Pesticide Program Dialogue Committee October 31, 2018 Get to Know the

Biological Products Industry Alliance Keith Jones – Executive Director





Who is BPIA?

Started in 2003 with 5 member companies

Today: 129 Member Companies

Manufacturers, Marketers, Distributors, Service Providers from North and South America, Asia, Europe, and Middle East

Members Range from Sole Proprietors to Multinational Companies

Incorporating biostimulant issues and members

Expanded to include Growers and Food Processors





Our Mission

Advancing Sustainability Through Biological Solutions





What Does BPIA Do?









Collaborate





Member-Driven Committees & Meetings

Committees:

Biostimulants
Communications
Finance
Government Affairs
Finance
Membership
Nominating
Regulatory
Specialty Markets

Meetings:

Annual Meeting
Capitol Hill "Fly-Ins"
Symposiums
Workshops





Industry Collaboration

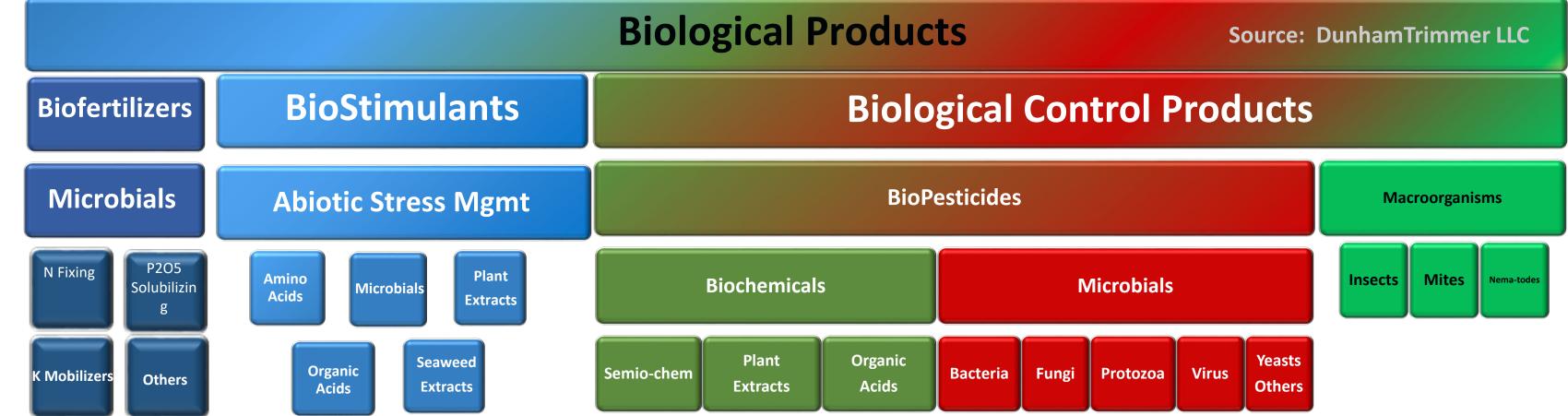
While BPIA member companies hold membership in multiple industry trade groups that represent diverse commercial interests, BPIA itself has joint initiatives with industry associations to collaborate on common goals.

- ASTA (American Seed Trade Association)
- BIO (Biotechnology Innovation Organization)
- CLA (Crop Life America)
- EBIC (European Biostimulant Industry Council)
- IBMA (International Biocontrol Manufacturers Association)
- TFI (The Fertilizer Institute)









Biofertilizers

- Microbials used to enhance plant nutrient uptake from soil
- Nitrogen fixing bacteria make up largest group
- Others include mobilizers of specific nutrients (zinc, sulfur) and mycorrhizal fungi
- Biofertilizers regulated under country/state fertilizer regulations

Biostimulants

- Seaweed Extracts make up the largest segment in this group
- Microbials, primarily bacteria, often used as seed or soil treatment to aid in nutrient assimilation
- Organic acids are humic and fulvic acids used as soil amendments, formed by the microbial degradation of plant matter.
- Definition and regulation of biostimulants is still under development in most parts of the world

BioPesticides

 Biopesticides are derived from natural materials, such as plants, bacteria and certain minerals. Biopesticides target specific pests and are inherently less toxic than synthetic pesticides.

Biochemicals

- Plant Extracts;
 Semiochemicals; Organic Acids
- Plant Extracts make up the largest segment in this group
- Semiochemicals (pheromones) has the largest actual number of products
- Largest challenge for Plant Extracts is manufacturing and consistent quality in the active ingredient(s)

