The Pesticide Registration Branch

Desk Manual Chapter 4

2013

California Department of Pesticide Regulation

Chapter

4

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1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request
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B. Antimicrobial Products

(Products that contain active ingredients found in currently registered products)

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request
2. Detailed Description of Items that should accompany the Product Submission (internal and external documents)
3. Verification for Completeness
4. Review of the Label

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(New active ingredients and products that contain active ingredients found in currently registered products)

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request
2. Detailed Description of Items that should accompany the Product Submission (internal and external documents)
3. Verification for Completeness
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5. Verification for Completeness
6. Review of the Label
7. Return to Applicant, Incomplete Submission
8. Preparing the Data Package for Scientific Evaluation
9. Entering the Scientific Evaluation Process
10. Exiting the Scientific Evaluation and the 30-day Comment Period
11. Propose to Register, Conditionally Register, or Deny a 24(c) Application
12. Final Decision to Register or Deny

G. Experimental Use Permit (EUP)

(Products that contain active ingredients found in currently registered products)

1. Quick Reference - Items that must be submitted by the Applicant to Support the EUP Request
2. Detailed Description of Items that Should Accompany the Product Submission (internal and external documents)
3. Verification for Completeness
4. Review of the Label
5. Return to Applicant, Incomplete Submission
6. Products that do not Require Scientific Evaluation
7. Preparing the Data Package for Scientific Evaluation
8. Entering the Scientific Evaluation Process
9. Exiting the Scientific Evaluation and the 30-day Comment Period
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5. Return to Applicant, Incomplete Submission
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1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request
2. Detailed Description of Items that Should Accompany the Product Submission (both internal and external documents)
3. Verification for Completeness
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M. Research Authorizations

I. Introduction

Pesticide products must be registered by DPR & U.S. EPA (except adjuvants) before they can be sold, offered for sale, or used in California. The term pesticide includes any product intended to repel, kill, prevent, destroy, control, or mitigate any pest. Pesticides include insecticides, herbicides, plant growth regulators, rodenticides or other vertebrate control agents, repellents, desiccants, fungicides, miticides, disinfectants, sterilants, and sanitizers. Spray adjuvants are pesticides under California law.

The registration process includes submission and review of labels, data, application form, and fee. This section discusses the different types of registrations and the processing of registration requests.

For a brief overview of the process, see Chapter 1 of this manual.

FIFRA Sec. 2

40CFR 152.3, 152.5

FAC 12753, 12754.5, 12811, 12993

3 CCR 6000, 6145

II. Products that Do Not Require California or U.S. EPA Registration

The following products are not defined as pesticides or are adequately regulated by another agency and therefore, do not require registration by U.S. EPA or DPR:

- Fish drugs
- Contact lens solutions. Contact lenses are defined as medical devices; FDA regulates disinfecting solutions.
- Macroorganisms that control pests such as insect predators, nematodes, and macroscopic parasites
- Any product intended to be used solely for medicinal or cosmetic use on humans or on commercial feed as stated in FAC, section 12801
- Deodorizers, deodorants, and cleansers, unless pesticidal claims are made

40 CFR 152.6

40 CFR 152.10

- Pediculicides (lice control) products on humans (on the body) are defined as human drugs and are regulated by FDA

- Livestock or animal drugs as determined by 40 CFR152.8. These are regulated by CDFA's Feed, Fertilizer, Livestock Drugs and Egg Regulatory Services Division

- Ozone and chlorine generators. These are defined as devices.

- Devices as defined by FIFRA, section 2(h), with the exception of those structural pest control devices intended to control wood-destroying organisms.

- Natural cedar. The label cannot claim use against ticks or claims to retard mildew. Cedar oil may qualify for exemption but is not synonymous with natural cedar.

- Treated articles. Label may only include claims to protect the article itself. Treated lumber is an example.

- Preservatives for biological specimens

- Liquid chemical sterilants (including products with subordinate disinfectant claims) used on critical or semi critical devices. To be exempt, the product must be no longer defined federally as a pesticide, have pre-market clearance from FDA, and not include ethylene oxide as an active ingredient.

- Attractants or pheromones used solely for survey or detection purposes and that are not used with a pesticide

- Substances intended to inactivate, inhibit growth of, or destroy fungi, bacteria, or viruses in or on living man or other animals

- Substances used to inhibit the growth of, inactivate or destroy bacteria, viruses or fungi in or on processed food, beverages, or pharmaceuticals including cosmetics

Memo 12-15-94,

PR Notice 94-6,

40 CFR 152.6

Federal Reg. Notice 2007

FAC 15300
CA Notice 2000-7

40 CFR 152.25
3 CCR 6147

40 CFR 152.25

40 CFR 152.25

40 CFR 152.6
3 CCR 6146
FAC 12804

40 CFR 152.10, 152.25

40 CFR 152.5, 152.20

40 CFR 152.5, 152.25

- Certain bacteriostatic water filters. These are reviewed on a case-by-case basis by DPR and require certain criteria be met for exemption by U.S. EPA

memo of 2-19-97

- Fertilizer products that do not contain a pesticide. CDFA's Feed, Fertilizer, Livestock Drugs and Egg Regulatory Services Division regulate fertilizers. If a product is both a fertilizer and a pesticide, the manufacturer must apply to both DPR and CDFA.

