Support for Biopesticides in Modern Agriculture

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Overview of Presentation

- Regulation
- Growth and Trends
- Benefits
- New Biopesticides
- Organics and Biopesticides
- Developing Issues
- Opportunities for International Collaboration
- Concluding Thoughts

Regulation in the U.S.
Definitions

- Naturally occurring chemical substances that control pests (biochemical pesticides)
- Microorganisms that control pests (microbial pesticides)
- Pesticidal substances produced by plants containing added genetic material (plant incorporated protectants)

Regulation in the U.S.
Statutory Framework

- Federal Insecticide, Fungicide, and Rodenticide Act
- Federal Food, Drug, and Cosmetic Act
- Food Quality Protection Act
- Pesticide Registration Improvement Act
- Endangered Species Act, Migratory Bird Treaty Act, and Clean Water Act

Regulation in the U.S.

Biopesticides & Pollution Prevention Division

- EPA's vision is to be a world leader in biopesticide regulation and pollution prevention
- Division dedicated to registering biopesticides
- Registered 400+ biopesticide active ingredients with approximately 1,500+ active product registrations (as of October 2016)
- Registered 13 new active ingredients in fiscal year 2016.
- Awarding of grants to research efficacy of biopesticides for specialty/minor crops

Regulation in the U.S. (FY2016)
Microbial and Biochemical Active Ingredients

Microbials

- *Helicoverepa armigera*
- *Bacillus mycoides* isolate J
- *Spodoptera exigua*
- *Bacillus amyloliquefaciens*
- *Bt kurstaki* EVB 113-19
- Phlebiopsis gigantea VRA

Biochemicals

- Choline chloride
- Hexanoic acid
- California Red Scale Pheromone
- Male sea lamprey mating pheromone

Growth and Trends

- Biopesticides represent $2-3 billion of the $56 billion pesticide market
- Used on ~18 million acres in US
- Growth projected to outpace conventional pesticides with compounded annual growth rate >15%
- With the projected increase in the global population, there is an increasing need to produce more food more sustainably

Growth and Trends

- Increasing market share over last 15 years
  - U.S. use quadrupled (0.9 to 4.1 M lbs) from 2000-2012
- Multi-national companies are acquiring smaller biopesticide companies
- Non-organic fruit and vegetable growers more inclined to try biologicals
- Biopesticides being used in rotation with conventional pesticides
- Marketing opportunities for bee safe biopesticides
- Growing international interest

Benefits

To the Environment

- Less toxic than conventional pesticides
- Generally affect only the target pest and closely related organisms
- Often effective in small quantities
- Decompose quickly = lower exposures to non-targets
- Useful in IPM programs

Benefits
To Growers

- Short restricted entry interval for workers
- Tolerance exemptions are the rule, but some exception
- Low / No pre-harvest intervals
- More pest control tools

New Biopesticides

Addressing Bee Issues

- Potassium salts of hops beta acids, a biochemical, was registered in 2015 to combat the Varroa mite in honey bee colonies
  - Illustrates how EPA works to provide beekeepers the tools to control the Varroa mite
  - Indicates our commitment to protecting pollinator health consistent with President Obama's 2014 pollinator health initiative
- Rotating pesticides delays resistance and prolongs product usefulness

New Biopesticides

Targeting Invasive Sea Lamprey

- Two new biopesticides with male sea lamprey mating pheromone
  - Used to attract and trap breeding females whose control is critically important to the Great Lakes
- Jointly registered in US and Canada
  - US Fish and Wildlife Service and Fisheries and Oceans Canada will use the products in a coordinated management effort
- May reduce the use of conventional pesticides

