

The Arduous Pathway to a Section 18

International Spinach Conference
October 2011



Outline

- Quick view of EPA's requirement for a Section 18
- Germains starting point of development
 - Failures and challenges
- Current position

Working within US Federal Guidelines

- In 2006, the EPA published a final rule that revises the regulations governing emergency exemptions to allow unregistered uses of pesticides to address emergency pest conditions for a limited time. These exemptions are authorized by Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

<http://www.epa.gov/opprd001/section18>

Title 40 of the Code of Federal
Regulations, part 166

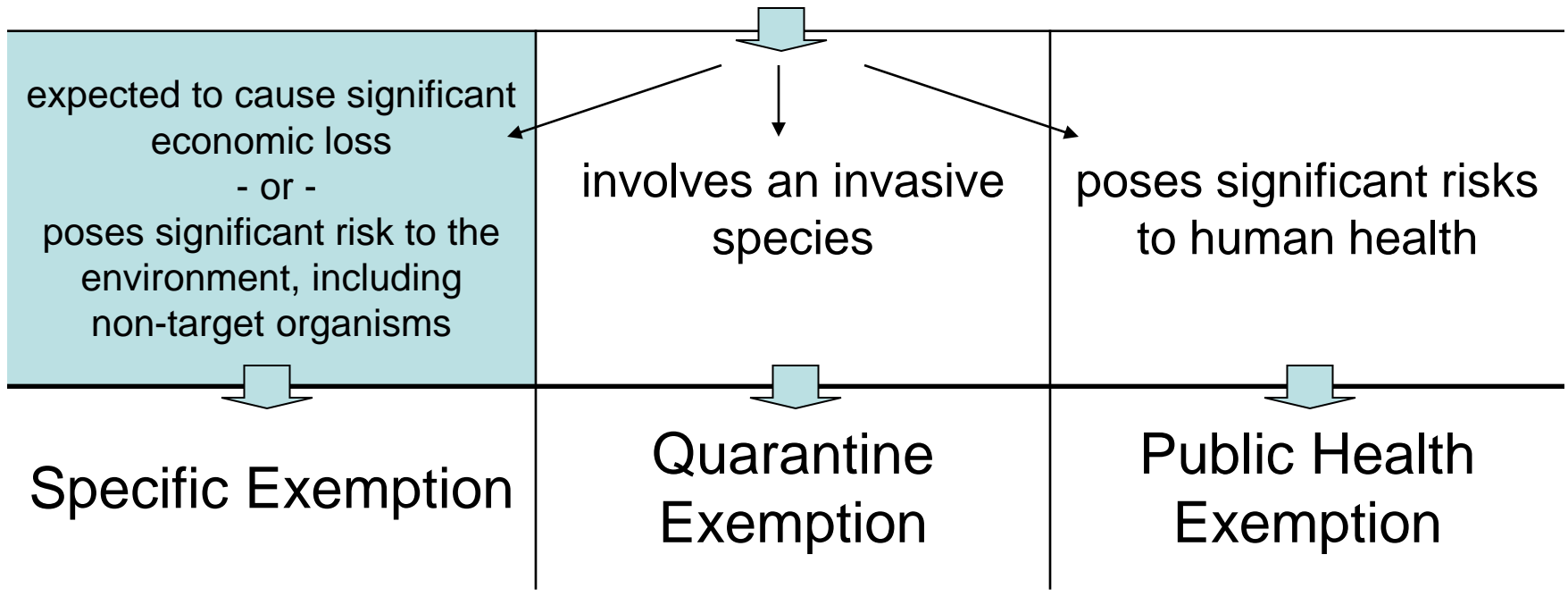
How Does the Process Get Started

- Growers or agricultural research scientists identify a pest situation which registered pesticides will not alleviate.
- Growers request their state led agency to request an emergency exemption from EPA
- In the Case of Verticillium, the California Seed Association and California Leafy Greens Research board are acting on behalf of the CA spinach growers
- Federal Law Prohibits Chemical Companies from applying : Offers unfair advantage

THE EPA has Defined Emergency Conditions and Four Types of Exemptions

Urgent and Non-routine Pest Problem

No Effective Controls and Problem . . .