40 CFR 152.8

- An individual's personal use of a substance to control their residence or garden pests provided no treated food or feed commodity is sold or distributed or fed to animals that are sold or distributed for human consumption.

3 CCR 6301

- Exempted products described in FAC, section 12803 and 3 CCR, section 6147. These include food-grade type products.

FAC 12803
3 CCR 6147

- Certain nitrogen stabilizer products as indicated in 40 CFR, Part 152.6.

40 CFR 152.6

- Spray adjuvants that are labeled solely for manufacturing or repacking into spray adjuvant end use products.

III. Products that Do Not Require U.S. EPA Registration but Do Require Registration in California

U.S. EPA does not require registration of certain products. However, the following products **do** require registration in California:

- Spray adjuvants including but not limited to wetting agents, water modifiers, drift control agents, spreading agents, etc.

- Certain products that qualify for exemption pursuant to FIFRA, section 25(b) but do not qualify for exemption in California pursuant to 3 CCR, section 6147, such as

topical citronella products that contain over 1% citronella

IV. Suspended, Cancelled, or Severely Restricted Compounds

DPR does not "ban" pesticides but has the authority to suspend, cancel, or severely restrict certain active ingredients/products based on scientific evidence and evaluation if the ingredients pose a threat to human health or the environment. This process is complex and may require a hearing. Although the enactment of certain regulations that canceled or suspended certain products in the California Code of Regulations have been repealed (note: the chemicals are listed but the regulations are repealed), 3 CCR sections 6350 to 6379 provide a useful guide for active ingredients that are either no longer registered in California or are severely restricted. Restrictions can also be found in FAC sections 14061-14063. U.S. EPA also provides further information on active ingredients that have been "banned" or are severely restricted at the federal level. A chemical that is "banned" at the federal level cannot be sold, used, or distributed in any state in the country.

V. Evaluation and Notice of Decision Time Frames

California regulations establish the following evaluation time frames for product registration:

- The time frame to complete the evaluation of data submitted for a pesticide containing a new active ingredient or major new use is 120 days
- The time frame to complete the evaluation of data submitted for a pesticide that does not contain a new active ingredient is 60 days
- The time frame to complete the evaluation of additional data requested by DPR is 30 days

When a product exits scientific evaluation, it must be posted within 1

3 CCR 6255

week for a period of 30-days. Products exiting evaluation are posted publicly as Notice of Decisions (NODs).

VI. General Intake Process

A.Intake

The Intake Technician(s) receives a registration submission, logs the submission into the database (mail log), and complete the following (process may vary for section
18's, 24(c)'s and other unique registration actions):

- Generate a status sheet that will include information about the product, such as the active ingredient, chemical(s) and DPR chemical code, applicant, and type of registration request. See sample copy in Appendix F.

- For microbial products, determine genus, subspecies, and strain

- Create a folder to facilitate routing. The status sheet and tracking ID# remain with the registration request throughout the process.

- If data are submitted, forward the package to the Indexer

- If there is an attention flag on the status sheet, give the entire sheet to the designated supervisor who will forward the package to the Indexer or the Regulatory Scientist

The procedures in "Intake through Archiving" guidance document must be followed when processing and tracking any submission. Use it in conjunction with this desk manual. It is available on the branch home page. See Intake through Archiving.

Memo:
10-25-94

Memos:
8-29-97
7-10-96
5-28-93

3 CCR 6151

B. Indexing

If data are submitted with a registration request, the Indexer will process the data and complete following:

- Index the data by entering study information into the database that will include the study title, date study was conducted, U.S. EPA test types, and assigned volume numbers

- Generate a letter to the data submitter acknowledging receipt of data that includes the assigned tracking ID# and a report of the indexed data

- Forward the registration submission to the Regulatory Scientist

Applicants must submit data in the format outlined in California Notice to Registrants 2006-6. Upon receipt of an incorrectly formatted data submission, the PRB will contact the data submitter and inform them that the data will be shredded. DPR will follow-up with a letter notifying the applicant that, with the exception of the data, which were shredded, DPR will maintain the remainder of the submission for six months. If the applicant resubmits the data, properly bound, DPR will again begin processing the submission. If data submitted to support an application for registration or amendment is not resubmitted within six months, an additional application fee is required.

More detail about indexing data can be found in the "Intake through Archiving" manual on-line.

C. Determining Special Features of the Submission

Many products have features that require special handling. The RS determines whether the registration request contains any of the following special features:

- Have the proposed use sites, pests, etc. been approved for another product with the same formulation or is the product identical to one currently registered or recently inactivated? Identical products must have the same formulations and label claims with some minor differences allowed. If you are not certain whether a product is identical, check with a chemist.

    - Examples may include additional brand names, changes in ownership, brand name changes, and

Memo: 10-25-94

Memo: 4-4-91

CA Notice 2006-6

Memos : 1-1-99 6-23-93

subregistrations.

