

*Overview of the California Department of  
Pesticide Regulation Biopesticide  
Regulatory Activities*

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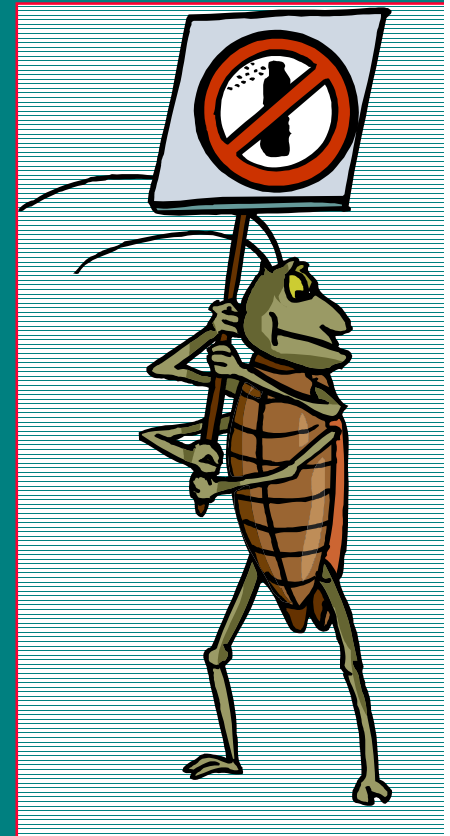
*California Department of Pesticide Regulation*

Biopesticide Registration Workshop  
November, 2001



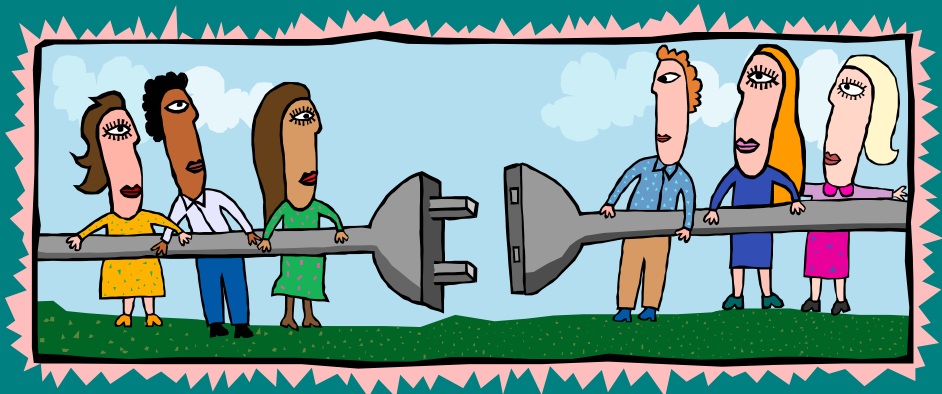
# Department of Pesticide Regulation

- DPR has a comprehensive pesticide regulatory program
- Our mission:
  - To protect human health and the environment by regulating pesticide sales and use and fostering reduced-risk pest management.



# DPR Program and Staffing

- \$55 million budget, about 450 employees, including more than 30 toxicologists and more than 50 environmental scientists
- Enforcement augmented by 325 biologists working for agricultural commissioners in all 58 counties



# DPR Regulatory History

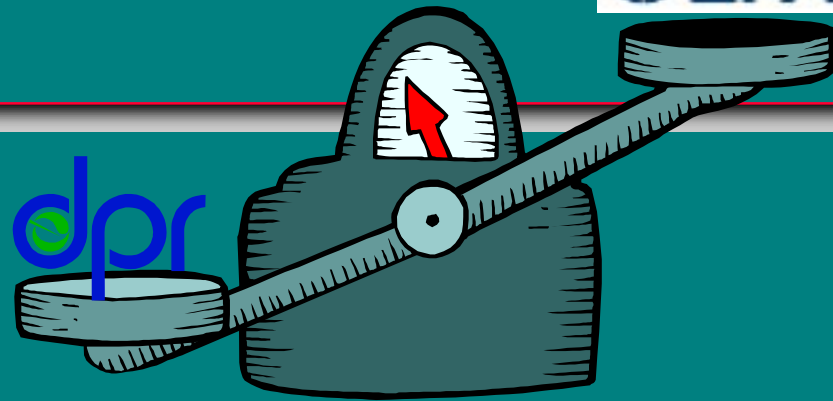
- First laws: 1901 & 1911
- 1921: Registration required
- 1926: First residue monitoring
- 1940's: Regulations to limit drift
- 1950's: First limited use reporting
- 1970's: Worker protection rules
- 1980's: Risk assessment unit
- 1990: Full use reporting