Crisis Exemption - any situation with very limited time

Nature of the Emergency: “Urgent and Non-routine”

or

What do you mean my problem isn't a
problem?



EPA: Nature of the Emergency: “Urgent and Non-routine”

- Urgent
 - Consequences of the pest problem must be fairly immediate
 - No time to obtain a Section 3 or 24(c)
- Non-routine
 - The problem must be unusual
 - Routine problems can be addressed via the Section 3 process
- We fall into the Non-Routine: we are stating that it is urgent because of the increasing number of highly infected fields where no one can plant lettuce .

No Available Alternatives

Two other conditions that constitute an emergency condition:

- No effective pesticides are available:
 - Detailed explanation of why any registered pesticides for the site/pest are not adequate to address the situation.
 - Claims of ineffectiveness of the alternatives must be supported by field data or, if such data are not available, statements from qualified experts
 - Claims of insufficient availability must be supported by communication with the registrant or supplier of the alternative product(s)
- Detailed explanation of why alternative practices, if available, are insufficient to address the pest situation

Demonstrating Significant Economic Loss (SEL) to Support a Specific Exemption



Purpose of SEL Requirement

- Show that pest problem is severe enough to justify exemption from pesticide regulations (Section 3 registration)
- Loss due to pest problem: Compare routine (normal) situation with non-routine situation
 - That is, With and Without Pest Problem
 - Not With and Without Requested Chemical

Two Definitions of SEL

1. For problems mainly affecting current crop or output
 - Yield loss of 20% or more, or **A lettuce field can be 30 – 100% loss by Vert**
 - Loss equal to or more than 20% of gross revenue, or
 - Loss equal to or more than 50% of net operating revenue.
2. For problems with other effects
 - Substantial loss or impairment of capital assets
 - Loss affecting long-term viability of productive activity

Example of a SEL Analysis

	Baseline	Emergency	Change
Utilized Yield (ton/acre)	12.7	12.1	-0.6
Processed (@ \$170/ton)	4.4	4.4	
Fresh (@ \$470/ton)	8.3	7.7	-0.6
Gross Revenue (\$/acre)	4,650	4,350	-300
Production Costs (\$/acre)	1,620	1,620	
Establishment Costs (\$/acre)	370	370	
Harvest Costs (\$/acre)	840	840	
Marketing Costs (\$/acre)	1,060	1,210	+150
Net Operating Revenue (\$/acre)	760	310	-450

