Bacteriophage-based Technology

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AGENDA

- Intralytix
- Basics on Bacteriophages
- Food Safety Products, regulations, certifications
- Product and Segment Fit
- Application
- General Capabilities and Benefits
- Questions

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Bacteriophages

- Viruses that attack bacteria
- From the Greek “phago” meaning “to eat” and “bacteria”
- Estimated 3 billion years old
- Discovered in 1915-1917
- Most ubiquitous organisms in nature
- Play a key role in maintaining balanced bacterial populations in all ecosystems where bacteria exist
- Highly specific for bacterial host

All things compared…

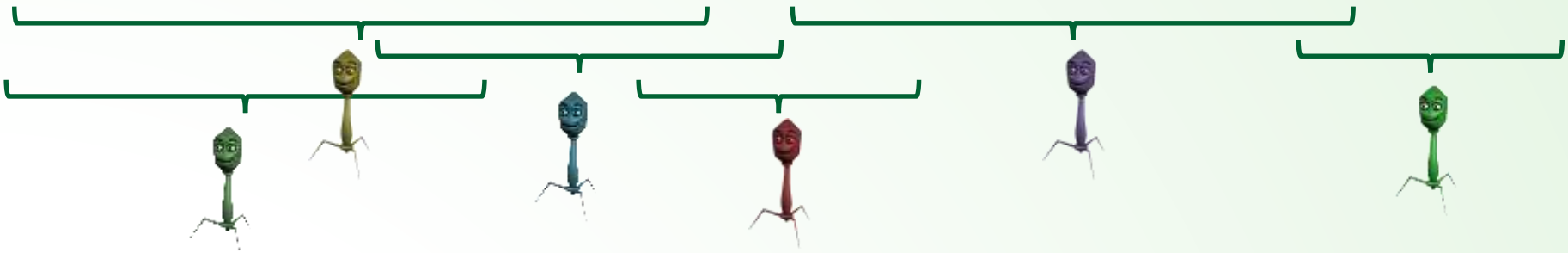
Most ubiquitous organisms on earth

- Total number of phages on Earth is estimated to be $1x10^{30} – 1x10^{32}$
  - Outweigh world's population of elephants
- More than 100 million phage species
- In 1mL non-polluted water, ~$2x10^{8}$ PFU of phages
- Common in human mouth and GI tract
  - 10^{15} phages in human gut

Phages are common in foods

- Fresh ground beef
- Canned corned beef
- Fresh pork sausage
- Fresh chicken meat
- Delicatessen meat
- Farmed freshwater fish
- Oil sardines
- Cheese and raw milk

- Levels ranged:
- $4x10^{10}$ PFU/100g fresh chicken and pork
- $3x10^{10}$ PFU/100g roast turkey breast
- Up to 10^{9} PFU/mL of yogurt and cheese whey
- 67-83% of all animal feed, ingredients, & diets examined



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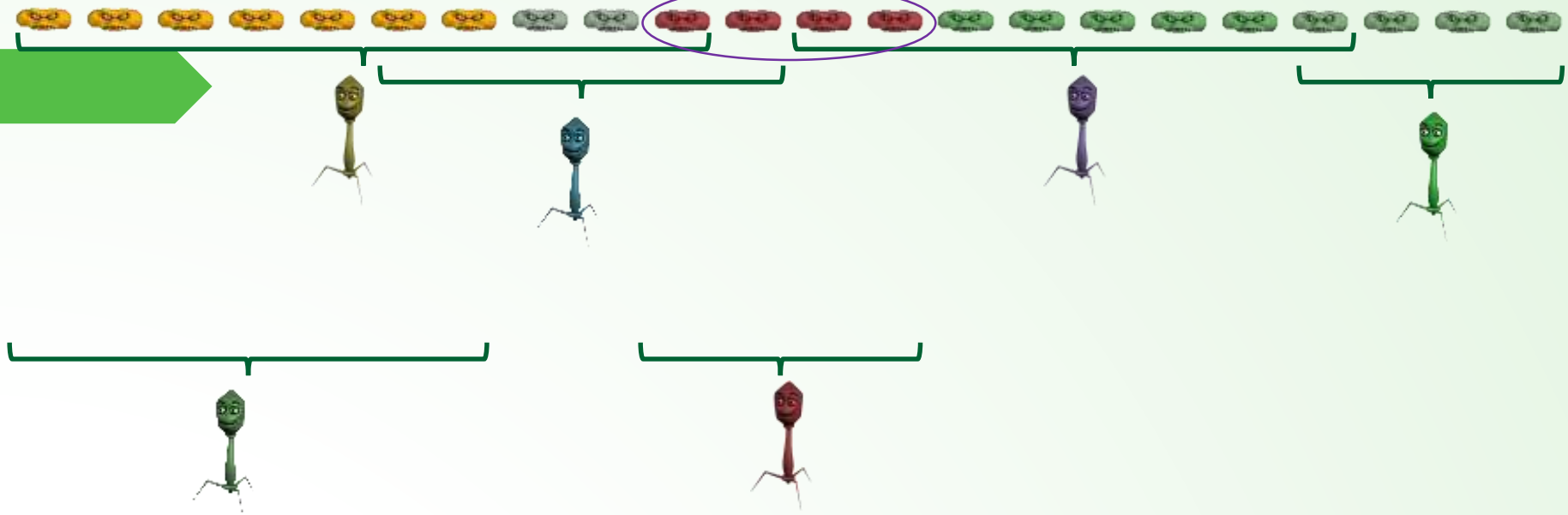

