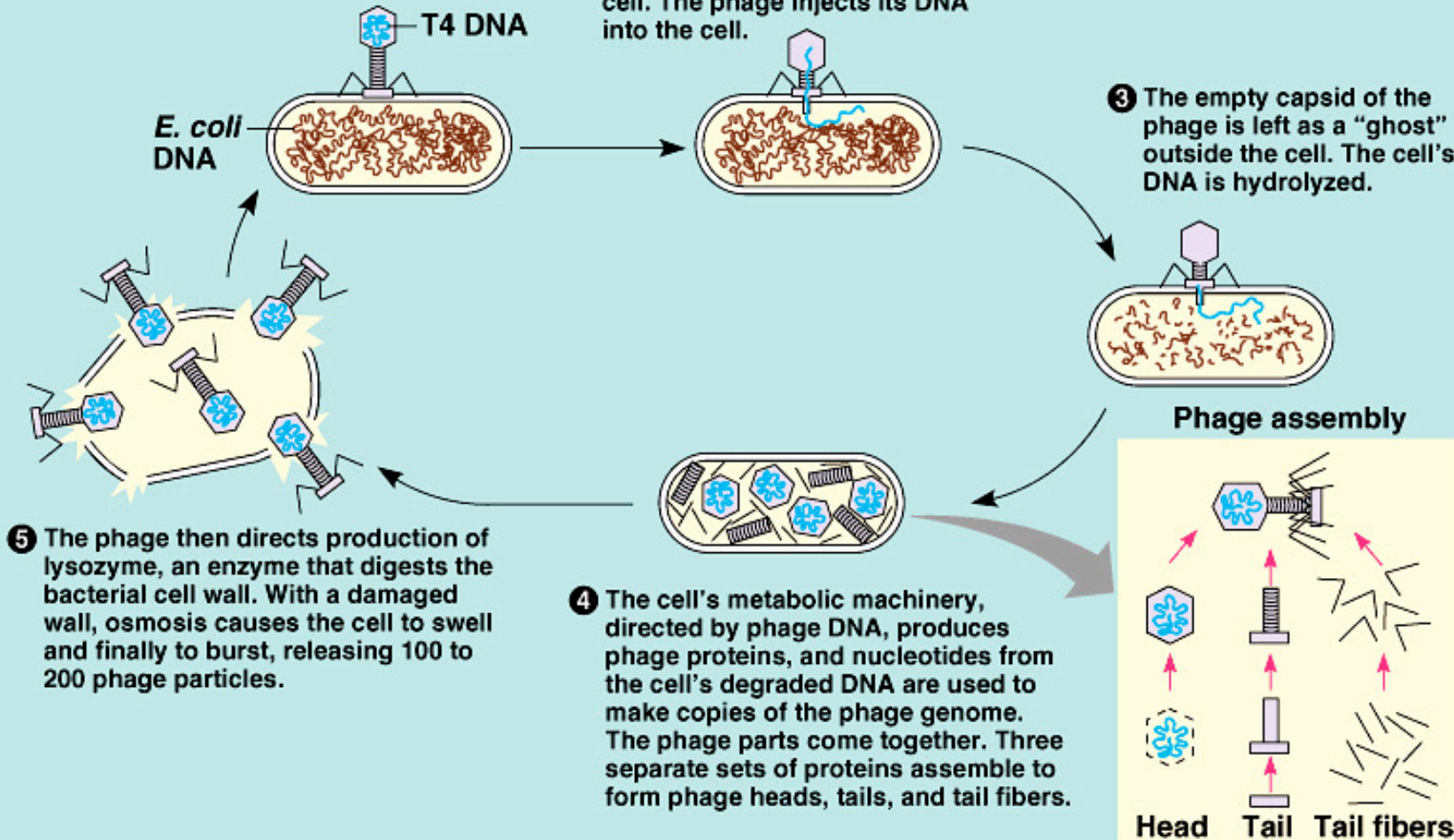
# OmniLytics- The Phage Company

1 The T4 phage uses its tail fibers to stick to specific receptor sites on the outer surface of an *E. coli* cell.

2 The sheath of the tail contracts, thrusting a hollow core through the wall and membrane of the cell. The phage injects its DNA into the cell.

