Opportunities for Challenges to Commercialization of Biopesticides

Microbial Biocontrol of Arthropods, Weeds and Plant Pathogens: Risks, Benefits and Challenges

November 28-December 1, 2010
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Executive Director, Biopesticide Industry Alliance (BPIA)

Regulatory Consultant:
- Prophyta Biologischer Pflanzenschutz
- JET Harvest Solutions
- Becker-Underwood Inc.
- Sylvan Bio
- Bayer CropScience
- EMD Crop BioSciences
- others...

Manufacturing/Development Consultant:
- Sylvan Bio
- Osprey Biotechnics

Organic Materials Review Institute (OMRI) Board of Directors

Independent Organic Inspector - USDA-NOP
BPIA

IRS – 501(c)(6) Organization

Membership: 56

**Industry** - Biopesticide Developers/marketers/manufacturers
Certis, Valent BioSciences, NuFarm, BioSafe, BioWorks, Bayer CropScience, Becker –Underwood, Becker Microbials, Prophyta Biologischer Pflanzenschutz and many others...

**Ad Hoc** – Service companies (Regulatory Agents, testing laboratories, etc.)

**Individuals** – researchers and consultants, etc...
Outline of my approach

1. Definition of Biopesticides – as defined by BPIA
2. Lack of new chemistries and organic demand are new driving factors to the development and growth of our industry – There are opportunities.
3. The chemical v. biological paradigm
4. Money and organizational sustainability
5. Making biopesticides work better
6. BPIA – who we are and our strategies for promotion of biological pesticides
What are biopesticides?

There may be some confusion about what biopesticides are...

**BPIA defines biopesticides:** as those organisms or compounds registered as pesticides by agencies such as the US EPA under the BPPD (Biopesticide Pollution Prevention Division) with the exception of PIPs (Plant Incorporated Pesticides)
What are biopesticides

**Microbial** (e.g., bacteria, virus, fungus)

**Biochemical** (e.g. plant extracts (some), pheromones, fatty acids, organic acids, hydrogen peroxide, others...) - *nontoxic mode of action* to the pest, plant pathogen, weed, etc... 25B products are not registered as biological pesticides

**Note:** Spinosad (pure compound from the microbe *Saccharopolyspora spinosa*) and pyrethrum (plant extract) have organic formulations, but are registered as chemicals because of their (neuro)toxic mode of action to the pest
There are opportunities

World population growth (billion) (UN)

- 1950: 2.5
- 1975: 4.1
- 2000: 6.1
- 2025: 8.1
- 2050: 9.2
There are opportunities

- Algae ($10+ bil)
- Weeds ($40+ bil)
- Post harvest losses ($300 bil)
- Stress & Fertilizer Efficiency ($500+ bil)
- Sucking insects ($5 bil)
- Plant parasitic nematodes ($80 bil)
There are opportunities

*New Chemistries*

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**Cost to Develop a New Synthetic Chemical ($Mil)**

- **Launches**
- **New Leads**

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*Only one new chemical active ingredient was approved by the EPA in 2009*
There are opportunities

*New Biopesticides*

12 biopesticides EPA-registered in 2009

**Global Biopesticides**

- 2003: 500
- 2004: 600
- 2005: 1,000
- 2010: 1,500

*Source: BCC Research*

**US Organic Food**

- 1980: 0
- 1997: 1
- 1999: 2
- 2001: 3
- 2003: 4
- 2005: 5
- 2007: 7
- 2008: 9

*Source: Organic Trade Association*
There are opportunities

Biopesticide Growth Outpaces Chemical Growth
(15.6% vs. 1.3% CAGR)

(source: BCC Research)
There are opportunities

>50 year history of safe use

- All registered biopesticides registered for food use are exempt from tolerance (can use right up to harvest)
- Most have very low toxicity (>5000 mg/kg rat oral, dermal, inhalation)
- Non toxic mode of action; most are soft on beneficials
- Most have 4-hour (EPA’s minimum) re-entry period
- Do not contaminate ground and surface water
- Are not ozone disruptors; do not emit VOCs
- Highly biodegradable - do not persist in the environment
- Use the safest (often food grade) inerts (4a and 4b inerts)
The Chemical v. Biological Paradigm

There is the persistence of a chemical paradigm for pest control products that undervalues biologicals and undermines their development.

Compared to chemical pesticides, biologicals generally fail in areas such as speed of kill, storage, range of targets, ease of use, distribution, and cost.

Source: Alternative Paradigms to Commercialization of Biological Pesticides, Experiment Station Committee on Policy - Biological Control Working Group (ESCOP-WGBC) and Rutgers University, New Brunswick, New Jersey, May 31 - June 2, 1998.
The Chemical v. Biological Paradigm

“Our charge is to think risk taking, think unconventionally, but above all think of new paradigms for biological control.”