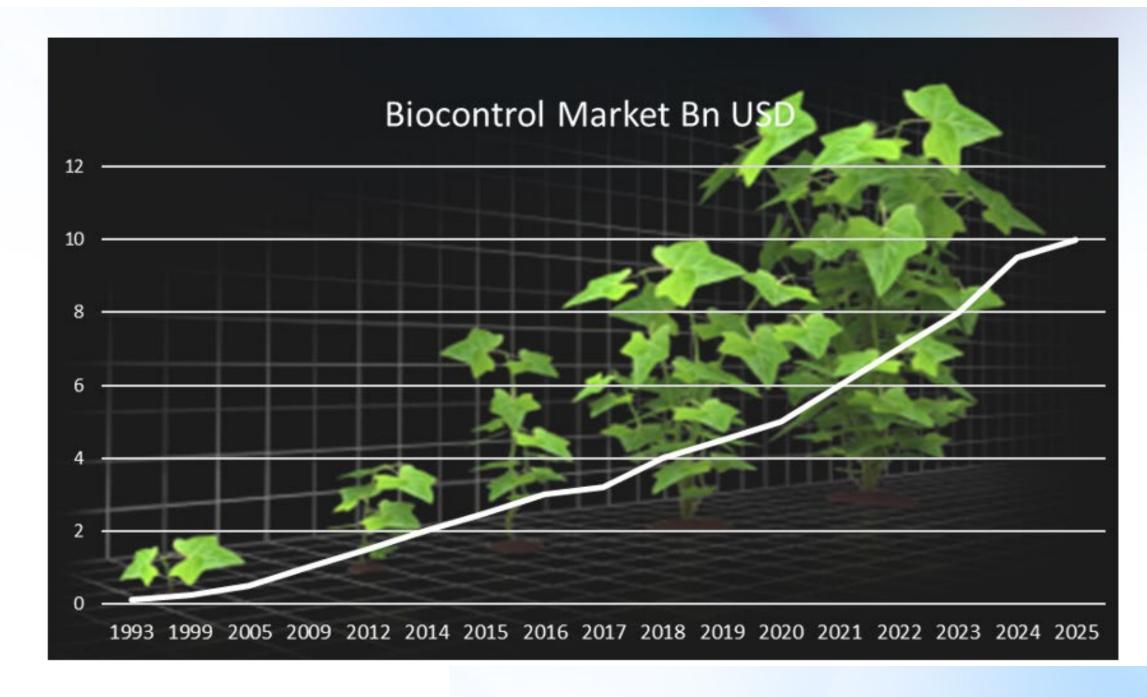
Microbials

- Bacteria; Fungi; Virus; Protozoan; Yeasts
- Bacteria, followed by Fungi make up the largest groups commercially (>90%)
- Microbials are the largest market of biopesticides.
- Biggest challenges for microbials are formulation related: 1) Shelf-life; 2) Stability; 3) Performance enhancement

Macroorganisms

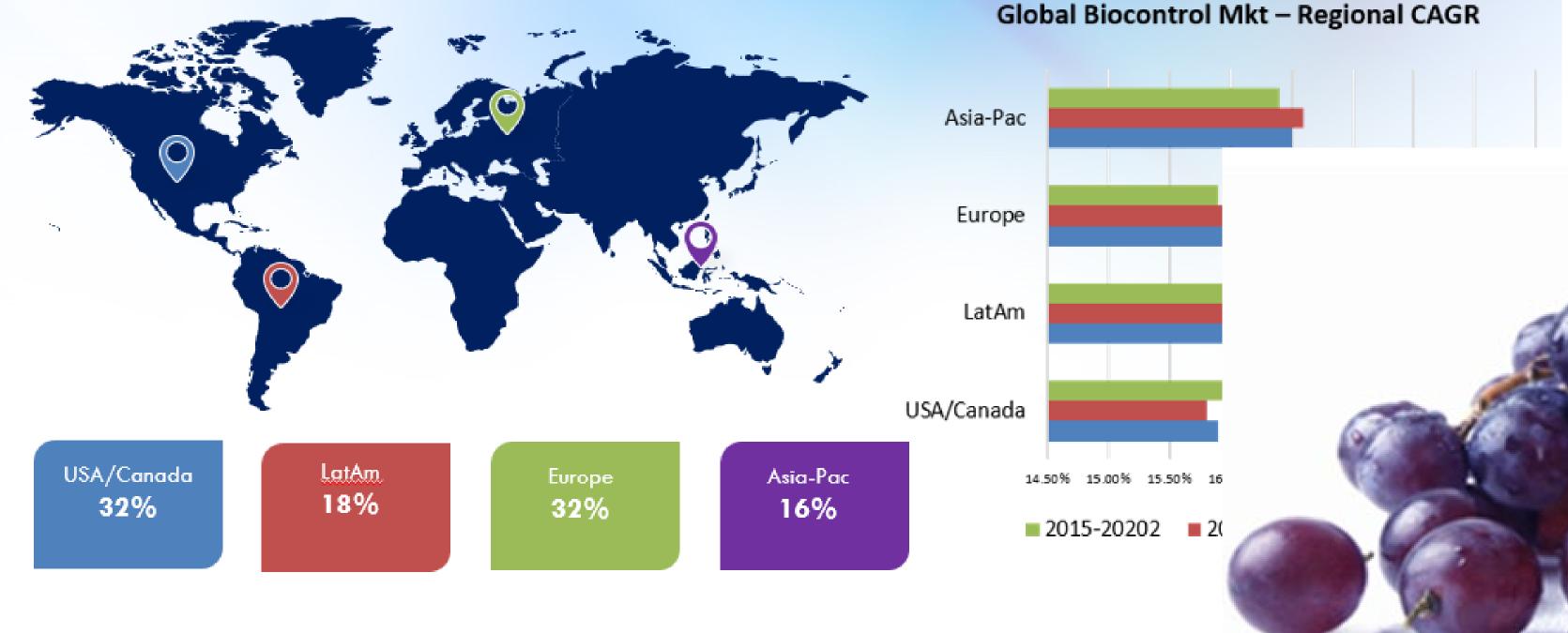
- Insects; Mites; Nematodes
- Insects followed by mites makeup the largest groups
- Unique in that the live organism in the form of eggs, larvae, pupae or adult is used.
- Most important challenge for Macros is logistics—shipping live organisms that have to have special care to survive
- Normally not classified as a Biopesticide—only as Biological Control Products





Biological products are a rapidly growing global business





What are Biopesticides?

Biopesticides are reduced risk pesticides that are naturally derived or synthetic equivalents of natural materials such as animals, plants, bacteria, fungi and certain minerals, generally posing little risk to humans or the environment. (aligns with EPA OPP definition)

Biopesticides:

- Allow conventional growers to integrate reduced risk pesticides into their pest management program
- Allow organic growers to control pests while maintaining their certified status
- Play an important role in public health protection
- Are important components of IPM Programs
- Allow greater flexibility when harvesting due to minimal re-entry and pre-harvest intervals
- Minimal Personal Protective Equipment (PPE) for agriculture workers
- Are effective resistance management tools because of their alternative modes of actions
- Can be used as residue-management tools





What are Biostimulants?