3 The empty capsid of the phage is left as a "ghost" outside the cell. The cell's DNA is hydrolyzed.

4 The cell's metabolic machinery, directed by phage DNA, produces phage proteins, and nucleotides from the cell's degraded DNA are used to make copies of the phage genome. The phage parts come together. Three separate sets of proteins assemble to form phage heads, tails, and tail fibers.



5 The phage then directs production of lysozyme, an enzyme that digests the bacterial cell wall. With a damaged wall, osmosis causes the cell to swell and finally to burst, releasing 100 to 200 phage particles.

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## PHAGE SAFETY ASSURANCE

- ▶ Phages are bacteria specific and cannot infect mammalian cells (including humans and animals)
- ▶ Phage sequencing verifies the absence of toxins, allergens, antibiotic resistance genes, etc.
- ▶ Non-transducing phages cannot transfer undesirable genes from bacteria
- ▶ Our phages are natural isolates from the environment (not GMO)
- ▶ Long history of use in humans and animals without adverse effects
- ▶ FDA, USDA, and EPA have approved phage products.

# OmniLytics- The Phage Company

- ▶ OmniLytics has been developing bacteriophage products since 2002.
- ▶ Current Products:
  - ▶ Crop Protection:
    - ▶ AgriPhage Tomato Spot/Speck (*Xcv* and *Pst*)
    - ▶ AgriPhage Pepper Spot (*Xcv*)
    - ▶ AgriPhage Tomato Canker (*Cmm*)
    - ▶ AgriPhage Fire Blight (*Erwinia amylovora*)
    - ▶ AgriPhage Citrus Canker (*Xcc*)

Currently being routinely applied on approx. 25,000 acres of fruit and veg.

USDA ORGANIC (NOP approved)

MRL Exempt

# OmniLytics- The Phage Company

- ▶ OmniLytics has been developing bacteriophage products since 2002.
- ▶ Current Products:
  - ▶ Food Safety:
    - ▶ Finalyse Hide Wash- E. coli O157-H7
    - ▶ Finalyse-STECS: E.coli cocktail (FDA-GRAS)
    - ▶ Finalyse-SAL: Salmonella (FDA-GRAS)