# California: A Minor Crop State

- 350+ “crops,” mostly dairy, fruit, flowers, vegetables and nuts
  - More than half of U.S. production





# Federal and State Responsibilities Differ



# Responsibilities Divided and Shared

- No pesticide can be used in the U.S. if not registered by U.S. EPA
- But states can set up parallel registration system with requirements stricter than U.S. EPA's
  - States can review for state-specific conditions (for example, climate, cropping patterns, environmentally sensitive areas)
  - States can cancel registrations on state-specific grounds



# Responsibilities Divided and Shared

- Feds have exclusive authority over pesticide labeling
  - But states may decide not to register a product
- U.S. EPA authorizes states to issue Section 18 “emergency exemptions” -- after U.S. EPA review of application
- States issue 24(c) “special local need” registrations under strict U.S. EPA guidelines



# Workload Sharing with U.S. EPA

- Efforts to 'harmonize' our programs began in early 1990s
- Passage of FQPA distracted U.S. EPA, and project languished
- Process reinvigorated and refocused in recent months

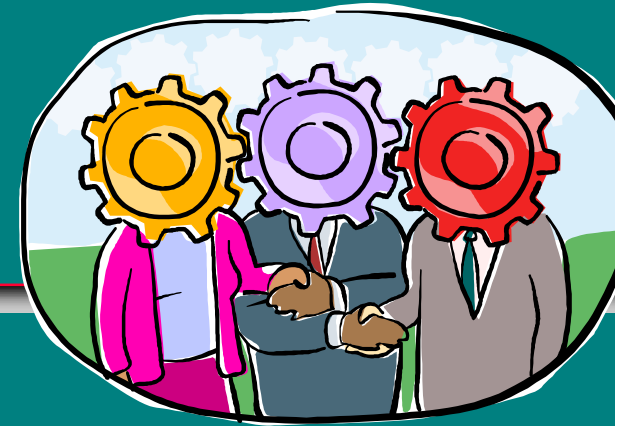


# Workshare: Biopesticides

- U.S. EPA looking for ways to work collaboratively to bring reduced-risk products to market
- This project still in early stages
- Will involve worksharing of data reviews for biopesticides
  - California a big share of the biopesticide market



# Workshare: Biopesticides



- Success of this project dependent on registrant support of DPR-U.S. EPA collaboration

# DPR Registration Data Requirements

- California-only requirements for new active ingredients, including California-specific data
- Limited flexibility to waive requirements



# Major Statutory Mandates

- Birth Defect Prevention Act of 1984 (SB950) requires submission of specified chronic health effects studies before registration
- Biopesticides require reduced data requirements but ability to waive data limited



# Major Statutory Mandates



- Pesticide Contamination Prevention Act of 1985 (AB 2021) requires submission of specified environmental fate data for ground water protection
- Most biopesticides do not require submission of additional environmental fate data

# To Register in California

- Submit data to DPR for review, U.S.EPA label, and proof of registration
- DPR scientific evaluation
- Proposed decision posted for public comment
- License issued or product denied

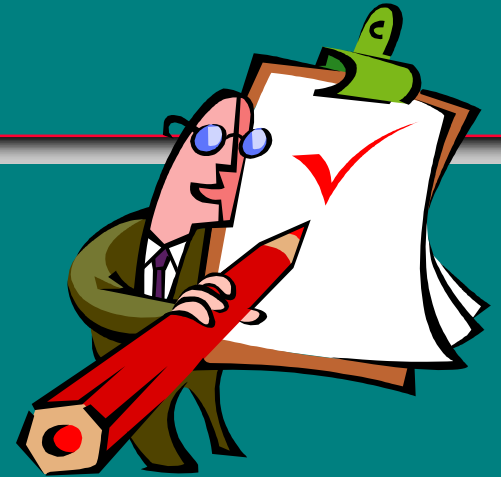
# Concurrent Review

- For most biopesticides, DPR will review data before products are registered by USEPA
- Goal: to register just after USEPA



# Types of Required Data for Biopesticides

- Acute toxicology
- Product chemistry
- Efficacy (includes phytotox, if applicable)
- Fish and wildlife, if applicable
- Most do not require residue chemistry



# After a Product is Registered

- Label or formula revisions must be reviewed and approved by DPR
- Products are subject to renewal, mill assessment, data call-ins, reevaluations
- Formal risk assessment occurs after the new active ingredient is registered; for most biopesticides no risk assessment

