

ROLE OF CONSULTANTS IN THE REGULATORY PROCESS



Why do you need a consultant
anyway?

**Biopesticide registration is a
complex process.**



Person responsible for registration needs to know



Rules, Regulations, Guidances, Data Requirements –

- FIFRA, FFDCA and FQPA
- Code of Federal Regulations (Title 40)
- PR Notices
- OPPTS Guidelines / Subdivision M
- Label Review Manual
- Inert Ingredient Listings
- Enforcement Policies
- 6(a)(2) Adverse Effects Reporting
- Import/Export Regulations
- Record-keeping and Establishment Reporting
- State Regulations

Person responsible for registration needs to know



How to fulfill the data requirements –

- preregistration guidance from BPPD
- contracting studies
- protocols that meet OPPTS guidelines
- using non-guideline studies
- using foreign data
- using published literature
- citing data
- data waiver rationales

Person responsible for registration needs to know



How to present the data -

- compliance with PR 86-5
- complete EPA forms (especially the CSF)
- summaries
- distilling literature references
- electronic Notices of Filing & Docket Index
- readability!!


Person responsible for registration needs to know



How to interact with EPA -

- tracking the registration action
- working with the RAL
- the BPPD review and approval process
- responding to questions/issues
- troubleshooting

Why use a consultant?



Person(s) responsible for registration
must know the process.

Benefits of Using a Consultant



A good consultant -

- knows the registration process
- knows the rules and regulations
- has a good relationship with EPA staff
- has experience and a successful track record on registering biopesticides

How to find a consultant

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- EPA Partial List of Biopesticide Consultants

http://www.epa.gov/pesticides/biopesticides/otherdocs/regulatory_consultants.htm

- Ask around.

- Screen potential consultants.