A plant biostimulant is a substance or substances and/or microorganisms whose function when applied to seeds, plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, crop quality and/or yield.

Biostimulants:

- Derived from natural or biological sources
- Enhance plant growth and development
- Improve the efficiency of plant nutrients, as measured by either improved nutrient uptake or reduced nutrient losses to the environment, or both; and/or
- Act as soil amendments, with demonstrated ability to help improve soil structure, function or performance and thus enhance plant response





Integrating Biostimulants

- ✓ Globally:
 - √ >400 Companies have a commercial interest in Biostimulants
 - √ ~200 Companies have Biostimulant products in the market or in development
- ✓ BPIA officially included Biostimulants in it's scope, mission and priorities
- ✓ Established a committee infrastructure to focus on biostimulant issues, give voice to the industry, and integrate biostimulants into existing BPIA initiatives & priorities
- ✓ Dedicated member volunteers with expertise to drive key biostimulant initiatives in coordination with BPIA staff and consultants



Thank you for your time and attention!

For more information, contact: Keith Jones, Executive Director (202) 570-1411

> jones@bpia.org www.bpia.org





The Benefits and Regulatory Challenges of Biopesticide Industry Perspective

Nina Wilson
Gowan Company LLC
Representing Biological Products Industry
(BPIA) Companies and Products





WHAT DO THINK WHEN YOU HEAR THE WORD BIOPESTICIDE?









The Conundrum — what is a biopesticide?

EPA Biopesticides:

- Biochemical
- Microbial
- Plant Incorporated Protectants (PIP)
- New technology

But can also be described as:

- Pesticides
- Biorationals biological products
- Low-risk pesticides
- Organic inputs
- Not organic
- Microbial
- Plant extracts
- Natural occurring
- Not naturally occurring
 - Synthetic equivalents (of natural occurring



Biopesticide Profile

- Novel mode of action(s)
- Minimal Personal Protection Equipment (PPE)
- Minimal 4-hour reentry interval (REI) and Preharvest interval (PHI)
- Caution signal word
- Favorable safety profile
- Can be used across all agriculture/non-ag systems in IPM or resistance mngt programs

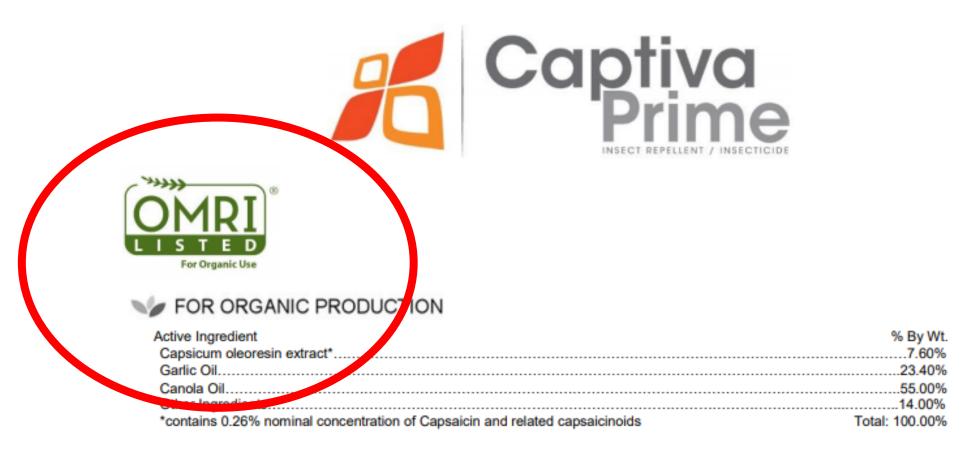
 – technology neutral
- Generally, narrow spectrum; very selective for target pests
- Exempt from tolerance
- Decreased data requirement & timelines

Action	Review Time	Fee
New ai; food use; tolerance exemption (BPPD)	17 mos	\$31,910
New ai; food use; reduced risk (RD)	18 mos	\$627,568
New ai; food use (RD)	24 mos	\$627,568





Which Product Was Registered as a Biopesticide (BPPD)? Both are naturally occurring plant extracts.



KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID		
If on skin or clothing	 Take off contaminated clothing Rinse skin immediately with plenty of water for 15-20 minutes Call a poison control center or doctor for treatment advice. 	
HOT LINE NUMBER		
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-888-478-0798 for emergency medical treatment information.		

PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear chemical-resistant gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- · Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and



Natural, Organic but not a Biopesticide



- Naturally derived chrysanthemum extract
- Not a BPPD registration
- National Organic Program designation

 Safety Standard & MOA dictates that this is not a biopesticide per OPP (but would be for BPIA)



FIFRA Definition and Safety Standards Applies to Biopesticides

Office of Pesticide Programs Organizational Chart

Richard P. Keigwin, Jr., Director

Edward Messina, Acting Deputy Director for Programs

Wynne Miller, Acting Deputy Director for Management

(703) 305-7090

Anna Lowit Sr. Science Advisor (703) 308-4735

Antimicrobials Division

Anita Pease, Acting Division Director, Neil Anderson, Acting Deputy Director. (703) 305-0392

Biological & Economic Analysis Division

Wynne Miller, Director, Kevin Costello, Acting Deputy Director (703) 308-8200

Biopesticides & Pollution Prevention Division

Robert McNally, Director, Frank Ellis, Acting Deputy Director. (703) 308-8712

Environmental Fate & Effects Division

Marietta Echeverria, Director, Brian Anderson, Associate Director, Kimberly Nesci, Deputy Director. (703) 305-7695

Field & External Affairs Division

Jackie Mosby, Director, George (Jeff) Herndon, Deputy Director, Patricia Parrott, Associate Director. (703) 305-7102

Health Effects Division

Dana Vogel, Director,
Don Wilbur, Acting Associate Director,
Elissa Reaves, Acting Deputy Director.
(703) 305-7351

Information Technology & Resources Management Division

Delores J. Barber, Director, Hamaad Syed, Deputy Director.