- Is this registration request submitted concurrently with the U.S. EPA application for registration? The following product types may be submitted to DPR and U.S. EPA concurrently:

  - All products that contain new active ingredients
  - All new microbial and biochemical products Antimicrobial or public health products that meet criteria outlined in FAC, section 12836
  - All applications for Experimental Use Permits
  - Any product approved by the Pesticide Registration Branch Chief

- Is this an antifouling paint containing tributyltin compounds (TBT)? See Chapter 5 of this manual.

- Is the product a bacteriostatic water filter? If so, advise the applicant to review Appendix O

- Is the product for medical waste treatment? If so, advise the applicant to review Appendix M

- Is the product a fumigant? Forward to the appropriate RS.

- Is the product for use around the home? If the product does not contain a new active ingredient, indoor exposure data may be required.

FAC 12836, 12836.5

CA Notice 2005-10

VII. Processing Applications for Registration

This part of Chapter 4 has been divided into 16 sections, with detailed descriptions and information on processing the various types of product submissions received by the Pesticide Registration Branch.

A. New Active Ingredients (Not including adjuvants)

New active ingredients are ingredients that have never been registered at DPR or have not been registered with DPR within the last calendar year. An active ingredient is defined in FIFRA as:

1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

New active ingredients require substantial review and on average take at least one-year to process (in some cases even longer). DPR must accept applications for registration of pesticide product containing new active ingredients concurrently with the application submitted to U.S. EPA for product registration (FAC 12836.5).

This section includes applications for all types of submissions that contain new active ingredients, with the exception of adjuvants. Adjuvants that contain new active ingredients are handled by the company Regulatory Scientist and are covered in section F of this chapter.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee

- Six copies printer's proof or final printed labels

- A copy of the U.S. EPA stamped-accepted label and accompanying letter (if available)

- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist. It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder

- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation

- Special flags/instructions

- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on- line and viewed by the public

To correct a status sheet, the Regulatory Scientist will:

- Make the changes on the original status sheet

- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted,

initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The Regulatory Scientist should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo: 8-31-98

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the license issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

CA Notice 2009-5

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the registrant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

Memos: 3-24-97 7-30-96

CA Notice 96-1

Since the product's brand name is often not chosen or is changed throughout the registration process, companies will often submit new application forms and final labels before the product is posted 30-to- Register. The RS should revise the status sheet and any other pertinent documentation before the product is posted 30-to Register (if possible).

Each active and inert ingredient in the product formulation sheet must be listed. The U.S. EPA Confidential Statement of Formula

(CSF), EPA form 8570-4, may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%. If the product contains a fertilizer, the components (generally NPK or nitrogen, phosphorus, and potassium) should be identified on the CSF.

3 CCR 6152

The brand name on the application form must be the same as the name shown on the label and consistent with federal documentation. However, for new active ingredients, a product's brand name may not yet be established. The RS should confirm that the brand name is consistent on all documents before the package is submitted to licensing.

40 CFR 156.10 (b)(2)(ii)

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1. Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2. Registrants assigned more than one company number (e.g. 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

U.S. EPA Label Review Manual

U.S. EPA Label Consistency Web page

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

1. Are the same chemical composition; or

2. Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This**

regulation applies to California master labels!

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must also read left to right, top to bottom.

d) Application Fee

FAC 12812

3 CCR 6148

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application and the registrant's check is clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

e) Proof of Federal Registration

FIFRA Sec. 3

A copy of the U.S. EPA stamp, accepted label and a copy of the accompanying U.S. EPA letter are required for new active ingredients. The accompanying letter must be provided because it often contains label revisions that the registrant must conform to before distributing the product. These revisions must be reflected on the label submitted to California. If the product is being submitted concurrently to U.S. EPA, proof of federal registration will not be available until the product is federally registered and must be provided before the product is registered in California.

f) Six Copies of Printer's Proof or Final Printed Labels

3 CCR 6170

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The address on the label may differ from the application form and the license. Since most new active ingredient labels undergo multiple text and brand name changes throughout the registration process, a company may submit multiple labels before and through the 30-day posting period. It is important to verify everything is correct on the final printed label before the product is registered.

If the proposed labels are not final printed or printer's proof (e.g., Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All new active ingredients must be supported by data. All data submitted to U.S. EPA by the applicant in support of federal registration of their product, as well as all data required by 40 CFR must be submitted to DPR unless the data is currently on file. For specific data requirements for new active ingredients, please click here.

FAC 12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements. Although it is unlikely there would be data currently on file for new active ingredients, all staff should be familiar with this law.

h) Miscellaneous Items

Items such as draft labels, irrelevant documents addressed to U.S. EPA, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc. may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, part 156.10, matches the U.S. EPA stamped-accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s). Deleting uses is allowed on the proposed label.

Fertilizer Claims

In addition to pesticide labeling, there may be fertilizer claims on the label. The fertilizer composition must be separate from the pesticide ingredient statement on the label and must not detract from or obscure the required pesticide labeling statements. Fertilizers are regulated by the California Department of Food and Agriculture.