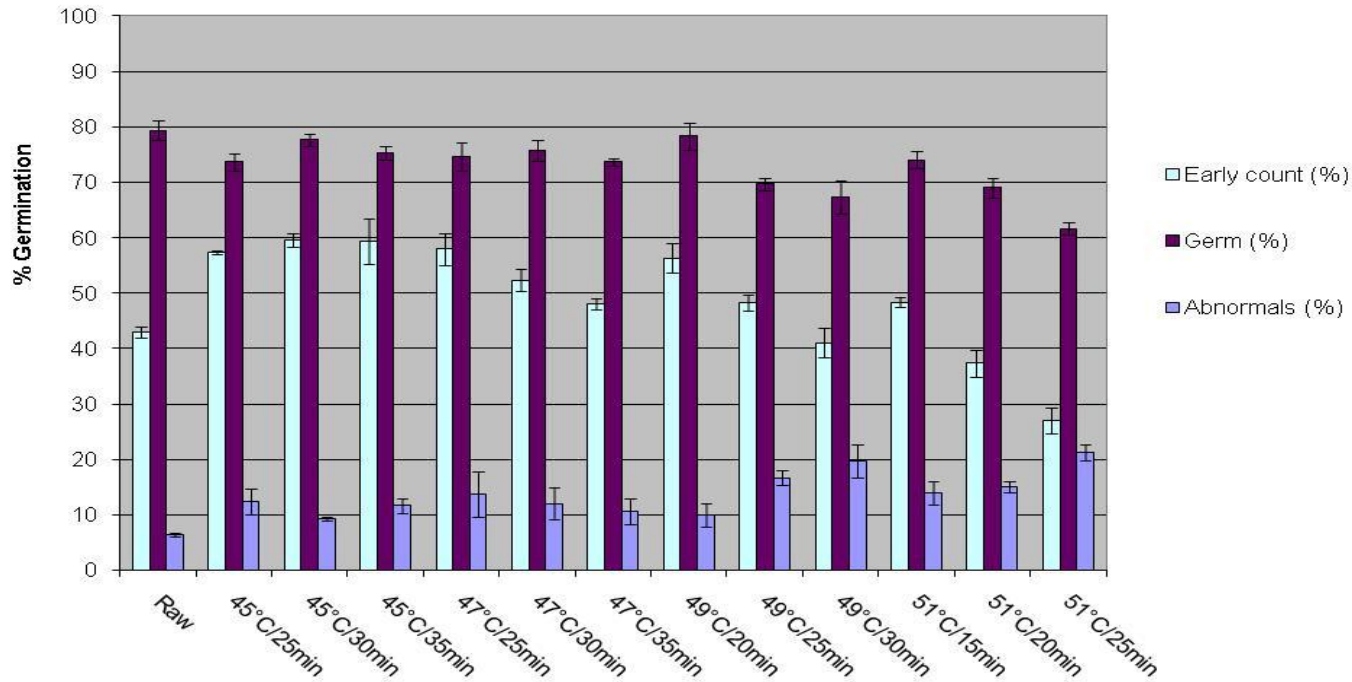
Sources: Nat'l Ag Statistics, University Crop Budget