Pesticide Re-evaluation Division

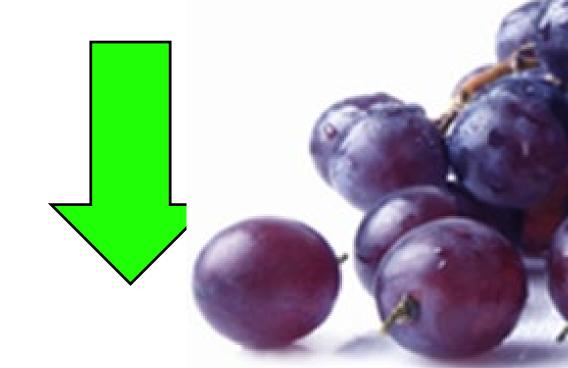
Yu-Ting Guilaran, Director, Charles "Billy" Smith, Associate Director. (703) 308-8000

Registration Division

Mike Goodis, Director, Dan Rosenblatt, Deputy Director, Donna Davis, Associate Director. (703) 305-5447

- Biochemical or microbial
- Naturally occurring or synthetic equivalent with a non-toxic mode of action (MOA)
- Plant incc protectan



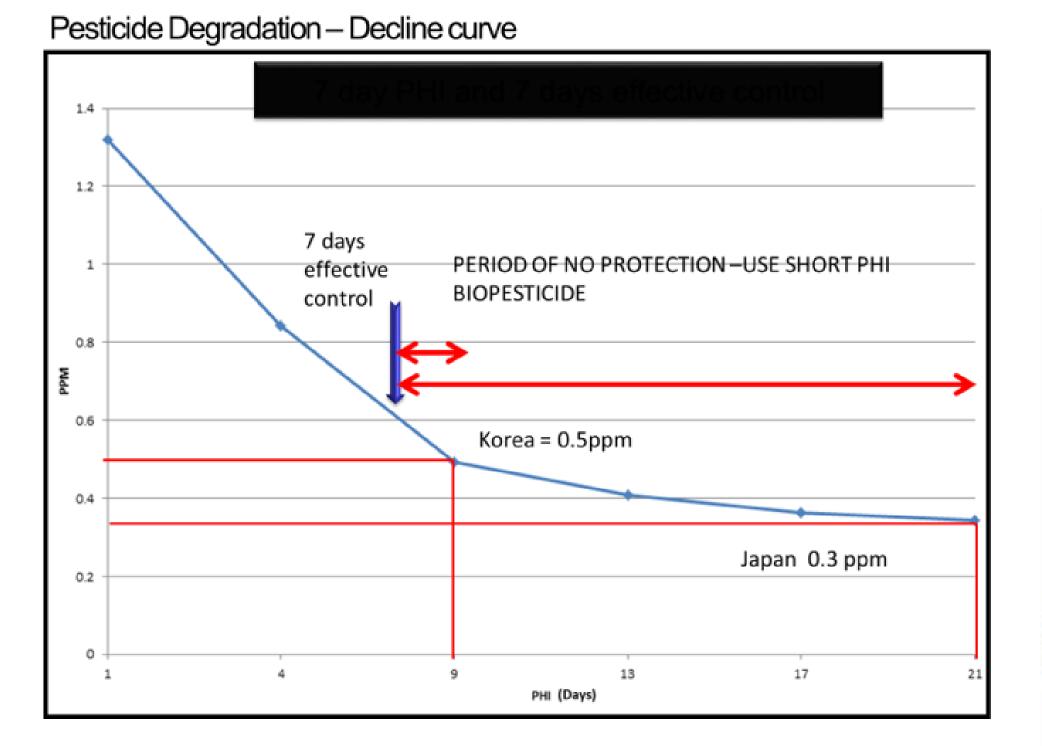


Biopesticide & Tolerance Exemptions

- Most biopesticide registered through BPPD are exempt from a tolerance
- There may be residues, but there are no residues of toxicological concern
- Very high safety standard

 Tolerance exemptions are not necessarily harmonized or recognized across the globe but can be used as a residue

management tool







Biopesticides: regulated to a higher safety standard

- Biochemical classification the safety funnel
 - Non-toxic mode of action
 - Naturally occurring or (synthetic equivalent) with a history of safe use
 - Informs a potential for reduced risk
 - Requires less (animal) studies in a tiered manner that discloses hazard potential
 - Does not guarantee biopesticide registration





This is not a biopesticide (obviously?)