Tank Mixes

It is also common to find tank mixes on agricultural use labels. DPR will accept U.S. EPA approved tank mix label claims without supporting compatibility and residue data if the following conditions are met (meeting these conditions are the responsibility of the company, not the RS reviewing the package):

- The pesticide product to be mixed with the product that is the subject of the application, does not contain a label prohibition against such mixing

- The label contains the following statement:

  "This product can be mixed with (chemical name, including percentage of active ingredient and type of formulation, or specific product name, or both) for use on (crop/sites) in accordance with the more (most) restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing. Where a specific product name is recommended for the tank mix, the label statements shall be more explicit, including such information as specific dilution and dosage

rates."

It is acceptable for a label to mention an unregistered product in a tank mix, provided:

- The statements are permissive rather than mandatory and,
- The product is effective without the unregistered product and,
- The label does not require use of the unregistered product

Note: The RS may notify the registrant that it is illegal to sell or use the unregistered product in California

Use of Asterisks to Omit Uses

A company may choose to omit crops, use sites, pests, etc. on their pesticide label in California until such uses can be supported by data. It is acceptable for a company to place an asterisk next to the crop, crop group, pest, etc. accompanied by a statement that the product may not be used on, or at that use/use site in California (or unless accompanying by a supplemental label). The RS' supervisor can provide additional information on this subject.

When adding asterisks and labeling to omit various uses to the label, the registrant must obtain an amended label from U.S.EPA that reflect these changes.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.
- Make one copy of the letter for the "return package," a

yellow surname copy (this will be returned to the RS once processed), and a return envelope

- Include a copy of the proposed label highlighting areas of concern if applicable

- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy

- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system

- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant

- Enter the date from the cover letter into the return section on the application form

- Return the surname copy of the letter to the RS

- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified in the original return letter within 6 months, another $1,150 application fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness (see part 2 of this section), the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable (if available), and data requirements identified, the RS should prepare the package to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Note: Products that contain new active ingredients are prepared differently than products that contain currently registered active ingredients.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

Use Appendix E "Evaluation Station Responsibilities and Purpose of Review" to determine the appropriate scientific evaluation stations. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch.

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The colored folder does not accompany new active ingredients into evaluation and is kept by the RS. Unlike currently registered active ingredient packages, new active ingredients are submitted to each evaluation station concurrently, not sequentially. Therefore, copies of the entire package (excluding the data) must be made for each evaluation station so it is important not to staple anything together. If documents were stapled together by the registrant, the staples should be removed. Also, all documents should be one-sided. If a label or other document has text printed on both sides of the page, a one-sided copy must be made before submission into evaluation.

The package should be assembled as follows:

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. See sample in Appendix G.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to

the PREC committee members.

- A second copy of the route sheet
- The applicant's cover letter (if provided)
- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form
- A second copy of the proposed label
- The U.S. EPA label (if available) and all other pertinent U.S. EPA documentation

Note: Chemistry pre-screens certain ground water related data for all new active ingredients before they are sent to Environmental Monitoring (EM). If chemistry has concerns, they will alert the RS and the package will subsequently be routed to EM.

Once the package is assembled, it is placed in a designated box for processing. The appropriate support staff member makes copies and each evaluation station is color-coded on the route sheet.

7. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

The RS indicates the appropriate evaluation stations on the route sheet and submits the registration request into scientific evaluation. The designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is simultaneously routed to all evaluation stations for review.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. Because all evaluation stations review new active ingredient data simultaneously, the evaluation station entry and exit dates may seem inaccurate. To identify accurate entry and exit dates for new active ingredients, check with the Tracking Coordinator. It should be noted that this process differs from products submitted with currently registered active ingredients.

Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the

registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

Note: When the registrant, applicant, or authorized party (such as a consultant) **is not** the data holder, the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation memos are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front cover of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of

the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval
- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"
- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e. the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e. the registrant requests the package be returned), a supervisor should be consulted.

8. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed
- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed with the applicant
- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted
- If an adverse effect disclosed by data pertains to any other currently registered products, contact the Reevaluation Coordinator and see Chapter 8 for guidance on Reevaluation
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

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DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30- day notice is to allow for public comment on the proposed product and the Department's decision to register or deny the product application. The Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible.

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation after the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised.

- If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will repost the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the

end of the original 30-day comment period

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature
- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet
- Give the package to the Tracking Coordinator who will revise the registration decision in the database
- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

9. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration
- The label mitigates any hazards or possible adverse effects
- No additional data or information are required to support full registration

Concurrent submissions:

If the submission is being processed concurrently, the proposed decision to register may be posted for the 30-day comment period. However, the RS must verify receipt of the U.S. EPA stamped-accepted label with the accompanying letter, and must

compare the final U.S. EPA label to the proposed label before registration can be granted. Significant changes may require the package to be resubmitted into evaluation. The RS may hold concurrent submissions that are proposed for registration up to six months if the U.S. EPA registration has not been granted.

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluator has recommended denying the Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the PRB Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the PRB Chief for their signature

- Provide a copy of the signed pinky to the evaluator and the Program Manager of Evaluation

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows

the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product
- Acute dermal LD50 data on the product
- Acute LC50 data on products that produce respirable aerosols or gases
- Primary eye irritation data on the product
- Primary skin (dermal) irritation data on the product
- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level or interval, when human contact is likely to occur
- Preliminary efficacy data indicating the effectiveness for the proposed use
- Groundwater protection data as required by the Pesticide Contamination Prevention Act - AB2021 data, for the first agricultural use of an active ingredient, unless Interim Registration is requested
- The mandatory health affects data as required by the Birth Defects Prevention Act - SB950 (may be waived after consulting with OEHHA.)

