

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Le groupe de travail technique de l'ALENA sur les pesticides

Biopesticides Registration Improvement Course

Overview of EPA's Biopesticides and Pollution Prevention Division Regulatory Activities



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Office of Pesticide Programs

BioPesticides and Pollution Prevention Division



Overview for Biopesticide Registration in USA

- Legal Framework
- What is a biopesticide?
- Biopesticides vs. conventional pesticides
- Presubmission meeting
- Flexibility in information (or data) needs
 - Data waiver justification
 - Non-guideline data acceptability
 - Additional data that often may be needed





Legal Framework

US Pesticide laws:

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - http://www.law.cornell.edu/uscode/html/uscode07/usc_sup_01_7_10_6.html
- Federal Food, Drug, and Cosmetic Act (FFDCA)
 - http://www.law.cornell.edu/uscode/html/uscode21/usc_sup_01_21_10_9.html
- Pesticide Registration Improvement Act (PRIA)
 - <http://agriculture.senate.gov/Legislation/Compilations/Fifra/FIFRA.pdf#page=97>
- Food Quality Protection Act (FQPA)

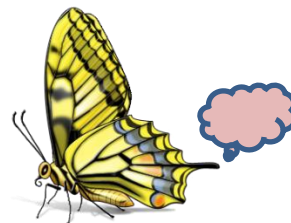




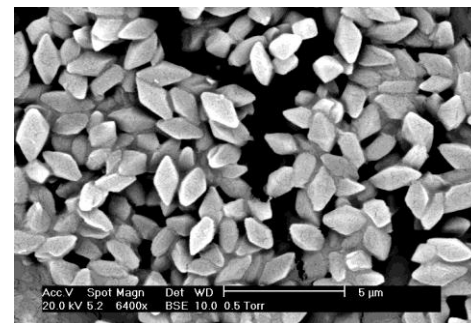
What is a Biopesticide?

Short answer:

- Biochemical pesticide
- Microbial pesticide
- Plant-incorporated protectant (PIP) [not covered in BRIC]