- Plant extract
- MOA: Central nervous poison
- Acute LD50 :200-400 mg/kg
- Adverse affects: mild cerebral hyperemia, occasional psychotic-like self mutilation, gastric ulcers, and inhibition of oogenesis; hypertrophy of the salivary glands, gastrointestinal tract, liver, heart, kidneys, and lungs; a stressor reaction in the adrenal and thymus glands; minor changes in organ water levels; an occasional death apparently from bronchopneumonia (1965 Boyd)



This is not a biopesticide (caffeine)





This Photo by Unknown Author is licensed under CC BY-NC-ND

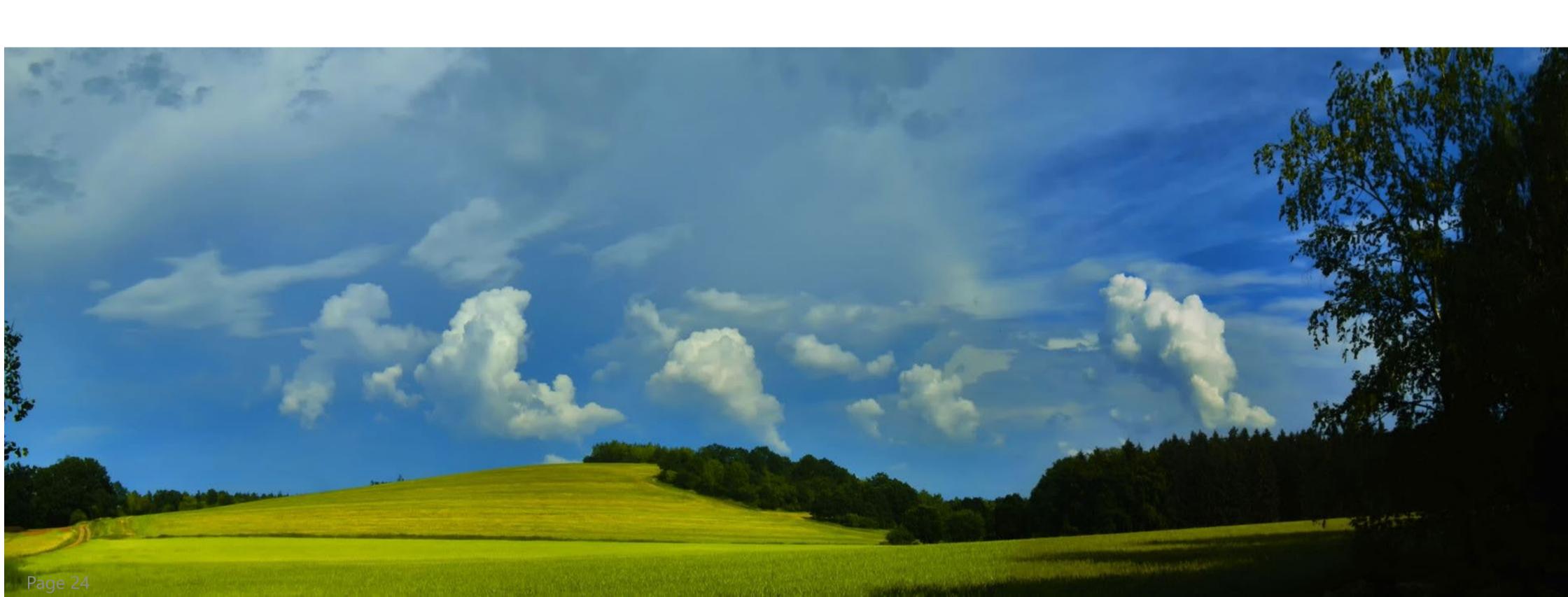
This Photo by Unknown Author is licensed under CC BY-SA





Biopesticide Benefits Product Examples

The largest market for biopesticide is the conventional crop acres.



Biochemical Pesticide Rescue! Disposable Yellowjacket Trap

Active ingredient (attractant): Heptyl butyrate

•Found abundantly in fresh apples and plums

•Trap design and attractant *selectively* catch yellowjackets

Yellowjackets drown inside the trap

•No harm to honeybees and other beneficial insects

•No human exposure to the attractant or the trapped

yellowjackets

Residential use product





Polyoxin D Zinc Salt







- •Fermentation product of naturally occurring microorganism (non-GMO)
- Used on many fruit and vegetable crops, turf, and ornamentals
- Mode of action:
 - Stops sensitive fungi from growing; stops the pathogenicity
 - Does <u>NOT</u> kill the fungus
- •Resistance management tool: Unique mode of action (FRAC 19)
- •IPM Tool: Very low environmental risk (birds, bees, soil, water, etc.)
- Dietary risk management tool:
 - <u>No</u> mammalian toxicity observed in any study, including in chronic studies
 - May be applied up to the time of harvest (0-day PHI)







