Biopesticides in the United States

Past, Present and Future

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Overview of Presentation

- Regulation in the U.S.
- Growth and Trends
- Benefits
- Recent New Active Ingredients
  - Combating Varroa Mites to Address Bee Issues
  - Targeting Invasive Sea Lamprey
- Organics and Biopesticides
- Developing Issues
- Opportunities for International Collaboration
- Concluding Thoughts

Regulation in the US: 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 (PIPs)

Regulation in the US: Statutory Framework

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Food Quality Protection Act (FQPA)
- Pesticide Registration Improvement Act (PRIA)
  - Biopesticides are easier, cheaper, and quicker to register as compared to conventional pesticides

Regulation in the US: Biopesticides and Pollution Prevention Division

- EPA's vision is to be a world leader in biopesticide regulation and pollution prevention
- We have a specific division dedicated to registering biopesticides
- As of October 2015, EPA has registered more than 430 biopesticide active ingredients, and has over 1,400 active product registrations
- Awarding of grants to research efficacy of biopesticides for specialty and minority crops

Biopesticides: Growth and Adoption

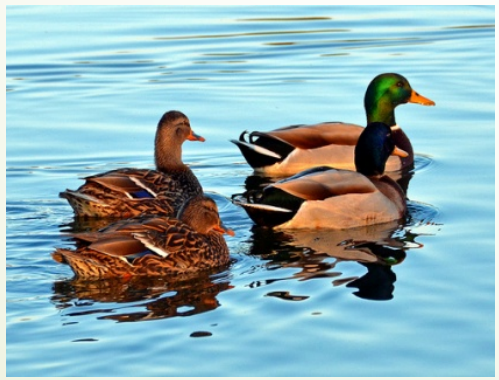
- Biopesticides represent $2-3 billion of the $56 billion pesticide market
- Used on ~18 M acres in US
- Growth projected to outpace chemical pesticides, with compounded annual growth rate >15%
- With global population expected to increase to 9 billion by 2050, there is an increasing need to produce more food more sustainably

Biopesticides: Trends

- Increasing market share over last 15 years
  - Use in U.S. quadrupled from 2000-2012 (0.9 to 4.1 M lbs)
- Larger, multi-national companies are acquiring smaller biopesticide companies
- Non-organic fruit and vegetable growers more inclined to try biologicals
- Programs developed that rotate biopesticides with conventional pesticides
- Marketing opportunities for biopesticides that are *bee safe* and address bee issues
- Growing international interest

Benefits of Biopesticides: the Environment

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



Benefits of Biopesticides: Growers

- Short restricted entry interval for workers
- Tolerance exemptions are the rule, but some exception
- Low / no pre-harvest intervals
- Provide more tools in the pest control toolbox

New Biopesticide Active Ingredients Address Bee Issues

- In March 2015, EPA registered oxalic acid, a new biochemical miticide to combat Varroa mites in bees.
  - Illustrates how the EPA works to provide the Nation's beekeepers with the tools they need to control the Varroa mite in their honey bee colonies.
  - Is also indicative of commitment to protecting pollinator health consistent with President Obama's 2014 initiative on pollinator health.
- In September 2015, EPA registered Potassium Salts of Hops Beta Acids (K-HBAs), another new biochemical miticide, to combat the Varroa mite in honey bee colonies.
- Rotating products to control Varroa mites is an important tactic to prevent resistance development and to maintain the usefulness of individual pesticides.

New Biopesticide AI Targets Invasive Sea Lamprey

- Recent registration of two new biopesticide products that use Male Sea Lamprey Mating Pheromone
  - The products are used to attract and trap breeding female Sea Lampreys during their spawning season. The control of invasive Sea Lamprey is of critical importance to the aqua and ecosystems of the Great Lakes region.
- The United States and Canada jointly registered these two products
  - The U.S. Fish and Wildlife Service and Fisheries and Oceans Canada, the two governmental agencies charged with controlling this pest, will apply the products in a coordinated effort
  - Potentially, fewer conventional pesticides will be used in the Great Lakes as a result

Organics and Biopesticides

- Consumer demand in the organic market has grown by double digits every year since the 1990's
- Biopesticides that meet specific criteria can be labeled "for organic production" to indicate that the product meets USDA National Organic Program rule criteria
  - My office works closely with USDA's National Organic Program
- USDA's National Organic Program develops regulations and guidance on organically-produced agricultural products

Developing Issues in Biopesticides

- Maximum Residue Levels and Tolerances
  - Over the first two decades of EPA's Biopesticides program, EPA has almost always established tolerance exemptions
  - Some new AIs appear to have endpoints, generally necessitating establishing a tolerance
  - Field trial data is generally needed to support a tolerance
  - Generating these data may pose challenges for registrants
  - Having a tolerance can facilitate trade, though can be more costly to establish and register due to need for residue studies.
    - Some biopesticide registrants are likely to want tolerances while many others prefer exemptions depending on their anticipated markets (domestic or international) and business plans.

Developing Issues in Biopesticides

- Biostimulants include products that
  - Enhance plant growth/development, yield, crop quality, nutrient/water use efficiency
  - Stimulate processes in plant & soil
  - Contain numerous naturally-occurring substances and microbes already present in environment
  - Add/foster development of beneficial microbes in rhizosphere; may reduce need for pesticides
- Lack of certainty regarding whether these products need regulation
  - In 2015, EPA met with state regulators, and international and domestic industry organizations
  - EPA developing a policy in 2016
- Increasing market for biostimulants

Opportunities for International Collaboration

- United States-Canada Regulatory Cooperation Council (RCC)
  - Created in 2011 to increase regulatory transparency and coordination between the two countries.
  - Example of cooperative work that may be able to be done re: biopesticides
- Upcoming April workshop between EPA and EU on registration and risk assessment for biopesticide products
- Since 2011, EPA and Health Canada have jointly registered10+ biopesticides through joint review

Concluding Thoughts

- Biopesticide use and interest has grown tremendously in a few short decades
- EPA has been a pioneer on the biopesticide frontier
- Increased demand from consumers for organic products has helped to fuel that growth
- There is much we have done, but more we are doing
  - Ex: Increased efforts to collaborate with EU colleagues; creating guidance on data requirements; seeking clarity on tolerances
- The exciting challenge that lies ahead is how to make the international biopesticides market more robust to meet the demands of consumers worldwide
- EPA is committed to playing a leadership role in that effort