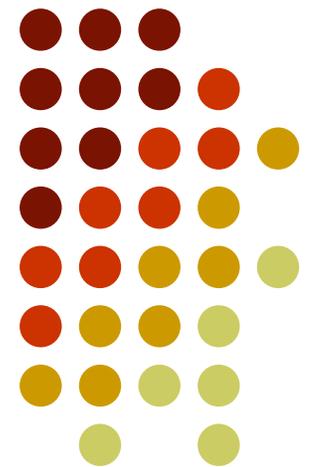
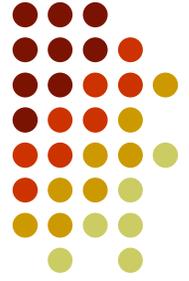


Special Processes

Andrew Yokoyama
May 2, 2006

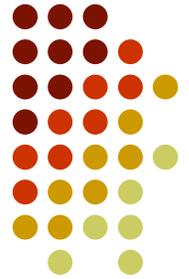




Subregistrations

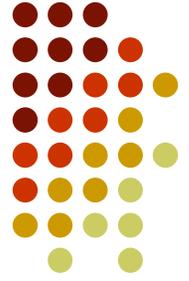
- Term used for the registration of a product that is being supplementally distributed by someone other than the basic registrant (AKA supplemental distributor).
- Must comply with U.S. EPA label requirements.
- Three part U.S.EPA Reg. No.

DPR Requirements for Subregistrations



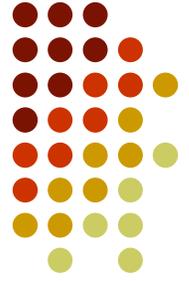
- A detailed cover letter.
- A \$750 registration fee and application form.
- U.S.EPA Form 8570-5, Notice of Supplemental Distribution of a Registered Pesticide Product (signed and dated by both companies).

DPR Requirements for Registration (cont.)

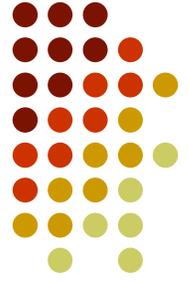


- Six copies of the proposed label. **All uses must be on the basic's U.S. EPA stamp accepted label** (uses may be deleted).
- A copy of the basic registrant's U.S. EPA stamp accepted label with accompanying letter.

Subregistrations: Things to Note



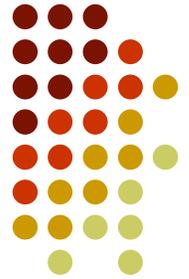
- Product brand name on the label should be consistent on all forms (application and 8570-5).
- No letter of authorization is required (AB1011).
- General procedures for subregistrations found on Registration Branch home web page, Chapter III of the Desk Manual.



Label Amendments

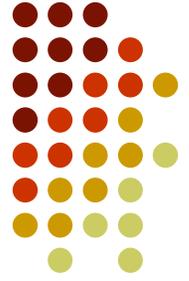
- Two types:
 - Label amendments that **don't** require data.
 - Label Amendments that **do** require data.

Label Amendments that Don't Require Data



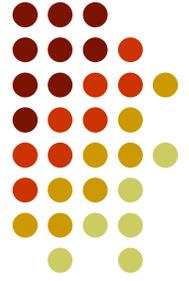
- **NO FEE REQUIRED**
- Minor revisions to the label, adding a pest similar to one already on the label (except antimicrobials), etc.
- Comply with U.S.EPA PR Notices (e.g. first aid, environmental hazards statements, storage and disposal).

Requirements for Label Amendments Not Requiring Data



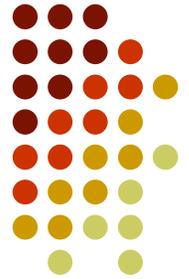
- A cover letter explaining the amendment(s).
- Six-copies printer's proof or final printed labels.
- U.S. EPA stamp accepted label.

Label Amendments that Do Require Data



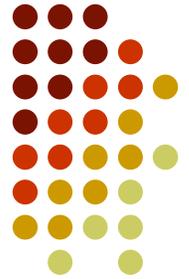
- Adding a pest or type of pest not currently on the label.
- Adding crops.
- Adding new use sites.
- Reducing the signal word, precautionary statements or application type.

DPR Requirements for Label Amendments Requiring Data



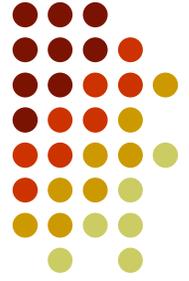
- A cover letter detailing the requested action.
- Application to amend pesticide product and \$100 fee.
- U.S. EPA stamp accepted label.
- Submission of data or reference products with approved uses currently on file in California.
- 6 copies printer's proof or final printed labels.

Spray Adjuvants: California Only Registration



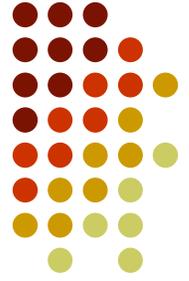
- A spray adjuvant is defined as a pesticide in California and is subject to the registration requirements.
- Definition: a spray adjuvant is a product sold in a separate package and intended to be used with another pesticide to aid the application or enhance the activity of the pesticide.