**PASSPORT**  
Food Safety Solutions powered by 

# OmniLytics- The Phage Company

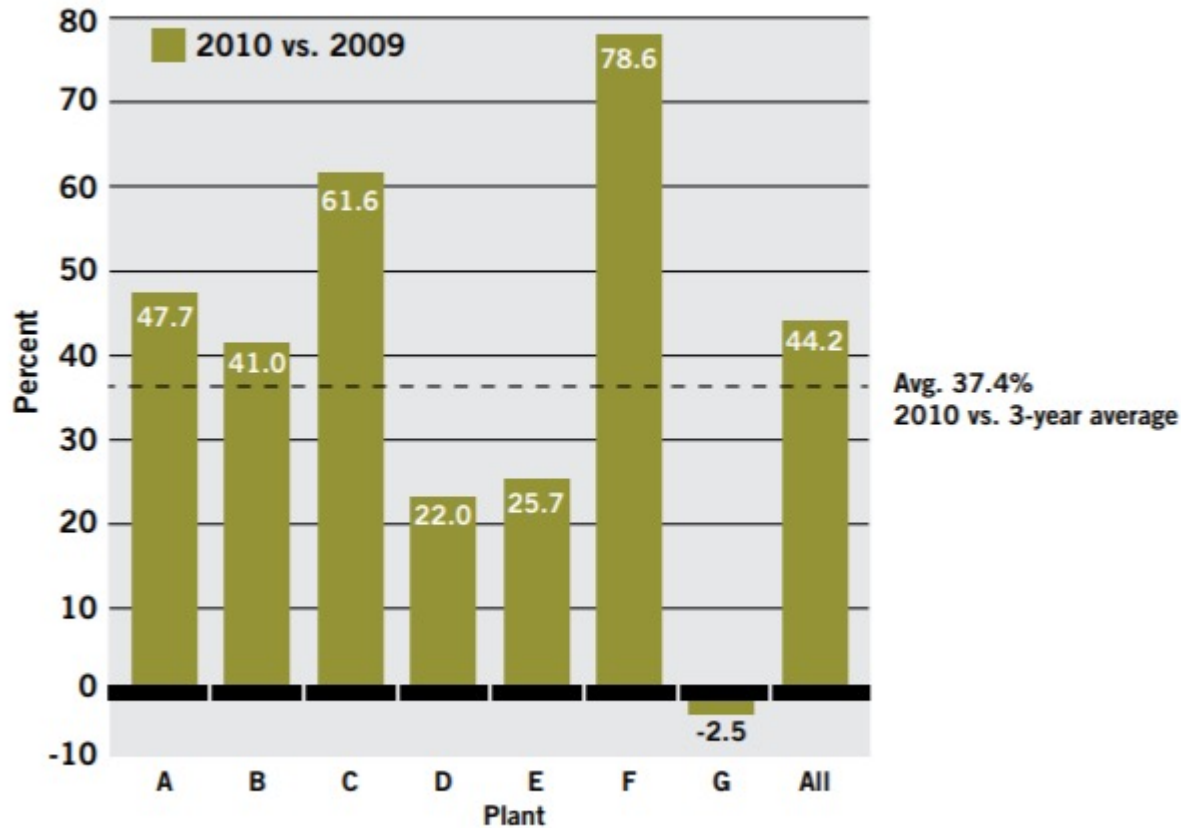
- ▶ Finalyse Hide Wash:
  - ▶ *E. coli* O157:H7
    - ▶ Sprayed on the hides of cattle before slaughter since 2006.

**Table 1. Counts of *E. coli* O157:H7 on cattle hides when treated with control (phosphate buffer) vs. Finalyse**

Exposure Time	Control Avg. Log CFU/g	Finalyse Avg. Log CFU/g	<i>E. coli</i> Reduction Avg . Log CFU/g
5 minutes	5.34	3.54	1.8
1 hour	5.58	3.66	1.92
4 hours	6.12	3.54	2.58

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**Table 2:** Prevalence of *E. coli* on variety meats<sup>3\*\*</sup>



\*\*Based on internal customer data. Data not analyzed for statistical significance.

