

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

ENVIRONMENTAL ASSESSMENT: REQUIREMENTS AND SCIENTIFIC RATIONALE 4.3



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U.S. Environmental Protection Agency

Office of Pesticide Programs

Biopesticide and Pollution Prevention Division



OVERVIEW

- **US Data Requirements (40 CFR 158.2150)**
- **Tiered Testing**
- **Presubmission meetings**
- **Must address all data requirements**
 - **Guideline studies**
 - **Scientific rationale for waivers**
 - **Alternative data: non-guideline studies**



RESOURCES

- **Biopesticide registration resource webpage**
 - <http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>
- **US Data Requirements (40 CFR 158.2150)**
 - Online CFR: <http://www.gpoaccess.gov/ecfr/>
 - Guidelines:
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm
- **REDs and BRADs**
 - <http://www.epa.gov/pesticides/biopesticides/ingredients/>



COMMON PROBLEMS / ISSUES

- **Global problems**
 - Registrant's responsibility to demonstrate hazard/no hazard
 - All data requirements not addressed
 - Data “dumps”
 - Incomplete studies
 - Dossiers from EU
 - Joint reviews, differing information





COMMON PROBLEMS / ISSUES

- **STUDIES**
 - Duration
 - Significant guideline deviations
 - Lack of attenuated or positive controls when needed
 - Studies with common problems
 - Aquatic studies
 - Honey bee studies





COMMON PROBLEMS / ISSUES

- **RATIONALE**
 - Sweeping statements, no scientific support
 - Commonly used statements
 - Citations, copies of referenced studies
 - Batching rationale for all taxa
 - Submitting studies as rationale