

## **Challenges to Commercialization of Biopesticides**

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The challenges to the commercialization are not the purview of only those of us in private industry, but the responsibility of all sectors of pest control and crop protection. Responsibility lies with academics, public researchers, private researchers, governments (both domestic and international) and their agencies, universities, public and private funding sources, and the development and marketing professionals in the private sector.

The Biopesticide Industry Alliance (BPIA) defines biopesticides as those organisms or compounds registered as pesticides, as required under FIFRA, by the US EPA under the Biopesticide Pollution Prevention Division (BPPD) with the exception of Plant Incorporated Pesticides (PIPs). Biopesticides may be formulations containing viable microbes (bacteria, fungi or viruses) or plant extracts and other biochemicals. Hydrogen peroxide and peroxyacetic acid are examples of chemistries registered as biopesticides because of their non-toxic modes of action – oxidation. EPA does include PIPs in this category. Some naturally occurring compounds and plant or fermentation extracts are not considered biopesticides and are registered as chemical pesticides by the US EPA because of their toxic modes of action (i.e. spinosad and pyrethrin). It may be generally accepted that 25B pesticides are also biological pesticides in that they are often made up of plant extracts and other natural materials. However, since they are not registered with the US EPA they are not considered biological pesticides by BPIA and perhaps even EPA. At least 36 US states require the registration of 25B products.

Development of new chemical pesticides is costly and limited. In 2009 only one new chemical active ingredient was registered in the United States while 12 new biopesticides were registered in the same year. The cost of a new chemical registration in the US can reach over \$250 million while biopesticides are significantly less expensive to discover, develop, test and register.

There are significant opportunities for development of new biological pesticides. The growth of the world population is expected to reach 9.2 billion by 2050. Increasing demand for food will mean increasing demand for crop protection. Development and adoption of biological pesticides will be important to help meet the growing demand for safe chemical residue-free food for this growing population. The potential market cost for pest control is more than \$1 trillion world-wide while global sales of biopesticides are about 1 billion in 2010. Interest in organic and sustainable methods and growth in organic food demand will continue to grow. Growth in organic foods has grown through the last decade at about 20% per year.

Safety and environmental considerations are a hallmark of biopesticides. In the US all registered biological pesticides are exempt from the requirement of a tolerance. Maximum Residue Limits are becoming a great issue to consumers and food buyers. Biopesticide residues are not at issue. They require no pre-harvest interval and generally have very short re-entry intervals with only CAUTION labels. Most biopesticides also have very low to non-existent mammalian toxicity (>5000 mg/kg rat oral, dermal or inhalation) and non-toxic modes of action. Most are highly biodegradable, have no impact on ground water, the ozone (no VOCs) and are soft on beneficial organisms. Many of the carriers or inerts used are safe common foodstuffs.

Biopesticides' reputation over time has suffered due to the failure of several business models employed in the 1980s and 90s. Many biopesticide developers overspent on staffing, buildings and equipment and made promises for financial returns that were realistically unattainable. Hundreds of millions of venture capital have been spent on early development without attention to real market opportunity. "If it sounds too good to be true it probably is"; an applicable old adage, applies in pest control and crop protection markets as elsewhere. The successful business models of the 80's and 90's for biopesticide development and market entry were those backed by ongoing business in other pesticide or business sectors. Examples include Gustafson's Kodiak® in the cotton seed treatment market backed by Gustafson's (now Bayer CropScience) then market dominance in seed treatments and Abbott Laboratories (now Valent Biosciences) support of the development of *Bacillus thuringiensis* products through their ongoing pharmaceutical businesses. Failed biopesticide developers often "burned" venture capital all the way through the development and regulatory processes expecting that once registered with the EPA, the product would sell. This "if we build it they will come" – Field of Dreams approach lead to the demise of some biopesticides and their developers and drying up of investment interest in this pest and crop protection category. Many biologists and business career were compromised during upheaval. Successful biopesticide companies developed through careful investment infusions, conservative and well planned expenditures, careful consideration of the market opportunities, efficacious products, carefully planned partnerships and the tenacity of their management.

Government registered biological pesticides share their market with other classes of unregistered biological inputs to production agriculture. Biofertilizers are popular in Europe and Asia as are inoculants and plant stimulants. Sometimes classified as Plant Growth Promoting Rhizo (bacteria or fungi) (PGPR), this class of biologicals avoid regulatory requirements by avoiding direct or implied pesticidal claims. Many of these products are in the North American market and lend to significant confusion of educators, key influencers and growers.

Integration of biopesticides into larger use for pest and crop protection will require the ongoing and increased efforts of academic research, public and private research, key influencers (PCAs, University Extension, etc...), and industry organizations like BPIA and government involvement. Key to the use of this class of pesticides is grower education and demonstration and the growth of the use of Integrated Pest Management (IPM) practices. Development of biological pesticides does not drive Integrated Pest Management - IPM and its adoption for pest control and crop protection provides significant opportunities for integration of biological pesticides.

#### BPIA's **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.