

Herbicide registration, reregistration and use tracking:

Tools to help make herbicide use
safe and effective.

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California Department of Pesticide Regulation

Cal-IPC Symposium - Laws & Regulations Session 4

October 2, 2008



Speech Layout

- Regulating authorities
- How to get a product registered in California
- Types of products registered
- What happens after a product is registered



Regulatory Authorities

- Federal Government:
 - U.S. Environmental Protection Agency
 - Office of Pesticide Programs
- State Government:
 - California Environmental Protection Agency
 - Department of Pesticide Regulation

Why Do We Regulate Pesticides?

- To ensure that the pesticide will not have unreasonable adverse effects on humans, the environment, and non-target species.





Types of Products

- Approximately 13,000 products currently registered in California (19,714 U.S. EPA), containing approximately 973 active ingredients.
- Products include agricultural, residential, industrial, sanitizers/disinfectants, hospital, rodenticides, avicides, home and garden, etc.



Similar and Different

U.S. EPA, OPP

- Pesticide product registration
- Pesticide use enforcement
- Register pesticide producing companies
- Review the safety of older pesticides
- Establish tolerance levels

California EPA, DPR

- Pesticide product registration
- Pesticide use enforcement
- Licensing applicators, sellers, others
- Worker/user safety
- Environmental monitoring



Why Does California Have an Extensive Regulatory Process?

- California covers a large geographical area
 - Active lawmakers and citizens
 - Many growing regions
 - 350 commercial crops
 - Different
 - Weather patterns
 - Soil types
 - Multiple growing seasons
 - Large population (36 million)
 - Many urban settings
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Getting Started for a Company




1. Research and development
2. Conduct studies
3. Obtain federal registration
(EPA Reg. No.)
4. Approved EPA label cannot be changed
by states



Federal Registration Requirements



Submit an application package including:

- Certification for citing data
 - Confidential statement of formula
 - Formulator's exemption statement
 - Five copies of draft labeling
- 
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Federal Registration Requirements



- Three copies of any data submitted
- Authorization letter where applicable
- Matrices where applicable
- An application fee of \$1,000 to \$500,000





Pesticide Products Must Be Registered
Federally by U.S. EPA

and Then...

In California by the DPR (except for
adjuvants)





Product Registration: California

- Company submits \$750 application fee, application form, product labeling, and data.
- Regulatory Scientist determines if complete or can return submission.
- DPR scientists may conduct scientific evaluation of data.



Product Registration: California

- Decision to Register or Deny is then posted for a 30-day public comment.
- If acceptable, issue product license
- If unacceptable, deny product license

Label amendments must also be approved by U.S. EPA and then by DPR. Some require data.



Each year, DPR processes 5,000 - 6,500 actions





Scientific Evaluation

- Scientific evaluation of data is conducted by chemists, toxicologists, biologists, entomologists, microbiologists, plant physiologists, as appropriate.





Types of Data

- Acute Toxicology (“six pack”)
- Product Chemistry
- Efficacy
- Phytotoxicity, if on plants
- Fish and Wildlife, if applicable
- Worker Safety, if applicable



Types of Data

For a new active ingredient in California:

- All of the above data, plus...
- Chronic toxicology
- Environmental fate (groundwater contamination) on first agricultural use

"Label is the Law"

Label is determined by data

- Signal word
 - Danger, Warning, Caution
- Precautionary statements
- Statement of active ingredient
- Crop or use site
- Directions for use
- Rates and method of application
- Environmental precautions





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Types of Registrations

- Regular registration, "Section 3"
 - Experimental use permit, "EUP or Section 5"
 - Special Local Need, "24(c)" or Emergency Exemption, "Section 18"
 - Research Authorization for small acreage in California
 - Spray Adjuvant
- ...and label amendments to any of the above



