Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

Role of Consultants in the Regulatory Process

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EPA Perspective on Biopesticides

EPA STRIVES TO PROMOTE THE USE OF REDUCED RISK PESTICIDES

- SIMPLIFY THE REGULATORY OF REGISTRATION
- ACCELERATE THE REGISTRATION OF BIOPESTICIDES

CREATE ONE STOP SHOPPING: BPPD

- REGISTER BIOPESTICIDES
- BROADEN THE ADOPTION OF IPM
- FOSTER SAFER PESTICIDE USE THROUGH THE PESTICIDE ENVIRONMENTAL STEWARDSHIP PROGRAM (PESP)
Pre-Submission Conference

Discussion between applicant and BPPD’s scientists and regulatory staff: Not Mandatory but Recommended

- Type active ingredient
- Kind of data needed (before development)
- Waivers
- Registration timing
Consultant’s Attributes and Qualifications

Extensive Knowledge in:
- FIFIRA, FFDCA, FQPA
- 40 CFR 150 to 189
- Data Requirements 40 CFR 158.690 (Biochemicals), 158.740 Microbilas PR Notices (up to date knowledge)
- Guidelines for performing Studies and generating data
- Labeling Requirements
- Package Assembly and Submission
Consultants Roles and Tasks

Selecting the Proper Action to pursue (I.e. EUP, Section3, Me-too, etc.)

Data Gathering, and Organization in Proper Format

Assisting in Waiver Requests Preparations

Product Labeling (proper Format, Precautionary Language, etc)

Application Preparation and Submission

Follow-up: liaison role between Agency and Applicants (Keeping applicant informed, and providing realistic expectations, etc.)