To propose a conditional registration the RS will:

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled “30 to Reg” and submit the action log to the appropriate person
- Send a letter to the applicant listing the conditions, the time frames, and the requirement within 30-days for a written

agreement to the conditions. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30- day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to- Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label
- Label claims were not supported by the information/data submitted
- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

10. Final Decision to Register or Deny

After the 30-day public comment period is complete, a final action to register, register conditional, or deny is taken. It should be noted that a

3 CCR 6254

public report detailing a description of the proposed action, a statement of any significant adverse environmental effects that could reasonably be expected to occur (directly or indirectly), etc., must accompany the registration of all products that contain new active ingredients. The report is not generated by the RS but by a designated staff person. Guidance on preparing a public report will not be covered in this manual.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and acceptable (Master labels don't require final printed labels)

- If the submission was submitted concurrently to U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

  Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

  - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
  - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
  - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB,

EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form (discussed in part 2 of this section).

- U.S. EPA forms if applicable (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiples labels (due to colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" and the tracking ID# in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. If the product contains a fertilizer, a note should be clipped or stuck to the front of the package indicating such, so that the Licensing Technician will know which letter to prepare. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once

the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. The product is not officially licensed until the license has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS will proceed as follows:

- Verify that final printed, or printer's proof labels were submitted and acceptable (Master labels don't require final printed labels)
- If the submission was concurrent with U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

  Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are

required, post the registration “30- to Deny.”

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over “E” and “M”.
    - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
    - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- When issuing an **EUP,** the RS will assign a number in the following manner: Firm number - 55000 (the last digits are assigned from the USEPA-assigned EUP number) - EX. For example, the Reg. No. may read: 123-55001-EX.

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first

page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" and the tracking ID# in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form (discussed in part 2 of this section)

- U.S. EPA forms if applicable (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center.

If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiples labels (due to colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. If the product contains a fertilizer, a note should be clipped or stuck to the front of the package indicating such, so that the Licensing Technician will know which letter to prepare. **Do not include the colored folder.**

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The Licensing Technician will prepare 6 or 7 copies of the conditional letter:

1 original letter for the company
1 copy for the company agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation memo(s) and is filed in order by the RS' last name.

Once the Licensing Technician prepares the letters and licenses, the technician will give the package back to the RS for sign off. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. The product is not officially licensed until the product license has been sent out by PRB.

Yearly Assignments

3 CCR 6253

P/P 2007-1

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the Evaluation Scientist who recommended the conditional registration, to determine if an extension is warranted. If the Evaluation Scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS should prepare a letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on "Changing a Conditional Registration to a Full Registration."

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, the original letter of authorization, copies of the evaluation memos, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and your signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration
- The $1,150 application fee
- All data or information identified as lacking in the previous submission

Note: If the application is denied because U.S. EPA did not approve the product registration before our comment period ended, the registrant has 18 months to submit the U.S. EPA stamped-accepted label to DPR without having to resubmit any documentation or the $1,150 application fee. They should however, provide a cover letter with the original tracking ID#, explaining their actions.

B. Conventional Pesticide Products for Commercial Use (Products that contain active ingredients found in currently registered products)

Conventional Pesticide - Conventional pesticide products are products that contain include most agricultural, structural, and home use products, as well as certain industrial and institutional products. They do not include biological (biopesticides) or antimicrobial pesticides. Conventional products contain active ingredients that are generally produced synthetically to prevent, mitigate, destroy, or repel any pest; or that act as a plant growth regulator, desiccant, defoliant or nitrogen stabilizer. Wood preservative and anti-foulant products that do not have antimicrobial uses, and agricultural fungicide and aquatic herbicide products are classified as either

conventional or biochemical pesticides. Biochemical pesticides with a toxic mode of action are classified for the purposes of the registration process as conventional pesticides.

Agricultural use is defined in the California Food and Agricultural Code, section 11408 as the use of any pesticide or method or device for the control of plant or animal pests, or any other pests, or the use of any pesticide for the regulation of plant growth or defoliation of plants. It excludes the sale or use of pesticides in properly labeled packages or containers that are intended for any of the following:

a. Home use
b. Use in structural pest control
c. Industrial or institutional use
d. The control of an animal or pest under the written prescription of a veterinarian
e. Local districts or other public agencies that have entered into and operate under a cooperative agreement with the State Department of Health Services pursuant to section 116180 of the Health and Safety Code, provided that any exemption under this subdivision is subject to the approval of the director as being required to carry out the purposes of this division.

Agricultural use in California includes, but is not limited to, commercial production of animals or plants (including forests), parks, golf courses, cemeteries, roadsides, power line rights-of-ways, nurseries, and schoolyards. **It should be noted that the federal and State of California definitions of "agricultural use" differ.** There is no federal "agricultural use" definition in FIFRA or 40 CFR. However, 40 CFR part 170.3 does define agricultural employer, establishment, and plant, as well as forests, greenhouses, and fumigants. It's easier to exclude uses that are not defined as agricultural use under federal guidelines than to determine those uses that are.