How Not to Treat Spinach Seed

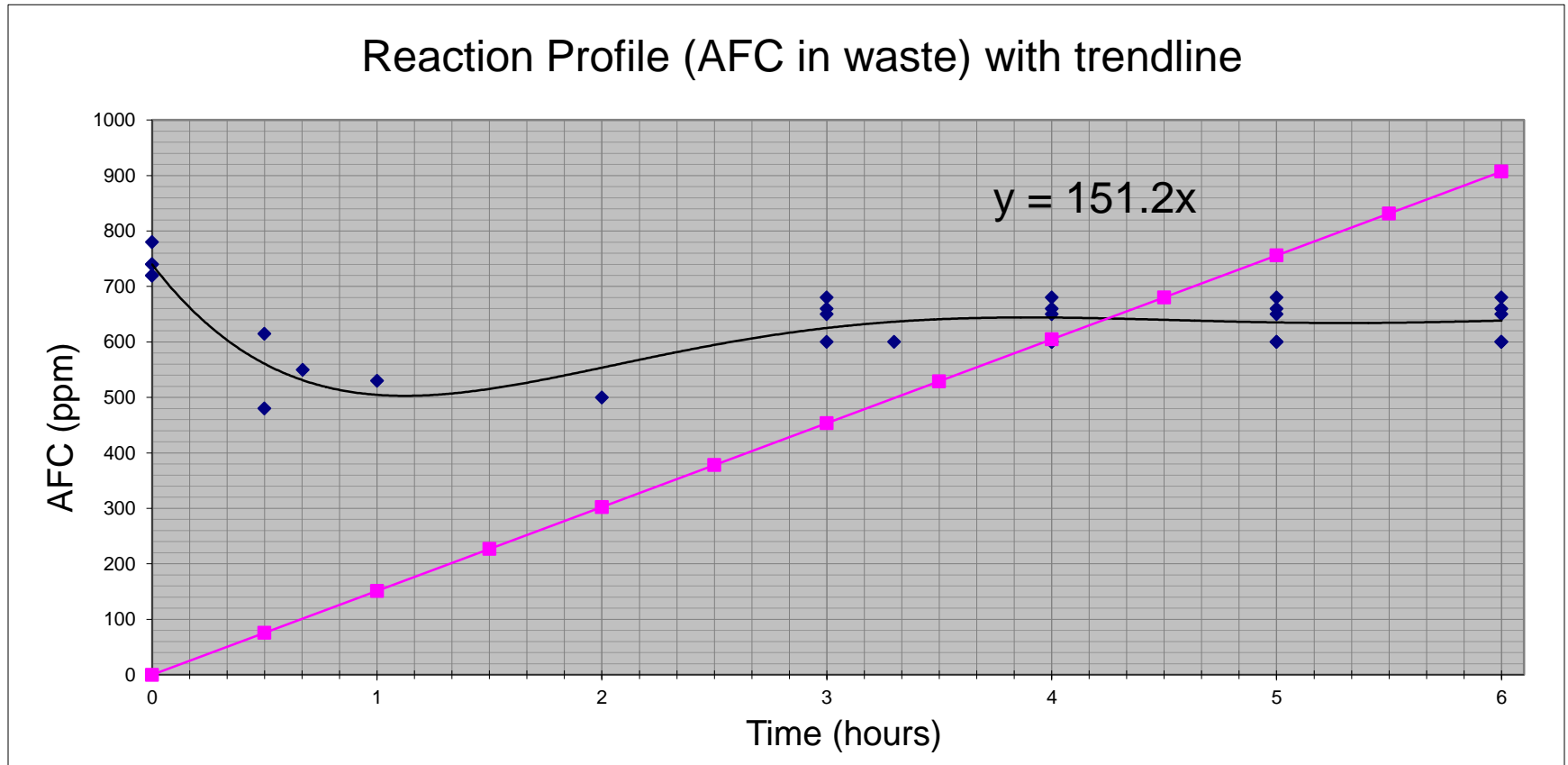
An Arduous Pathway



What We All Know: Hot Water Can Work, at the Cost of Decreasing Total Germination



Kick it up a Notch, add Bleach, “that kills everything!”



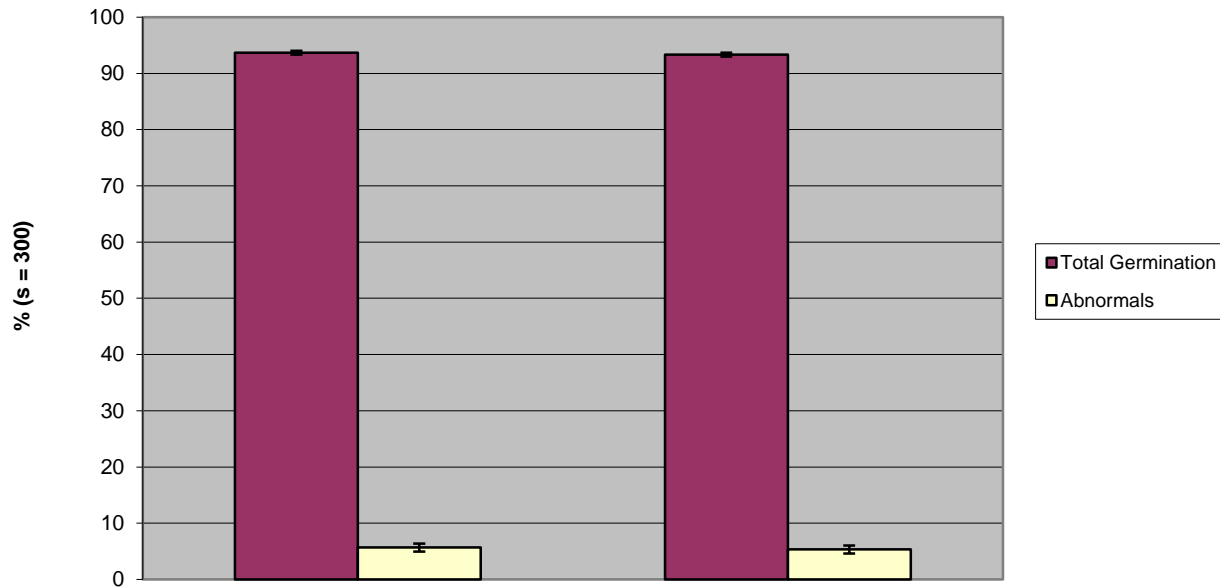
Measuring active free chlorine, the real disinfecting agent

WOW that really works

Spinach Disinfection - *Verticillium dahliae* - Wilt

18068 Spinach "Lot 3" - Germination \pm S.E.

% Infection (s = 400)



Let's do a field trial, it works in the lab!!!