Spray Adjuvant

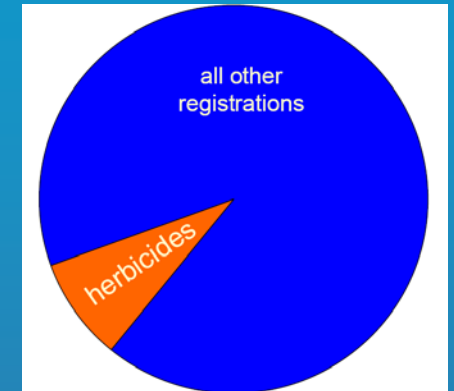
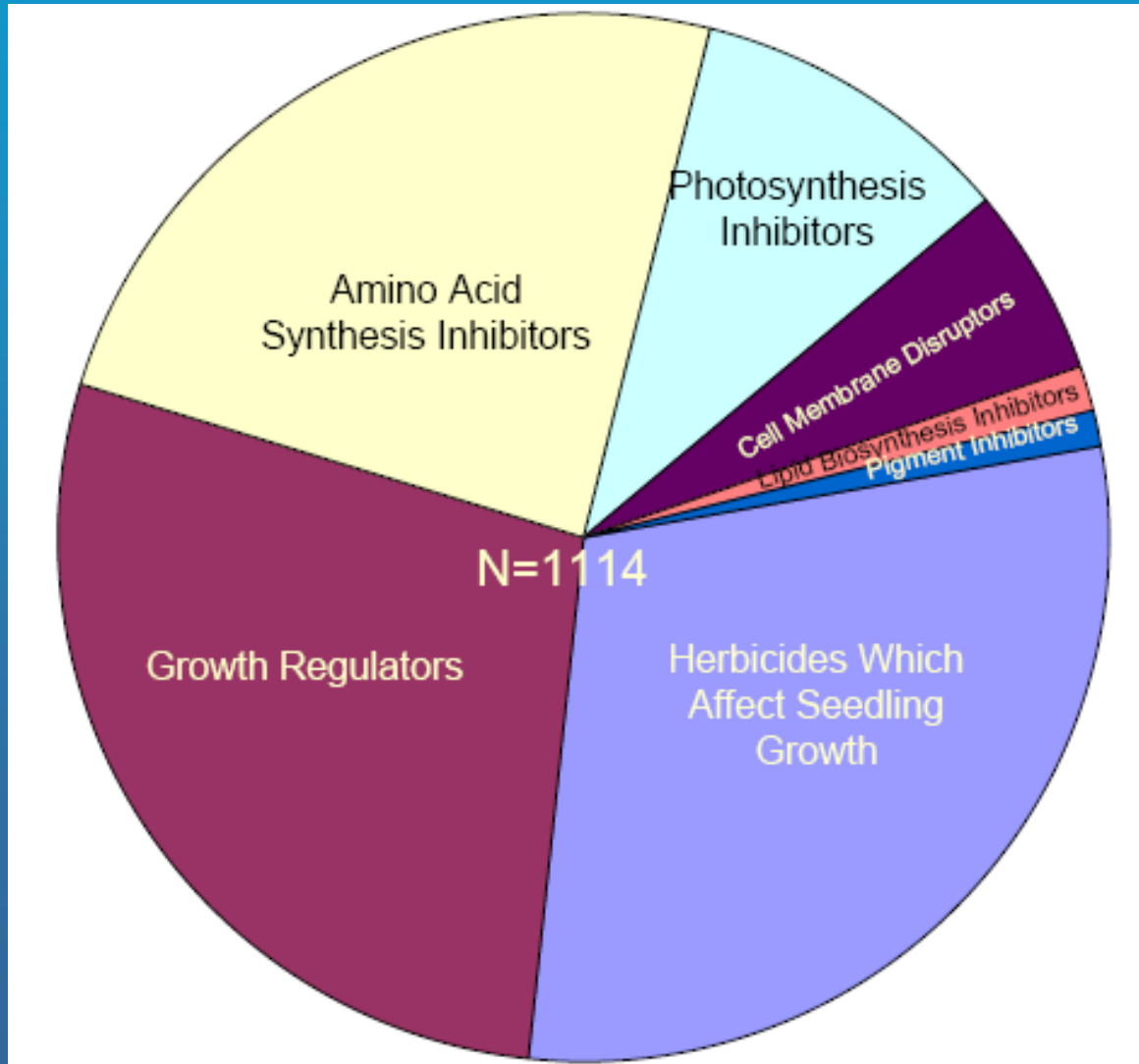
- A product that is packaged and sold separately to aid or enhance the effectiveness of a pesticide.
- Defined in California law as a pesticide.
- Data required to register:
 - acute toxicology, product chemistry, and efficacy
- Use sites on label are usually general
- U.S. EPA do not register these types of products



Types of Herbicide Registrations

- Growth regulators
- Photosynthesis inhibitors
- Lipid biosynthesis inhibitors
- Amino acid synthesis inhibitors
- Herbicides that affect seedling growth
- Cell membrane disruptors

Count of California Herbicide Registrations





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After the Product is Registered

It is subject to:

- Annual renewal fee
- Quarterly mill assessment payment
- Pesticide use reporting
- Data call-in
- Reevaluation
- Risk assessment
- Regulatory action





Pesticide Use Reporting

- Food and Agricultural Code (FAC) section 14011.5 and California Code of Regulations (CCR) sections 6624 - 6628 require monthly reporting.
- All applications must be reported except for home and garden use and most industrial and institutional uses.