Spray Adjuvant Examples



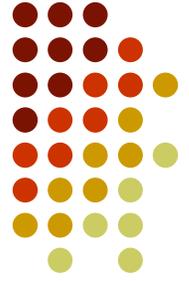
- Wetting or spreading agent.
- Deposit builder.
- Adhesive emulsifying agent.
- Deflocculating agents.
- Water pH modifier.

DPR Requirement for Registration

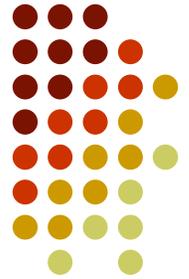


- Acute toxicology
 - Acute dermal
 - Acute oral
 - Primary eye irritation
 - Primary dermal irritation.
- Product chemistry.
- Efficacy.

FIFRA Section 25(b) Exempt Products



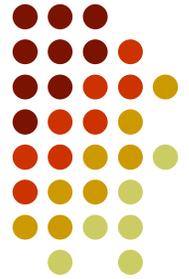
- Gives U.S.EPA authority to exempt any pesticide from the requirements of registration under certain conditions.
- Products must meet criteria in CA Notice to Registrants 2000-6 to qualify for exemption.
- California Code of Regulations (CCR) section 6147.



DPR Notification Process

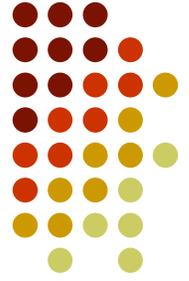
- **Not the same as U.S.EPA.**
- **Must comply with CA Notice 2002-1.**
- **Examples:**
 - **Delete pests or use sites.**
 - **Add indoor non-food sites for certain antimicrobial products.**

DPR Requirements for Submitting Notifications



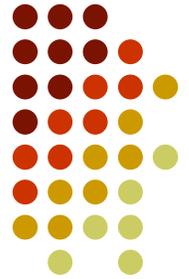
- DPR notification form 039-031.
- 3 copies of the final printed or printer's proof label.
- For formulation changes - a completed application for pesticide product registration DPR Form 39-030 (3 pages).

Biopesticides (Microbial and Biochemical Products)



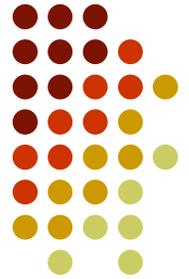
- Definition: Non-conventional pesticide products composed of microorganisms or derived from living organisms.

Microbial Pesticide Products



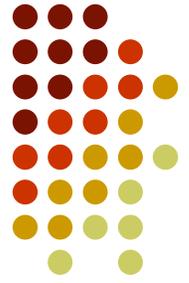
- Composed of living entities such as bacteria, fungi, viruses, and protozoan.
- Examples include:
 - Fungus used as a fungicide or insecticide.
 - Viral insecticides.
 - Bacterial insecticides and fungicides.

DPR Requirements for Submitting Microbial Pesticide Products



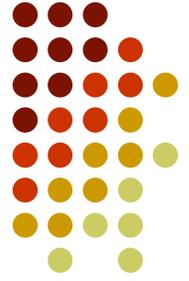
- General procedures for obtaining product registration are in Chapter III of the Desk Manual.
- DPR will follow the U.S. EPA requirements for these type of products plus other data in accordance with California Code of Regulations (CCR) sections 6176-6193.
- Ingredient information and product analysis.

DPR Requirements for Submitting Microbial Pesticide Products (cont'd)



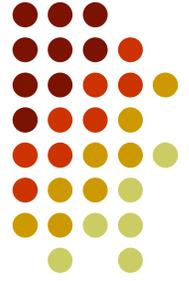
- Toxicology data.
- Efficacy.
- Fish and wildlife data (non-target organism and other Environmental Expression).
- Environmental Effects.

Biochemical Pesticide Products



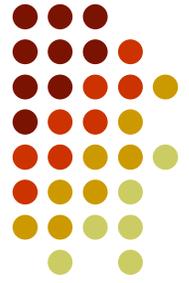
- Includes but not limited to, products such as insect pheromones, natural plant insect hormones and regulators (plant growth regulators, insect growth regulators, insect juvenile growth hormones), and enzymes.
- Examples:
 - Pheromones that disrupt mating behavior.
 - Insecticidal soaps.
 - Plant extracts used as antifeedants and growth regulators.

DPR Requirements for Submitting Biochemical Pesticide Products



- General application materials.
- Data requirements identified in 40 CFR 158.690 (Additional data may be requested depending upon results). If U.S.EPA granted a waiver of any study, a copy of the waiver should be submitted to DPR for consideration.
- Ingredient information.
- Toxicology data.

DPR Requirements for Submitting Biochemical Pesticide Products (cont'd)



- Efficacy data.
- Fish and wildlife data (non-target organism and other Environmental Expression).
- Environmental effects.
- Reference Chapter VIII of the Desk Manual (on-line) for more specifics regarding data.