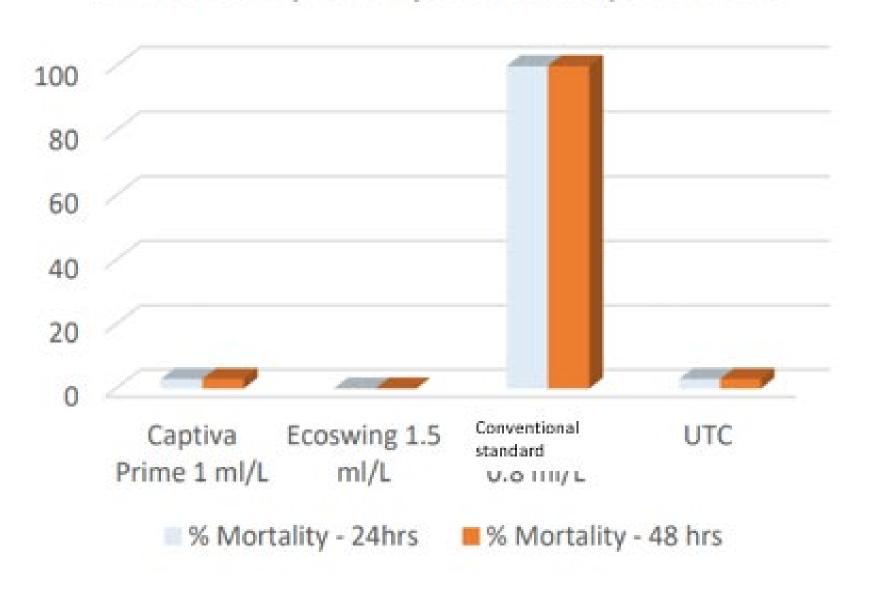


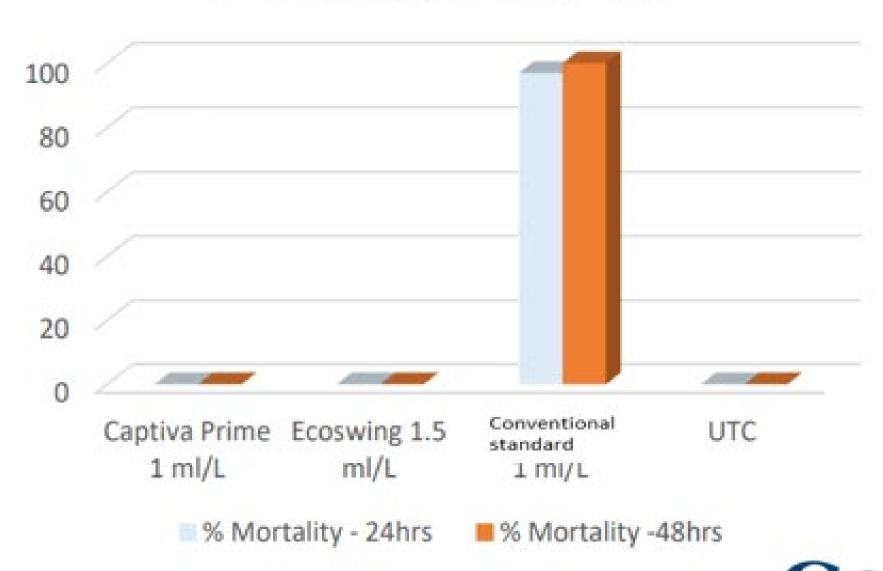
Ecoswing™ is tough on pathogens and easy on beneficials



% Mortality of Phytoseiulus persimilis

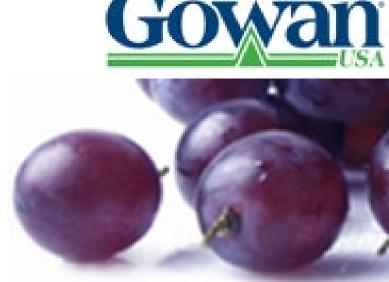
% Mortality of Orius spp.







IPM: Plant extract with safety to beneficial insects

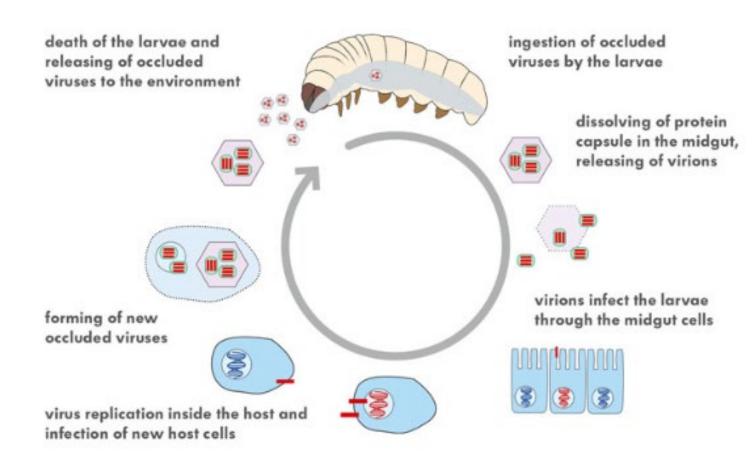


Baculoviruses – natural pathogens of insects

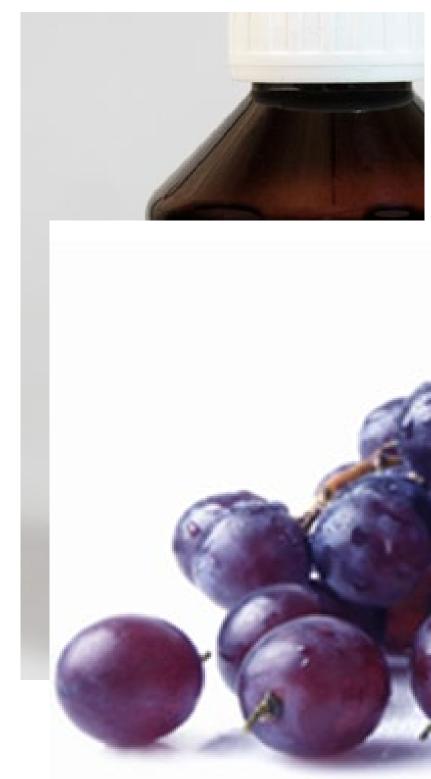
Only found in insects (mainly lepidopteran species)

- Safe for user and consumer (OECD Consensus Paper 2002)
- No effects on plants, mammals or aquatic organisms
- Narrow host range, no adverse effects on beneficial insects
- No production of metabolites or toxins
- Highly efficient control of the target lepidopteran insect pest
- Used in organic farming and IPM programs
- Excellent resistance management tool
- High compatibility with other products













For Your Crop Today, Your Legacy Tomorrow An Effective Rotation Program Starting with XenTari



Severe resistance

No cross resistance to XenTari

Starting rotation with λ -cyhalothrin leaves first generation

Starting with XenTari breaks resistance from the start

Location: University of Florida, Apopka, FL

Crop: Cabbage

Target: Plutella xylostella (DBM) and Hellula undalis (CWW)

Rate: XenTari DF @ 1 lb/A & Warrior (lamda-cyhalothrin) @ 0.027 lb a.i./A (54 gal/A)Bacillus thuringiensis subspecies aizawai (Bta) — resistance management

