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

- EPA Partial List of Biopesticide Consultants
  http://www.epa.gov/pesticides/biopesticides/otherdocs/regulatory_consultants.htm

- Ask around.

- Screen potential consultants.