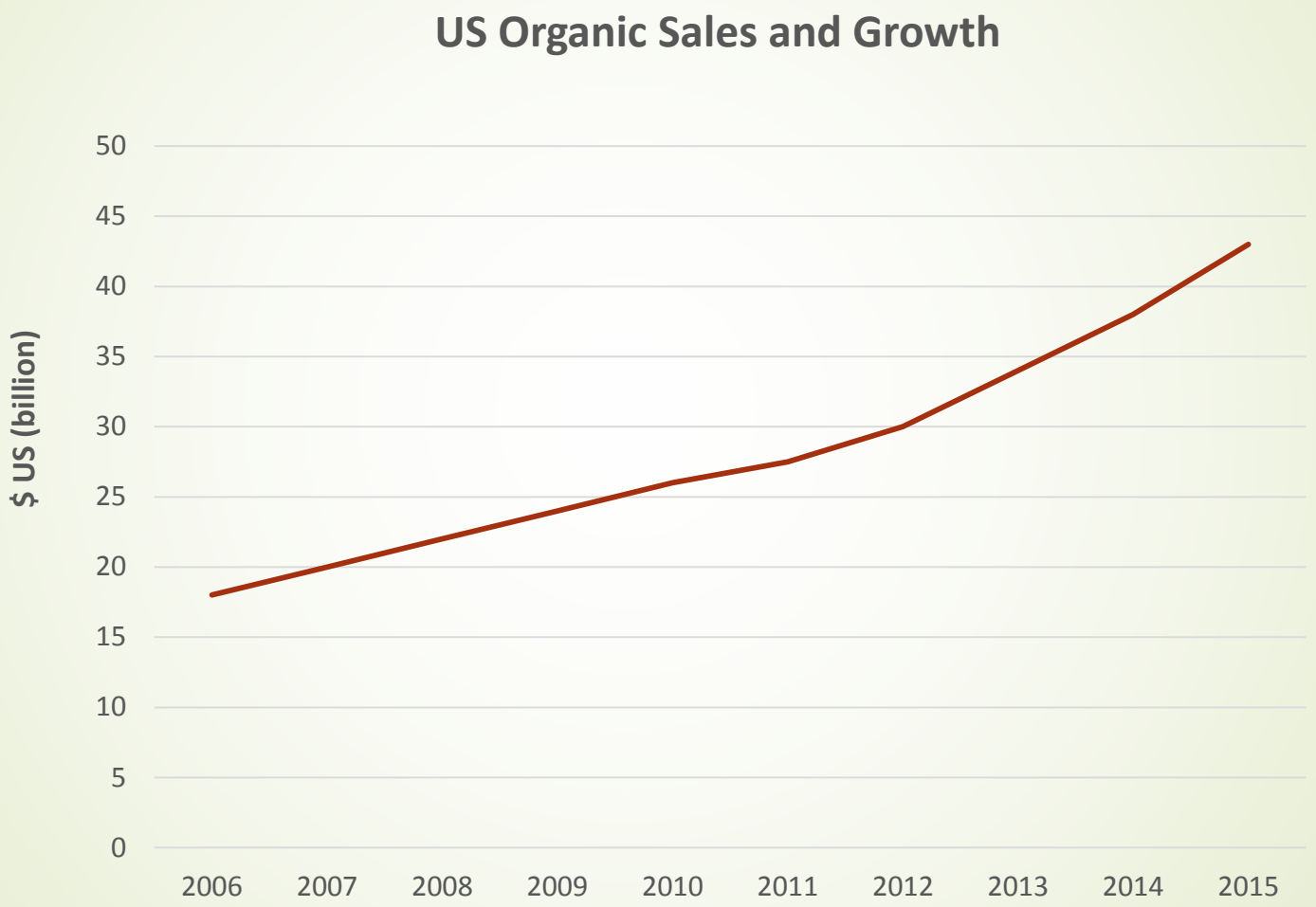
New Biopesticides - Targeting California Red Scale
Red Scale Pheromone

- California Red Scale (CRS) is an orchard pest that infests citrus orchards
- Resistance to conventional pesticides is developing
- EPA registered Red Scale Pheromone
- Red Scale Pheromone has a non toxic mode of action and degrades rapidly in the environment
- Red Scale Pheromone disrupts the normal mating cycle by misdirecting males during their small window of reproduction

Organics and Biopesticides

- USDA's National Organic Program develops regulations and guidance on organically-produced agricultural products
- Biopesticides meeting the program's criteria can be labeled "for organic production"

Organics and Biopesticides



Developing Issues

- Maximum Residue Levels and Tolerances
  - EPA has primarily established tolerance exemptions for biopesticides
  - However, some biopesticides warrant tolerances because they have toxic effects
  - Generating field trial data may pose challenges for registrants
  - Though costly, a tolerance can facilitate trade
  - Some registrants want tolerances while others prefer tolerance exemptions

Developing Issues
Biostimulants

- Characteristics
  - Enhance plant growth/development, yield, crop quality, nutrient/water use efficiency
  - Stimulate processes in plants and soil
  - Contain numerous naturally-occurring substances and microbes already present in environment
  - Add/foster beneficial microbes in rhizosphere; may reduce the need for pesticides
- Regulation
  - Lack of certainty regarding whether these products need regulation
  - EPA gathered state regulator and international/domestic industry organizations' input in 2016
  - EPA is developing guidance on how these products fit within the U.S. regulatory framework
- Increasing market

Opportunities for International Collaboration

- U.S./Canada Regulatory Cooperation Council
  - Created to increase regulatory transparency and coordination
  - Cooperative work model that could extend to biopesticides
- EPA - Canada joint biopesticide registrations (10+ since 2011)

EU/U.S. Biopesticides Risk Assessment Workshop April 2016

- WHO: Staff from the Board for Authorization of Plant Protection Products and Biopesticides (ctgb) in the Netherlands & EPA's biopesticides division
- WHERE/WHEN: EPA HQ on April 12th & 13th, 2016
- GOAL: Assess similarities and differences concerning –
  - Laws governing pesticide licensing
  - Registration processes
  - Approaches to risk assessment & risk management
  - Public process & transparency
- CONCLUSIONS:
  - Governing laws & registration processes different
    - Different registration timelines
    - Different public processes
  - Science-based approach to risk assessment similar

Concluding Thoughts

- Biopesticide use and interest has grown tremendously
- EPA has been a pioneer on the biopesticide frontier
- Increased consumer demand for organic products has fueled growth
- There is much we have done, but still more to do
- Challenge lies in expanding the international biopesticides market to meet worldwide consumer demands
- EPA is committed to a leadership role