Serenade: a microbial-based fungicide Beneficial soil bacterium

Using Serenade in programs can reduce pathogen resistance levels to synthetic fungicides

Three examples:

Alternaria in potato, Botrytis in grapes, Banana sigatoka



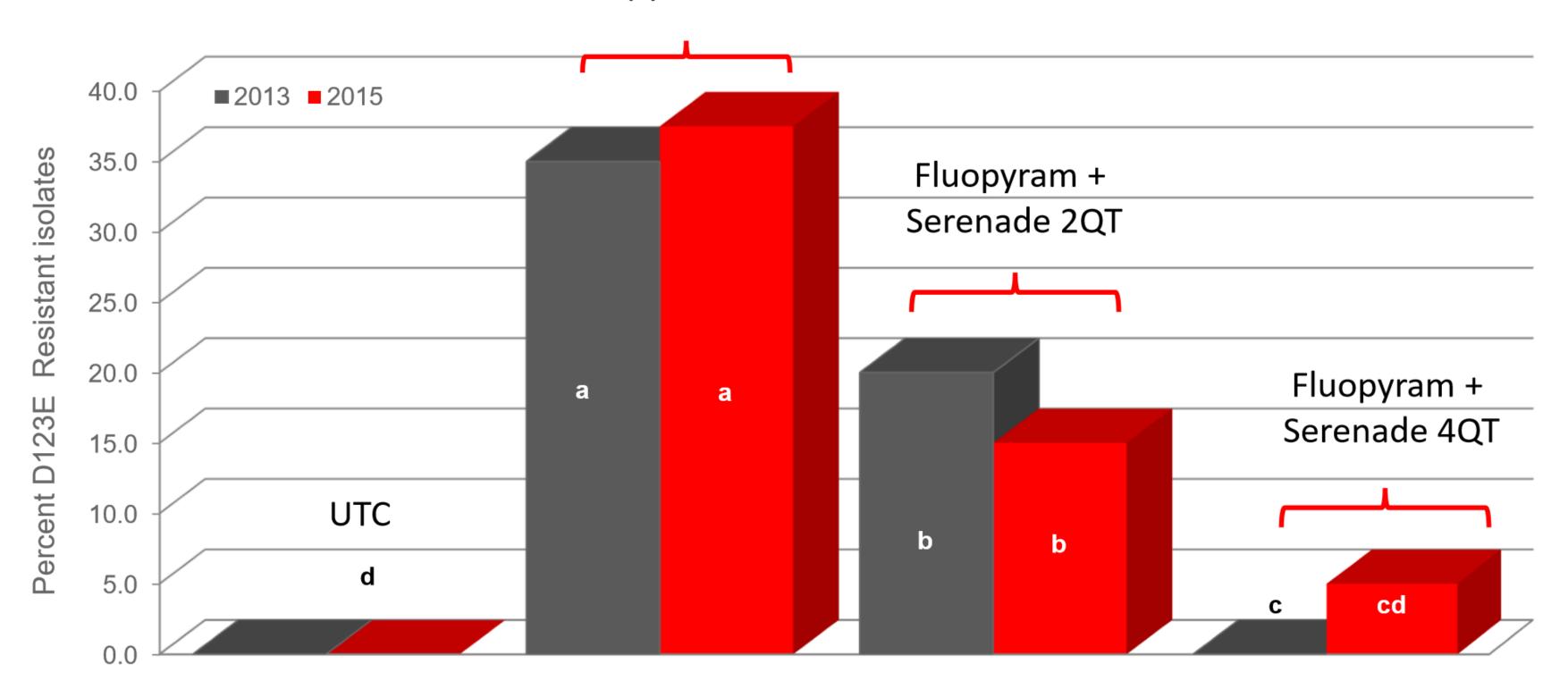




In-furrow tank mix of Fluopyram with SERENADE significantly reduces frequency of the D123E mutation in *Alternaria solani* compared with Fluopyram alone

Succinate dehydrogenase inhibitors (SDHI)

Fluopyram solo



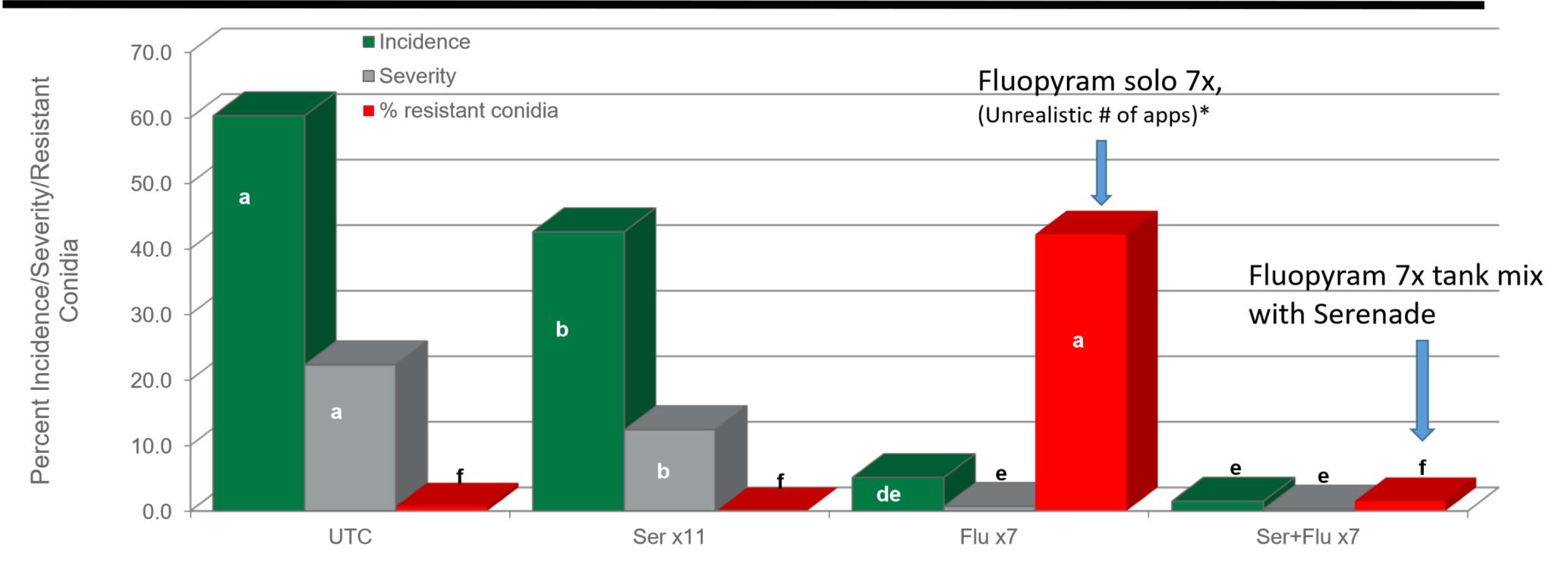
Bauske, M.J., Yellareddygari, S.K.R., Gudmestad, N.C.
Potential impact of Fluopyram on the frequency of the D123E mutation in *Alternaria solani*