- Beautifully clean seed post treatment
- Naked seed not able to withstand assault of soil pathogens, observed 20% loss in plants to pythium. fusarium

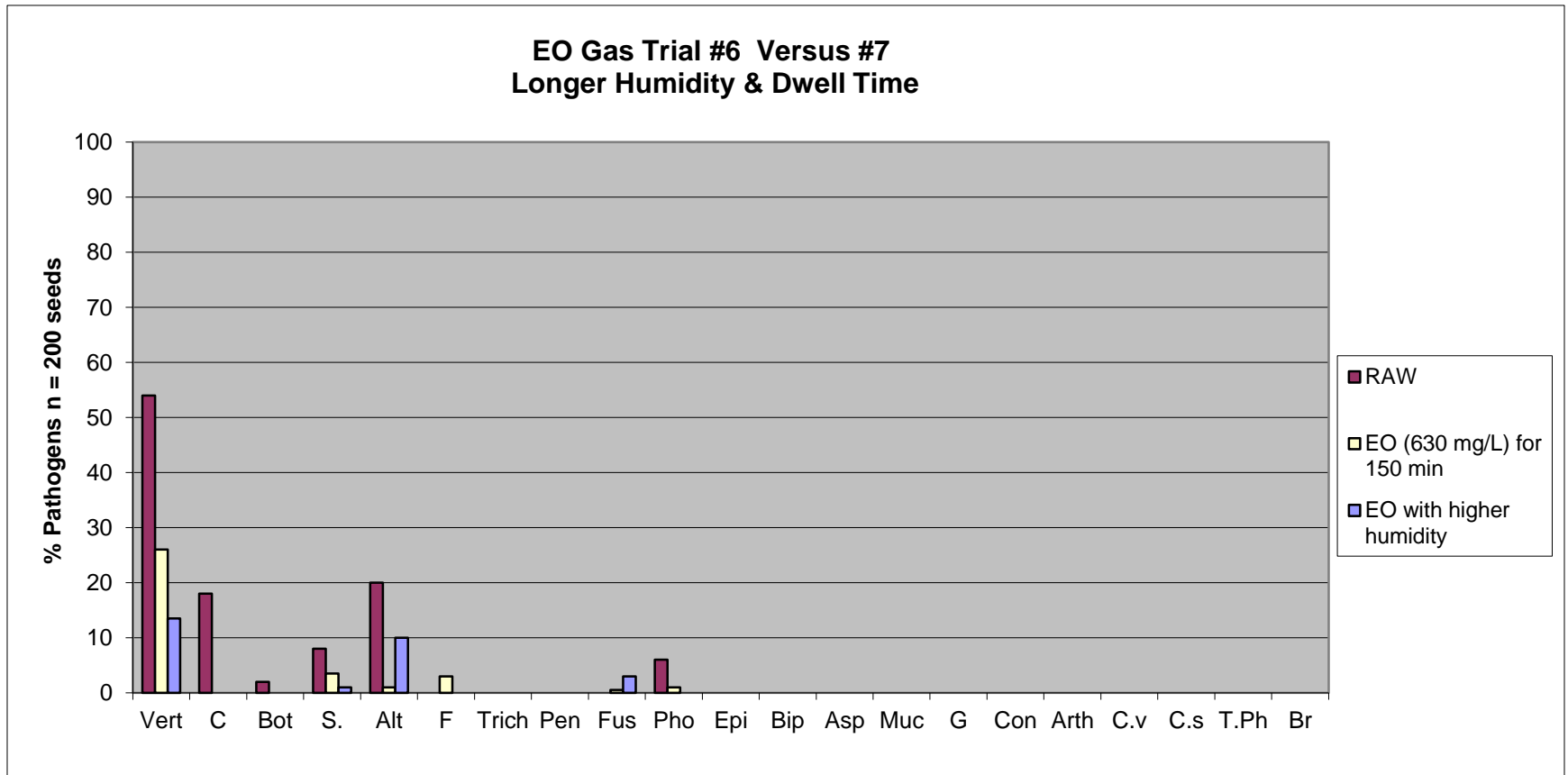
Protect the Seed Against Pathogens. This introduced new challenges