Home, structural, industrial and institutional uses are defined in Title 3, California Code of Regulations, section 6000.

Structural use is defined as, "A use requiring a license under Chapter 14 (commencing with section 8500), Division 3 of the Business and Professional Code."

Industrial Use is defined as, "Use for or in a manufacturing, mining or chemical process; or use in the operation of factories, processing plants, and similar sites."

Institutional use is defined as, "Use within the confines of, or on property necessary for the operation of, buildings such as hospitals, schools, libraries, auditoriums and office complexes."

Note: This section of Chapter 4 covers agricultural, structural, industrial, and institutional uses, not including products that are classified as antimicrobials,

biopesticides, or are solely home and garden products. These subjects are covered separately within this chapter.

If the product is considered **"dual use"** (e.g., agricultural and home and garden), all sections that are relevant must be referenced. A supervisor or trainer should be consulted if the RS does not have experience processing such labels.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies printer's proof or final printed labels
- A copy of the U.S. EPA stamped-accepted label and accompanying letter
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions

- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the RS will:

- Make the changes on the original status sheet with the corrections highlighted, initialed, and dated.
- Submit a photocopy with corrections highlighted to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the license issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo of 8-31-98

CA Notice 2009-5

must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

Each active and inert ingredient in the product formulation sheet must be listed. The U.S. EPA Confidential Statement of Formula (CSF), EPA form 8570-4, may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%. If the product contains a fertilizer, the components (generally NPK or nitrogen, phosphorus, and potassium) should be identified on the CSF.

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

- Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

- Registrants assigned more than one company number (e.g.,1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

- Are the same chemical composition; or

- Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as

Memos of
3-24-97
7-30-96

CA Notice 96-1

3 CCR 6152

40 CFR 156.10 (b()2)(ii)

U.S. EPA Label Review Manual

U.S. EPA Label Consistency Web page

those two products are basically identical. **This regulation applies to California master labels!**

> Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name
>
> Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name
>
> Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must read left to right, top to bottom.

d) Application Fee

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check is clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

FAC 12812

3 CCR 6148

e) Proof of Federal Registration

A copy of the U.S. EPA stamped-accepted label and a copy of the accompanying U.S. EPA letter are required. The accompanying letter must be provided because it often contains label revisions that the registrant must conform to before distributing the product. These revisions must be reflected on the label submitted to California.

FIFRA Sec. 3

If the U.S. EPA label is not provided, the RS may obtain the current label from the U.S. EPA website (if available), or from an available file in the Label Resource Center.

f) Six Copies of Printer's Proof or Final Printed Labels

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The

3 CCR 6170

address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

All products must be supported by data. All data submitted to U.S. EPA by the applicant in support of federal registration of their product and required pursuant to 40 CFR, must be submitted to DPR unless the data is currently on file. For specific data requirements for conventional products, please click here.

3 CCR 6158 6159

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

FAC 12811.5

h) Miscellaneous Items

Items such as draft labels, irrelevant documents addressed to U.S. EPA, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc. may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete, has all the required items listed above, and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, part 156.10, matches the U.S. EPA stamped- accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s). The RS should assume that the EPA label received is the most recent copy. This does not need to be verified. The applicant may choose to delete uses on the proposed label.

Fertilizer Claims

In addition to pesticide labeling, there may be fertilizer claims on the label. The fertilizer composition must be separate from the pesticide ingredient statement on the label and must not detract from or obscure the required pesticide labeling statements. Fertilizers are regulated by the California Department of Food and Agriculture.

Tank Mixes

It is also common to find tank mixes on agricultural use labels. DPR will accept U.S. EPA approved tank mix label claims without supporting compatibility and residue data if the following conditions are met (meeting these conditions are the responsibility of the company, not the RS reviewing the package):

- The pesticide product to be mixed with the product that is the subject of the application, does not contain a label prohibition against such mixing

- The label contains the following statement:

  ”This product can be mixed with (chemical name, including percentage of active ingredient and type of formulation, or specific product name, or both) for use on (crop/sites) in accordance with the more (most) restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing. Where a specific product name is recommended for the tank mix, the label statements shall be more explicit, including such information as specific dilution and dosage rates.”

It is acceptable for a label to mention an unregistered product in a tank mix, provided:

- The statements are permissive rather than mandatory and,

- The product is effective without the unregistered product and,

- The label does not require use of the unregistered product

Note: The RS may notify the registrant that it is illegal to sell or use the unregistered product in California

Use of Asterisks to Omit Uses

A company may choose to omit crops, use sites, pests, etc. on their pesticide label in

California until such uses can be supported by data. It is acceptable for a company to place an asterisk next to the crop, crop group, pest, etc. accompanied by a statement that the product may not be used on, or at that use/use site in California (or unless accompanying by a supplemental label). The RS' supervisor can provide additional information on this subject.