Using SERENADE in rotation or tank mix on Grapes reduces Botrytis population resistance to SDHI modes of action

Tank mix data shown below

Succinate dehydrogenase inhibitors (SDHI)



Rotolo, C., De Miccolis Angelini, R.M., Congiovanni, C., Pollastro, S., Fumarola, G., Di Carolo, M., Perrelli, D., Natale, P., Faretra, F., Use of biocontrol agents and botanicals in Integrated management of *Botrytis cinerea* in table grape vineyards

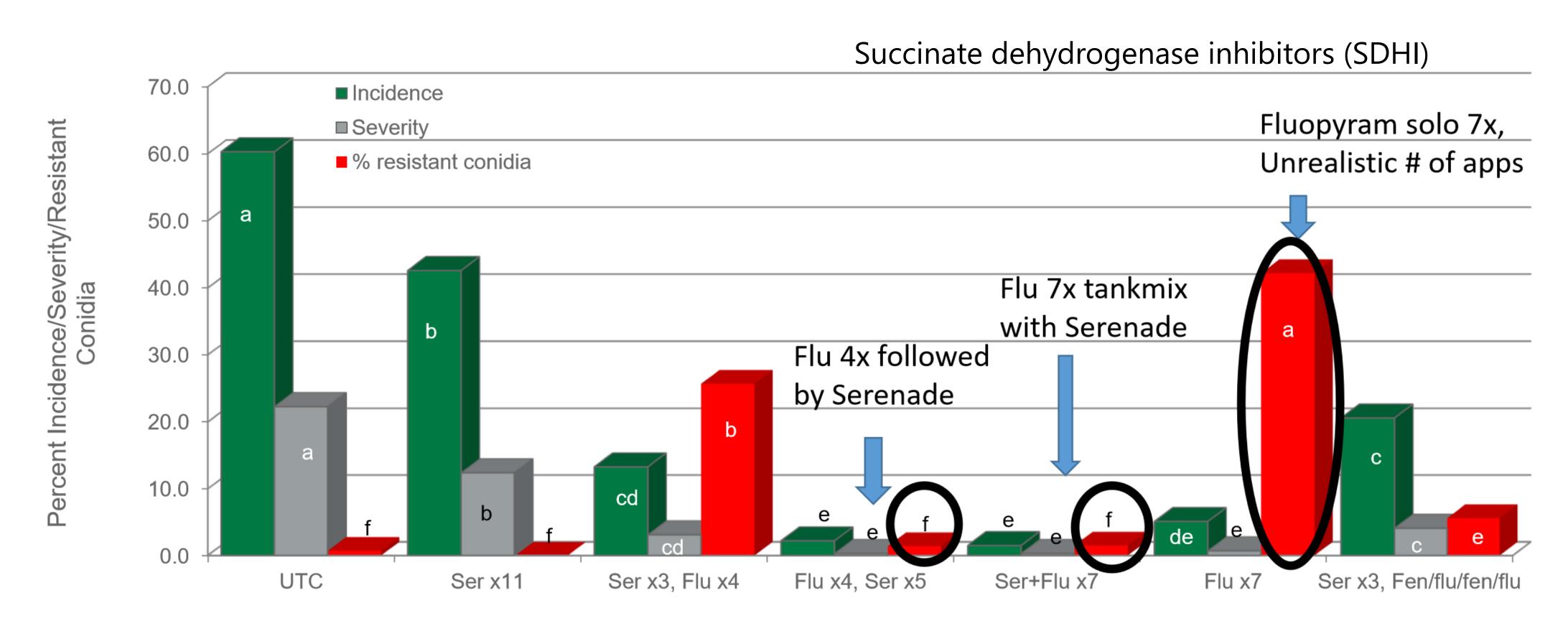
Pest Manag Sci 2017



^{*}For research purposes to force resistance development

Using SERENADE in rotation or tankmix on Grapes reduces Botrytis population resistant to SDHI

Rotation and tank mix data shown below



Rotolo, C., De Miccolis Angelini, R.M., Congiovanni, C., Pollastro, S., Fumarola, G., Di Carolo, M., Perrelli, D., Natale, P., Faretra, F., Use of biocontrol agents and botanicals in Integrated management of *Botrytis cinerea* in table grape vineyards

Pest Manag Sci 2017

BAŶE