## Finalyse STEC

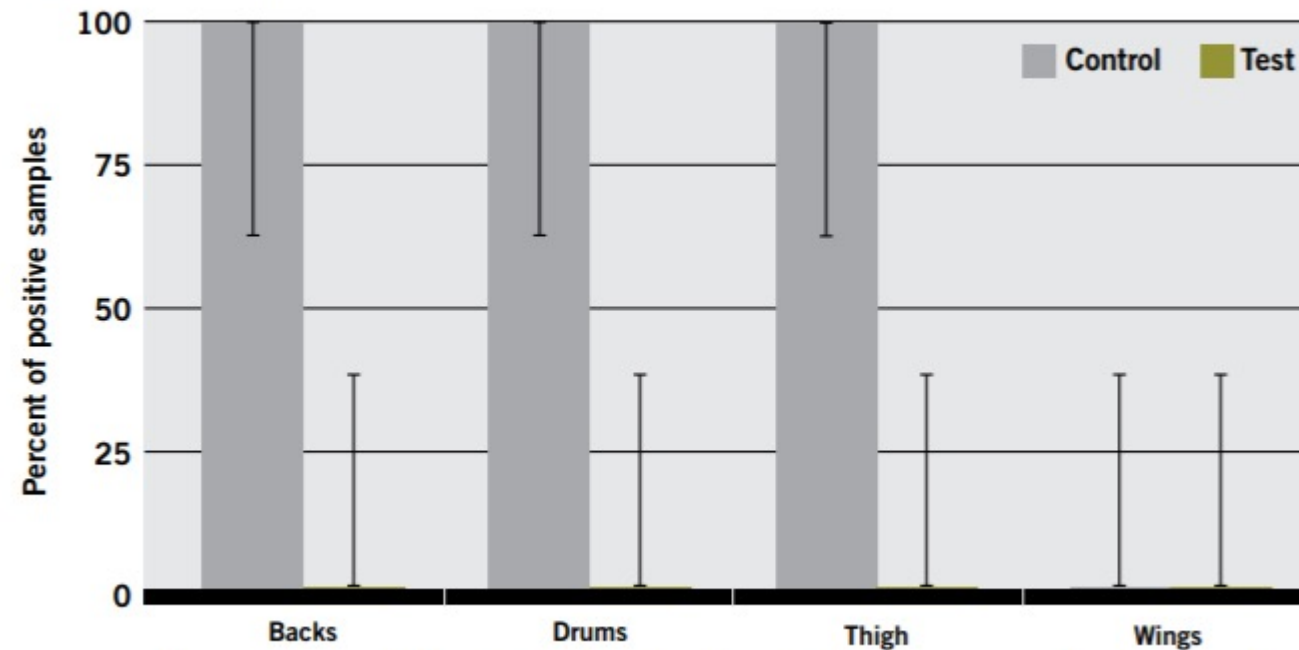
- ▶ Combines protection against all shiga-toxin producing strains:
  - ▶ *E. coli* (STEC O157:H7, O26, O45, O103, O111, O121, and O145)



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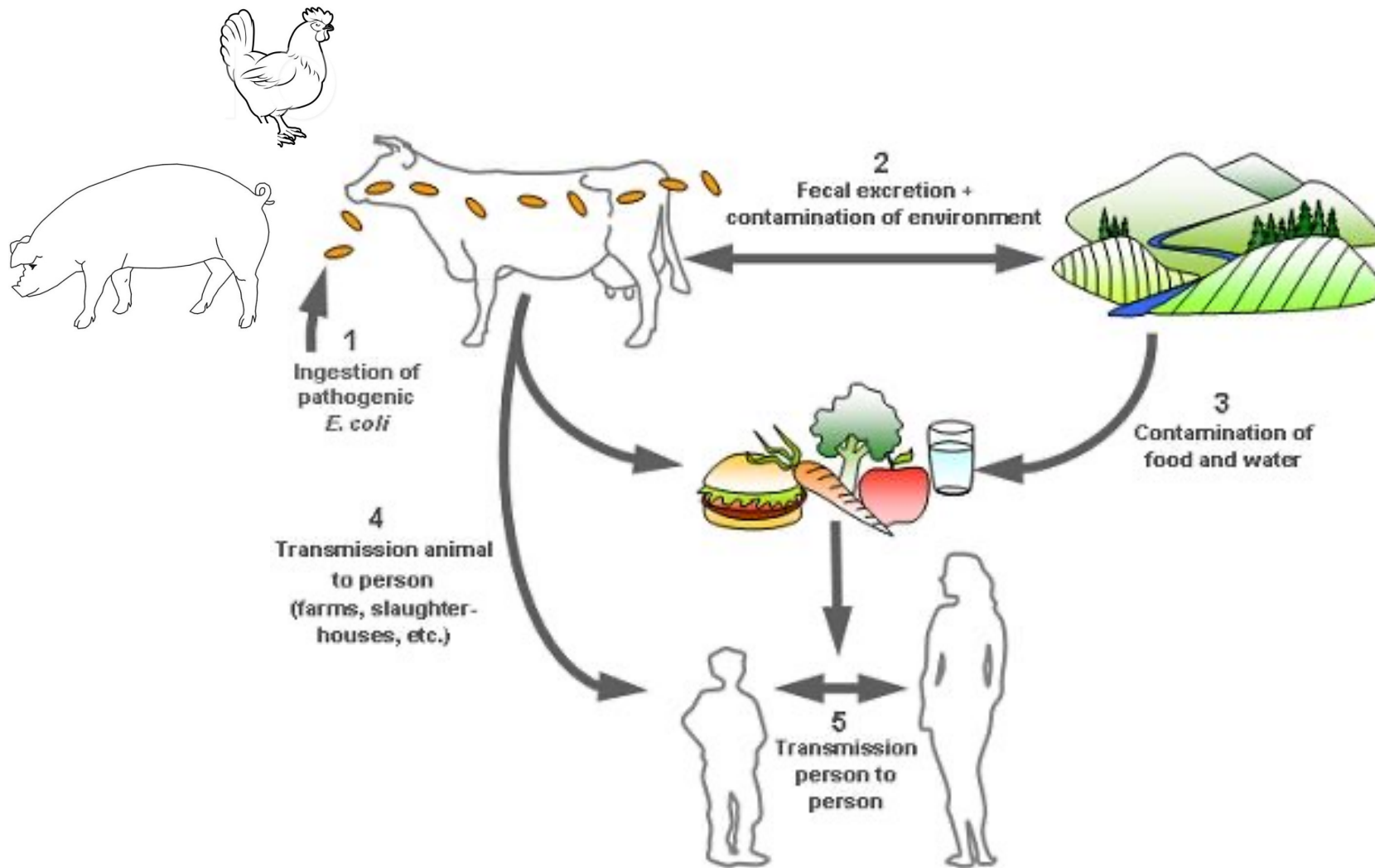
- ▶ Finalyse- SAL
  - ▶ Combines multiple Salmonella phages to provide broad spectrum strain coverage.