When adding asterisks and labeling to omit various uses to the label, the registrant must obtain an amended label from U.S.EPA that reflect these changes.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.
- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope
- Include a copy of the proposed label highlighting areas of concern if applicable
- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the RS
- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 application fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below)

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)

- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations

- Contain the same or substantially similar inert ingredient(s)

- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)

- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.

- Bear the same or substantially similar method(s) of application.

- Claim to control the same or substantially similar pests or site/pest combination(s)

- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to

the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR within the last 10 years and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness (see part 2 of this section), the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable, and data requirements identified, the RS should prepare the package to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

Use Appendix E "Evaluation Station Responsibilities and Purpose of Review" to determine the appropriate scientific evaluation stations. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet.

Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Label Resource Center but should be referenced on the route sheet. In general, all new products requiring evaluation are routed to chemistry, medical toxicology, and efficacy for review.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention

Fish and Wildlife
Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members.

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form
- A second copy of the proposed label
- The U.S. EPA label and all other pertinent U.S. EPA documentation
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e. Med. Tox., then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation memos that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staffs prepare written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation memos are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to

sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (e.g., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant

(propose registration or denial)

Note: for exceptions to the rule (e.g., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is completed, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed
- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant
- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted
- If an adverse effect disclosed by data pertains to any other currently registered products, see Chapter 8 for guidance
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30- day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not

give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends and; 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised

evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation after the Product is posted for 30- Day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated.

  The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will post the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet
- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Registerister for the public comment period. A proposed decision to register means:

- The data supported the registration

- The label mitigates any hazards or possible adverse effects

- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them

to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the
Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and the Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR evaluation staff find that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and

found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product
- Acute dermal LD50 data on the product
- Acute LC50 data on products that produce respirable aerosols or gases
- Primary eye irritation data on the product
- Primary skin (dermal) irritation data on the product
- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level or interval, when human contact is likely to occur
- Preliminary efficacy data indicating the effectiveness for the proposed use
- Groundwater protection data required by the Pesticide Contamination Prevention Act (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested
- The mandatory health affects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA)

To propose a conditional registration the RS will:

- Place the tracking ID# on the weekly action log under "30-to-Registerister"and submit the action log to the appropriate staff person
- Send a letter to the applicant listing the conditions, the time frames, and the requirement within 30-days for a written agreement to the conditions.

The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the

posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label
- Label claims were not supported by the information/data submitted
- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the deficient evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Place the tracking ID# under "30-to Deny" on the weekly action log and submit the action log to the appropriate staff person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and acceptable

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
    - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
    - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" and the tracking ID# in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- U.S. EPA forms if applicable (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" in the upper right-hand

corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

  Note: Additional copies of alternate formulas should not be included (e.g., the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that

did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product is not officially licensed until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required study(s), the RS should proceed as

follows:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

  - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
  - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
  - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
  - Section 18s approved by DPR for use in California (Alpha code EE)
  - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write “Product File” and the tracking ID# in the upper right-hand corner of the application. Verify that there is an RC#, fee, date and amount on the form.

- U.S. EPA forms if applicable (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer’s proof or final printed label. Write “Product File” in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with “Company” written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write “Coding” in the upper right-hand corner

  Note: Additional copies of alternate formulas should not be included (e.g., the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, conditional binder, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other Licensing binders. It contains a copy of the letter, license, and conditional evaluation memo(s) and is filed in order by the RS' last name.

L**icenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party** (e.g., the applicant who is not employed directly with the company). If the applicant, agent, or

other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The
RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Yearly Assignments

P/P 2006-6

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance

of the required data. See Chapter 8 on Changing a Conditional Registration to a Full Registration.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation memos, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration
- The $1,150 application fee
- All data or information identified as lacking in the previous submission

C. Home and Garden Products (Products that contain active ingredients found in currently registered products and are not antimicrobials)

Home use is defined in Title 3, California Code of Regulations, section 6000 as "Use in a household or its immediate environment." It is more limited than U.S. EPA's definition of "**residential use**" defined in 40 CFR, part 152.3 and 157.21.

Home and garden use labels indicate application of a pesticide associated with a household and include application in, on, or around all structures and vehicles, to humans or pets, or other areas associated with a household. A householder is a person who uses a pesticide either outside or inside a residential dwelling on property owned or rented by that person. All label text must be expressed in terms likely to be read and understood by a householder under customary conditions of purchase and use.

This section of Chapter 4 covers home and garden use products only. **Antimicrobial**

products for home use are covered in Part E of this chapter. If the product is considered **dual use** (e.g., agricultural and home and garden), you will need to reference all sections that are relevant. A supervisor or trainer should be consulted if the RS does not have experience processing such labels.

1. Quick Reference - Items that must be submitted by the applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies printer's proof or final printed labels
- A copy of the U.S. EPA stamped-accepted label and accompanying letter
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions
- The active ingredients listed are consistent with the label,

application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the Regulatory Scientist will:

- Make the changes on the original status sheet
- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the license issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo: 8-31-98

CA Notice 2009-5

designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

Each active and inert ingredient in the product formulation sheet must be listed. The U.S. EPA Confidential Statement of Formula (CSF), EPA form 8570-4, may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%. If the product contains a fertilizer, the components (generally NPK or nitrogen, phosphorus, and potassium) should be identified on the CSF.