Source: Alternative Paradigms to Commercialization of Biological Pesticides, Experiment Station Committee on Policy - Biological Control Working Group (ESCOP-WGBC) and Rutgers University, New Brunswick, New Jersey, May 31 - June 2, 1998.
## Crop Protection Company Landscape

### The Big Six
- $3-8$ billion; GM crops and synthetic chemicals
- Monsanto, DuPont, Dow, Syngenta, Bayer, BASF
- Focus - Large row crops; limited biopesticide R&D
- Biopesticide acquisitions and leveraging global sales force to sell others’ biopesticides

### Generic Suppliers
- $100$ million-$2$ billion; limited Biopesticide R&D
- Arysta, Makhteshim, Nufarm, UPI, Valent/Sumitomo, Advan/Sipcam, Gowan, Cheminova
- Leverage sales force to sell others’ biopesticides

### Biopesticides
- $0-$180 million; Microbials, pheromones, plant oils
- Valent Bio, Becker Underwood, Certis, Arysta, Shin-etsu, Novozymes, Suterra, AgraQuest, Plant Health Care, Bioworks, Prophyta, MBI, Pasteuria, Exosect, EcoSmart, etc...
- Some discovery/screening; Most in-license
Some failed industry models

EcoScience  Entotech  Biosys

Ecogen  Eden Biosciences

Mycotech  Eco Soil
Some successful industry models

Valent Biosciences
Bayer Crop Sciences
Becker-Underwood
AgraQuest
Prophyta Biologischer Pflanzenschutz

Certis USA
Becker Microbials
BioWorks
JET Harvest Solutions
Is the current commercial model the only viable approach to utilization of microbial biopesticides?

Yes and No...
Costs and models for registration and marketing of biologicals.

<table>
<thead>
<tr>
<th>System</th>
<th>Steps required</th>
<th>Approximate costs/step</th>
<th>Time to significant market penetration</th>
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| Full-scale registration and production—the chemical pesticide model | 1. Identification of good agent  
2. Development of production and formulation system  
3. Patenting of strain and/or process  
4. Toxicology and other testing  
5. Registration  
6. Building large-scale production system  
7. Nationwide or international marketing | 1,2. $100,000  
3. Up to $200,000 for international coverage, at least $30,000 for one country  
4. At least $500,000  
5. $100,000  
6. Up to $3-4 million  
7. $2-3 million  
Total: up to $8 million | 3 to 6 years |
| Biofertilizer, inoculant, or plant strengthening agent | 1. Discovery of a good agent  
2. Development of production and formulation system  
3. Patenting of strain and/or process  
4. Building large-scale production system  
5. Nationwide or international marketing | 1,2. $100,000  
3. Up to $200,000 for international coverage, at least $30,000 for one country  
4. Up to $1 million  
5. $0.5 million  
Total: $1.8 million | 1 to 2 years |
| Local production | Discovery of a good strain | $100,000 | Less than 1 year |
| Government sponsored or produced agents | Depends upon governmental direction and philosophy | Unknown | Unknown |

Source: Harmon, Gary L., Changing Models for Commercialization and Implementation of Biocontrol, in the Developing and the Developed World, Plant Disease / Vol. 94 No. 8, pgs. 928-939
The challenge to public researchers and institutions regarding commercialization is:

At some point the basic research has to lead to a decision...
So, how do we make biopesticides work better?

- Use them for Resistance Management
- Rotations and Alternations; Tank mixes
- Use them Early season - low pest pressure
- Use them Late season - short pre harvest interval; manage residues for export.
- Use them during critical field events and to save labor costs - short re-entry intervals get you back in the field
So, how do we make biopesticides work better?

IPM

Development of biological pesticides does not drive Integrated Pest Management.

IPM and its adoption for pest control and crop protection provide opportunities for integration of biological pesticides...
So, how do we make biopesticides work better?

**BPIA 2008 Survey: Perception Change**

- **CA PCAs**
  - 9% More Negative
  - 91% More Positive

- **Golf Course Supts.**
  - 100% No Explanation

- **FL Distributors**
  - 20% More Negative
  - 13% More Positive
  - 67% No Explanation

- **CA Growers**
  - 100% No Explanation

- **Florida Growers**
  - 14% More Negative
  - 29% More Positive
  - 57% No Explanation
BPIA’s Strategies for Growth of the use of biological pesticides

MISSION

❖ Improve the global acceptance of biopesticides as having a strong value proposition.

❖ Facilitate the successful development, commercialization, and adoption of biopesticides.
BPIA’s Strategies for Growth of the use of biological pesticides

PURPOSE

- Promote industry standards for biopesticides.

- Communicate the value of biopesticides in agriculture, forestry, turf and ornamental, public health, consumer, and other target markets.

- Develop collaborative working relationships with the authorities that regulate biopesticides and become a resource to these authorities in order to ensure timely, predictable, transparent, and appropriate registration and regulatory requirements.

- Become a leading source of information to key influencers who impact acceptance, commercialization, and adoption of biopesticides.
BPIA’s Strategies for Growth of the use of biological pesticides

OPERATING PRINCIPLES*

- Products that are supported have appropriate EPA, PMRA, EU or other equivalent registrations.

- Proper product stewardship at all levels of the value chain:
  a. Processes for maintaining product quality integrity and resolving product complaints
  b. Scientifically valid efficacy tests supporting claims and promotions
  c. Commercially acceptable product efficacy levels in target geography with minimal field trial variability
  d. Testimonials from customers and key influencers attesting to efficacy claims and satisfaction with product

* These guiding principles are expected to be followed by all members of BPIA and are a condition of membership. Signed initial membership applications include these guiding principles as will all membership renewals.
BPIA - Our 2010 Theme

“The Value of Biopesticides in Resistance Management”
BPIA - Our 2011 Theme

“Maximum Residue Limits (MRLs) and the Impact of Biological Pesticides”
So, how do we with BPIA intend to encourage greater development and adoption?

- Academic researchers
- Governments and their agencies
- Universities/extension
- The private sector (grocers, food processors, restaurant chains, etc...)
- Growers (conventional and organic)
Thank you!

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