**Figure 1:** Comparison of *Salmonella* Positive Rates After Grind



\*Error bars are created using Agresti-Coull method with 10 samples per part and treatment

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## VECTORS:

- ▶ Leafy Greens:
  - ▶ Bacteria colonize inside folds and recesses (very difficult to reach with conventional sanitizers)
  - ▶ Field packed
- ▶ Cruciferous Vegetables:
  - ▶ Also, difficult to reach surfaces
  - ▶ Products used in processing and cleaning facilities don't have enough dwell time to be effective. Bacterial resistance.
- ▶ Water/Irrigation Sources
  - ▶ Surface water and ground water contamination
- ▶ Livestock: Cattle, Poultry, Swine
- ▶ Field Labor
- ▶ Equipment Contamination

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- ▶ Current post-harvest chemicals have drawbacks:
  - ▶ Delicate Produce
  - ▶ Can alter taste or texture of food
  - ▶ May need to be rinsed off
  - ▶ Low dwell time
  - ▶ Can't reach all surfaces
  - ▶ Bacterial resistance

Our proposed solution.....

# AgriPhage- Food Safety

AgriPhage Food Safety would combine our Salmonella and E. coli phages into one product for use on produce as a PRE-HARVEST application.

- ▶ Leafy Greens
- ▶ Sprouts
- ▶ Machinery
- ▶ Irrigation sources
- ▶ Worker boot and hand cleaners

1-4 applications pre harvest to allow maximum dwell time and penetration.

# AgriPhage- Food Safety

## Regulatory Pathway

- ▶ EPA approval will require joint approval from both Antimicrobial Division (AD) and Biopesticide Pollution Prevention Division (BPPD)
  - ▶ OmniLytics met this Summer with both divisions in one room.
  - ▶ BPPD will take the lead and provide assistance to AD.

# AgriPhage- Food Safety

- ▶ CDC estimates *Salmonella* causes about 1.2 million illnesses, 23,000 hospitalizations, and 450 deaths in the United States every year. Food is the source for about **1 million** of these illnesses
- ▶ An estimated **265,000** STEC infections occur each year in the United States. STEC O157 causes about 36% of these infections, and non-O157 STEC cause the rest.