- Bacillus, Streptomyces, Trichoderma
 - All give varying results in the field
 - Colonies cannot establish fast enough
 - Residual bleach killing off organisms
 - No Shelf Life
 - No protection in the soil

Let's Scale That Up: NOT

- If 100 grams of seed requires 300 grams of solution to treat in the lab;
 - 1000 kg of seed requires 3,000 kg solution
 - A 5,000 liter vessel = very little capacity
 - Cost to build facility is greater than 4 years payback on investment
 - If a US grower buys seed for \$0.33 / 1000 will he now pay \$0.20 for treatment or \$0.53 / 1000 for his seed?

The Effect of Pathogen Loading Post Treatment with Ethylene Oxide: Strong Varieties are OK Germination while Low Vigor or Scarified Seed is Poor



What about hot water vapor?

- In 2008 We first chose to treat seed with 60 C vapor for 120 seconds of exposure
- We also did a similar matrix to that of hot water varying duration time with steam temperature
- Bottom line: Inconsistent pathogen removal, lower germination, loss of natural inhibitors to soil pathogens and expensive to scale up
- We understand that it will be prohibitive to the grower if the cost to treat is greater than \$0.10/1000 seeds

Other concepts that we have investigated:

- Various Acids / bases
- Sulfur
- UV light
- Loads of chemical fungicides
- Topsin
- Commercially available disinfectants
- In process: working on a multitude of organic and non-organic treatments