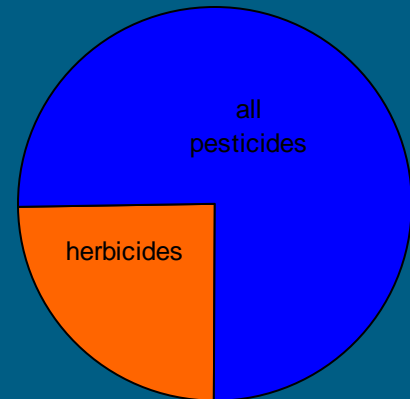
Herbicide Use in Three Counties for 2006

- Humboldt
- Marin
- Mendocino

Herbicide Use in Three Counties for 2006 - Humboldt

Top five sites in pesticide use:

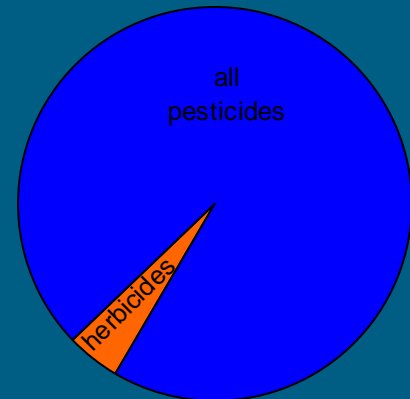
1. Forest, timberland
2. Outdoor nursery flower
3. Structural pest control
4. Outdoor nursery transplants
5. Rights of way



Herbicide Use in Three Counties for 2006 - Marin

Top five sites in pesticide use:

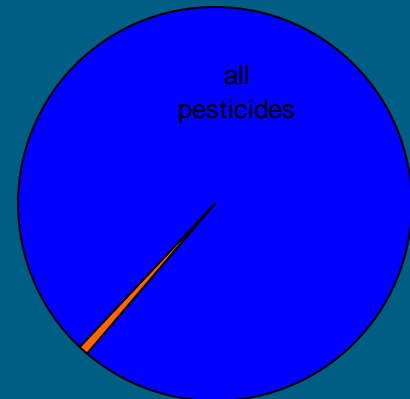
1. Landscape maintenance
2. Structural pest control
3. Wine grapes
4. Rights of way
5. Public health



Herbicide Use in Three Counties for 2006 - Mendocino

Top five sites in pesticide use:

1. Wine grapes
2. Pears
3. Treated lumber
4. Structural pest control
5. Apples





Data Call-Ins

- After a product is registered, additional data can be called in if either of the following occurs:

- Legislation requires it
- Reevaluation is initiated





Initiation of Reevaluation Process

DPR is required to investigate information indicating a pesticide may have, or is likely to, cause adverse effect:

1. Data submitted by registrant
2. Other state or local agency
3. Public




Factors that can Trigger Reevaluation

- Public or Worker Health Hazard
- Environmental Contamination
- Residue Over Tolerance
- Fish or Wildlife Hazard
- Lack of Efficacy
- Undesirable Phytotoxicity



Reevaluation Process

- DPR may require registrants to provide data.
- Status of reevaluation included in semi-annual report
- DPR may cancel products due to registrant's failure to provide data



Reevaluation: Possible Outcomes

- No further mitigation measures needed
- Mitigation measures needed:
 - Regulation
 - Permit Conditions
 - Label Amendments
- Adverse effect cannot be mitigated;
pesticide product(s) must be canceled



Risk Assessment

- Initiated where there is a “possible” adverse effect to human health.
- Three prioritization categories.



Cancellation

- No immediate hazard
- Written accusation sent, allowing 10 days to request a hearing
- Hearing requested, Administrative Law Judge makes ruling to cancel or not
- If no hearing requested, cancel
- Cancellation stops sales by registrant (and possibly dealers)



Suspension

- A product's registration can be suspended, if immediate hazard.
- Product remains registered, but the registrant (and usually dealers) can no longer sell product
- Have right to a hearing. Outcome may be cancellation



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- [VOC Emission Inventory Informational Meeting Oct. 24](#)
- [Field fumigant emission regulations amended](#)
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- [Obtaining and Preserving Well Water Samples \(standard operating procedure\)](#)
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Questions?

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