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Food safety regulatory approvals

Date	Agency	Phage preparation	Target application
2006, August	FDA, 21 CFR 172.785	ListShield	RTE meats
2006, October	FDA, GRN 198	Listex	Cheese
2007, January	USDA, FSIS Directive 7120.1	E.coli O157:H7 targeted	Hides of livestock
2007, March	USDA, FSIS Directive 7120.1	Salmonella-targeted	Hides of livestock
2007, June	FDA, GRN 218	Listex	Foods, generally
2008, July	USDA, FSIS Directive 7120.1	Salmonella-targeted	Feathers of live poultry
2010, September	Health Canada	Listex	RTE meat, dairy, fish
2011, February	FDA, FCN 1018	EcoShield	Ground beef
2012, August	FSANZ	Listex	Meat, seafood, cheese, RTE foods
2013, February	FDA, GRN 435	SalmoFresh	Poultry, fish, fruits, vegetables
2013, December	FDA, GRN 468	Salmonelex	Pork and poultry
2014, August	Health Canada	SalmoFresh	Poultry, fish, fruits, vegetables
2014, August	Israel Ministry of Health	SalmoFresh	Poultry, fish, fruits, vegetables
2014, August	Israel Ministry of Health	ListShield	RTE meats
2014, August	Israel Ministry of Health	EcoShield	Ground beef
2014, December	FDA, GRN 528	ListShield	Fruits, vegetables, dairy, fish

Cerifications

- **No barriers to processors' end customers**

Packaging

- Standard pack comes in 1 or 2-liter bottles

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Preparation and Dose Rate

- Products come highly concentrated 1 X 30
- Must remain refrigerated during shipping and storage
- “Working Solution” – combination of 1-part product and 29 parts water
- “Working Solution” dose rate at 2ml per lb. of product
- Surface coverage critical

Food safety applications

- Pre-harvest interventions
- Direct food applications
- Environmental

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Ecolicide PX™

Targets *Escherichia coli* O157:H7 contamination on hides of live animals.

Applied on hides of live animals

Goal to reduce contamination prior to animal entering processing facility

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ListShield™

RTE Meat, Fish, and Cheese

reduce or eliminate the risk of foodborne listeriosis

“zero tolerance” for *L. monocytogenes* in RTE foods

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SalmoFresh™

Fresh Poultry

reduce or eliminate the risk of foodborne salmonellosis

naturally occurring lytic bacteriophages that selectively and specifically kill *Salmonella*

most common / highly pathogenic serotypes Typhimurium, Enteritidis, Heidelberg, Newport, Hadar, Kentucky, and Thompson, Georgia, Agona, Grampian, Senftenberg, Alachua, Infantis, Reading, and Schwarzengrund.

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EcoShield™

effective against *E. coli* O157:H7

effective in reducing contamination of various foods (e.g., ground beef, fruits, vegetables, etc.)

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Capabilities and Benefits

- Killer of Bacteria – Not an Inhibitor
- Efficacy Data proving consistent 2-log reduction of bacteria will be achieved at standard recommended dose level
- Not a chemical. Safe for environment, equipment, and workers
- Processing aide status. No labelling required

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Capabilities and Benefits *cont.*

- No Organoleptic side effects. Color, order, taste, texture, etc. not affected
- 99% efficacy achieved in first 60 seconds after phages come in contact with bacteria. Lytic cycle will continue for another 24 hours to continue to pursue and kill additional bacteria cells
- Phages do not dissipate away during process like chemicals do and keep environment and equipment clean during production hours

Additional considerations

- How effective is effective enough?
  - Complete eradication of targeted pathogen is not always achievable
- Cost to the producer?
  - Many food industries operate on thin profit margins, cost may need to be under 1 -1.5 cents / lb
- Application equipment?
  - Requires spray equipment to apply phages
- Consumer / customer acceptance?
  - All food additives unpopular, phages outside scientific community a term widely unknown

For more information:

- www.intralytix.com
- http://www.cfsan.fda.gov
- http://www.asm.org/division/M/M.html
- http://www.evergreen.edu/phage/

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