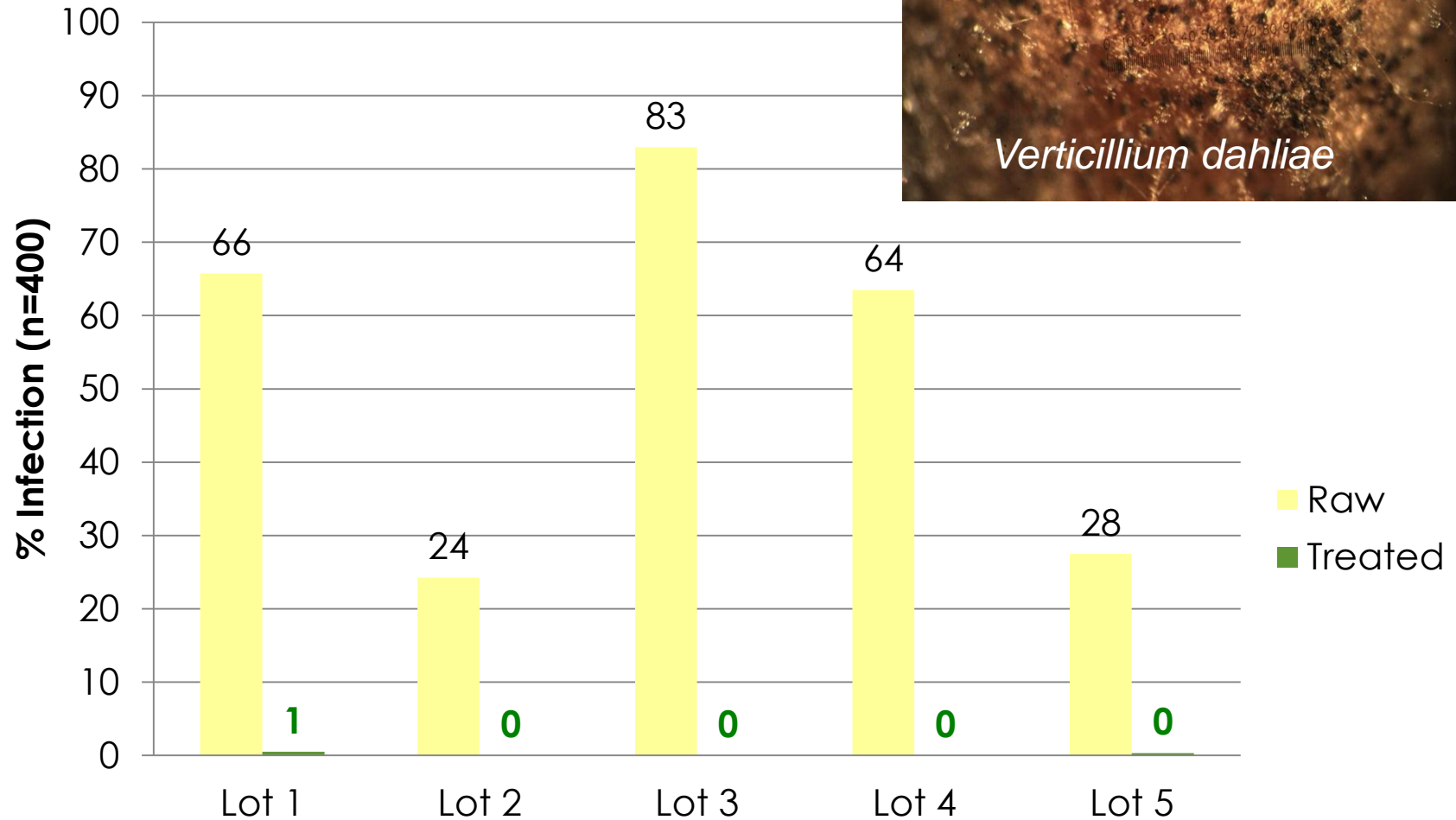
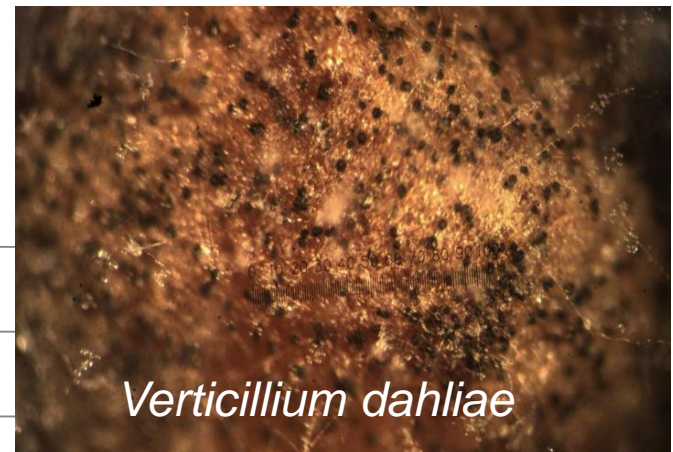
Where We are Today With A Section 18

- Submitted a Section 18 application to the California Leafy Greens Research Board in January 2011
- Submission is in the offices of the WA and CA department of Pesticide Registration
- Submission to the EPA was expected by July but was delayed due to overload of submissions to the EPA
- Official decision still pending

What is gopure Spinach

- A specially formulated process to treat spinach seed and remove the deeply rooted infection
- Conventional seed supplied fungicide treatment
- We have processed over 36 spinach cultivars, from various breeder-producers to show disinfection spinach's efficacy at removing *Verticillium* without impacting plant health
- Have conducted multiple field studies to show that the treatment produces a harvestable crop
 - We observed one trial with slow emergence and are working to better understand this.

Verticillium spp.



Section 3 Full Federal Label is in Progress

- Phytotoxicity / Efficacy and Residue
 - All results to date have shown no indication of negative effects

QUESTIONS??