Lepidopteran
pheromone

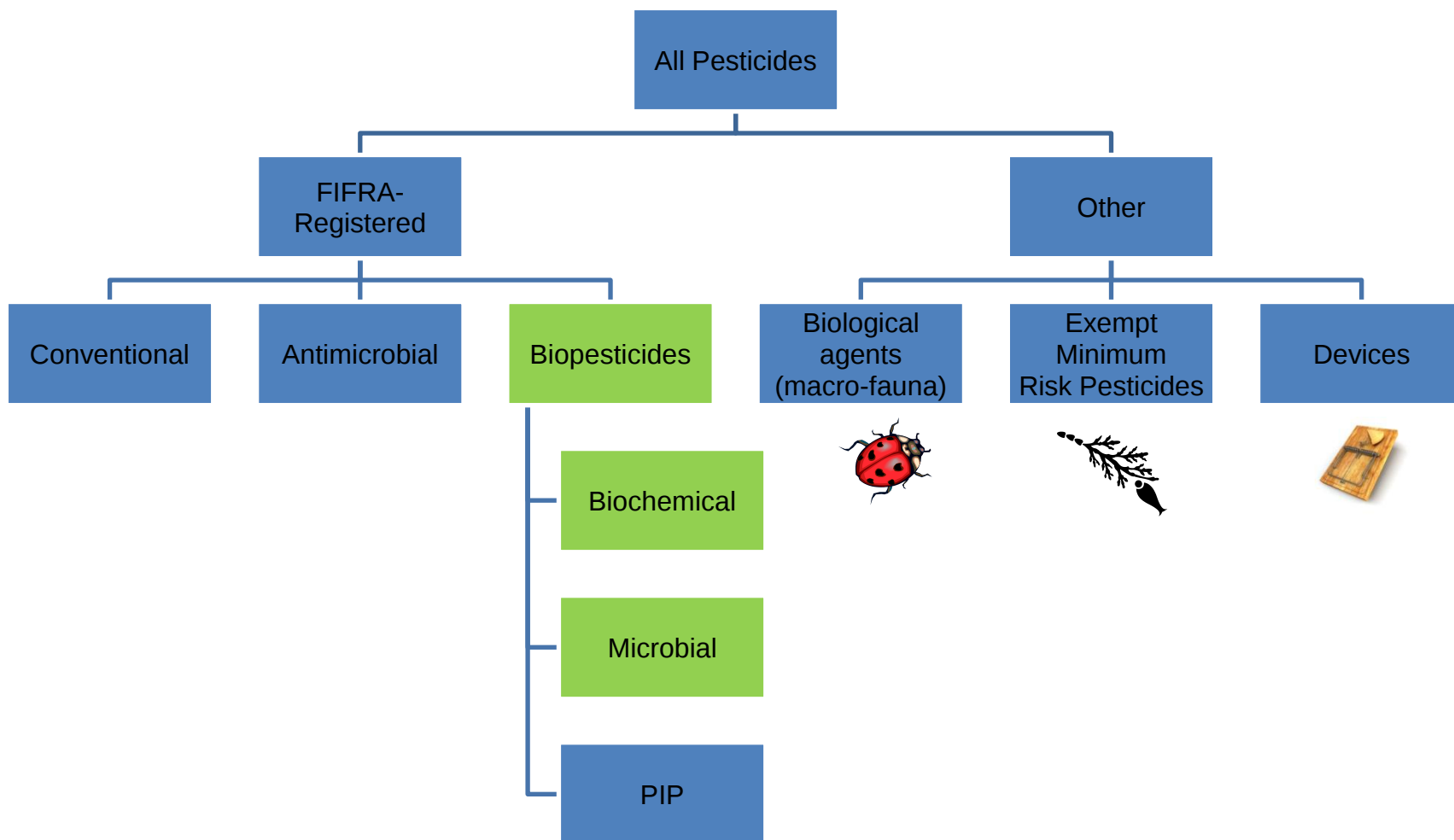


Bacillus thuringiensis

Other speakers will provide greater detail



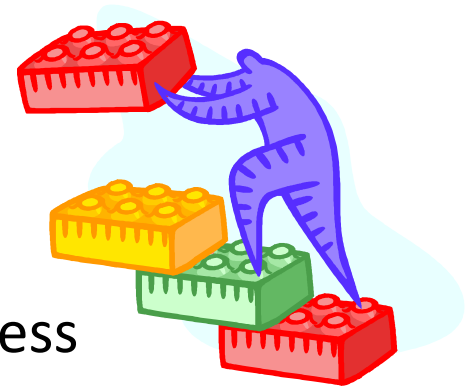
Pesticide Universe & Biopesticides





Biopesticides vs. Conventional

- Many aspects are identical – standard for registration, safety standard for food residues, submission format and criteria, science-based decision process, labels and labeling . . .
- Differences:
 - Data requirements are “tiered”
 - Generally, fees lower and processing times less
 - Most active ingredients exempt from tolerance
 - Many not toxic in traditional sense
 - Many more selective

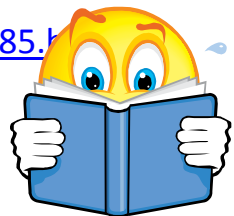




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Resources for Biopesticide registration

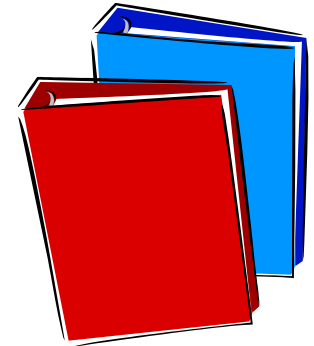
- Biopesticide registration resource webpage
 - <http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>
- US Data Requirements in 40 CFR 158.1500-2174
 - Online CFR: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=b321291a0d624270b7dd6acd0a083426&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl
 - Guidelines: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm
- Pesticide Registration Manual (Blue Book)
 - <http://www.epa.gov/pesticides/bluebook/>
 - Chapter 3 - <http://www.epa.gov/pesticides/bluebook/chapter3.html>





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Resources for Biopesticide Registration



- Label Review Manual
 - <http://www.epa.gov/oppfead1/labeling/lrm/>
- Pesticide Label Review Training
 - <http://www.epa.gov/pesticides/regulating/labels/pest-label-training/index.html>
- BPPD Ombudsman – Brian Steinwand
 - Email: Steinwand.brian@epa.gov
 - Tel: 703-305-7973





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Recurring Challenges

- Incorrect fee category or incomplete payment
- Incomplete submissions
- Deficient data submissions
 - Non-responsive data or study
 - Study quality concern
 - Insufficient data set for label claim
- Label mistakes
- Unsupported claims