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1. Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2. Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

1. Are the same chemical composition; or

2. Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Memos of
3-24-97
7-30-96

CA Notice 96-1

3 CCR 6152

40 CFR 156.10 (b()2)(ii)

U.S. EPA Label Review Manual

U.S. EPA Label Consistency Web page

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must read left to right, top to bottom.

d) Application Fee

FAC 12812

3 CCR 6148

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. The Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check, clips them together and sends them to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

e) Proof of Federal Registration

FIFRA Sec. 3

A copy of the U.S. EPA stamped-accepted label and a copy of the accompanying U.S. EPA letter are required. The accompanying letter must be provided because it often contains label revisions that the registrant must conform to before distributing the product. These revisions must be reflected on the label submitted to California.

f) Six Copies of Printer's Proof or Final Printed Labels

3 CCR 6170

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration

process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All products must be supported by data. All data submitted to U.S. EPA by the applicant in support of federal registration of their product and required pursuant to 40 CFR, must be submitted to DPR unless the data is currently on file. For specific data requirements for home and garden products, please click here.

FAC 12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

h) Miscellaneous Items

Items such as draft labels, irrelevant documents addressed to U.S. EPA, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc. may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, part 156.10, matches the U.S. EPA stamped- accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s). The RS should assume that the EPA label received is the most recent copy. This does not need to be verified. The applicant may choose to delete uses on the proposed label.

As a reminder, the following dilution rates, application rates, and use directions are appropriate for home or household use:

- Rates per square feet/cubic feet
- Spray for complete plant coverage including undersides of leaves
- Wet plants to point of run-off (dripping point)
- Dilution rates using appropriate volumes such as 1 to 10 gallons of water
- Technical terms if they are defined in lay person's language
- Directions to contact the County Agricultural Extension office for preventive spray schedules and timing of applications
- Storage and disposal statements such as "Wrap in newspaper, discard in trash."

The following dilution rates, application rates, and use directions are inappropriate for home or household use:

- Rates per acre
- Dilution rates using large volumes such as 100 gallons of water
- Directions to make a % solution unless the label contains instructions to use a specified amount of product in a specified amount of water or other diluent
- Terms such as Cover Spray, Delayed Dormant, Early Green Bud, Buckshot, Pre-ping, Popcorn Stage, Shuck Split (stone fruit), Shuck Fall, Layby, Boot, and Tiller, unless they are defined on the label
- Use of specialized equipment (except for swimming pool chemical metering devices)
- Storage and disposal statements such as "triple rinse"
- Graphics which contradict the text

The package should be returned if the label terms, statements, graphics, designs, etc., are not likely to be understood by the average householder.

Fertilizer Claims

Fertilizer claims are common on home and garden use product labels. The fertilizer composition must be separate from the pesticide ingredient statement and must not detract from or obscure the required pesticide labeling statements. Fertilizers are regulated by the California Department of Food and Agriculture.

Use of Asterisks to Omit Uses

A company may choose to omit use sites, pests, etc. on their pesticide label in California until such uses can be supported by data. It is acceptable for a company to place an asterisk next to the use site, pest, etc. accompanied by a statement that the product may not be used on, or at that use/use site in California (or unless accompanying by a supplemental label). The RS' supervisor can provide additional information on this subject.

When adding asterisks and labeling to omit various uses to the label, the registrant must obtain an amended label from U.S.EPA that reflect these changes.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.
- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope
- Include a copy of the proposed label highlighting areas of concern, if applicable
- Clip all items listed above to the outside of the colored

folder (application package) and submit it to his/her supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the RS
- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)

- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations

- Contain the same or substantially similar inert ingredient(s)

- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)

- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.

- Bear the same or substantially similar method(s) of application.

- Claim to control the same or substantially similar pests or site/pest combination(s)

- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR within the last 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness (see part 2 of this section), the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable, and data requirements identified, the package should be prepared to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as “Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date.”

Use Appendix E “Evaluation Station Responsibilities and Purpose of Review” to determine the appropriate scientific evaluation stations. **It is important to read the**

Evaluation Station Responsibilities and Purpose of Review section, as most home and garden products need limited review. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet. In general, all new products requiring evaluation are routed to chemistry, medical toxicology, and efficacy for review.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members.

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form.
- A second copy of the proposed label
- The U.S. EPA label and all other pertinent U.S. EPA documentation
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e. med. tox, then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. In rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (e.g., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (e.g., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- If an adverse effect disclosed by data pertains to any other currently registered products, see Chapter 8 for guidance

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front

of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation After the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not

given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will post the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration

- The label mitigates any hazards or possible adverse effects

- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Branch Chief for their

signature

- Provide a copy of the signed pinky to the evaluator and the Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product

- Acute dermal LD50 data on the product

- Acute LC50 data on products that produce respirable aerosols or gases

- Primary eye irritation data on the product

- Primary skin (dermal) irritation data on the product

- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level

or interval, when human contact is likely to occur

- Preliminary efficacy data indicating the effectiveness for the proposed use

- Groundwater protection data required by the Pesticide Contamination Prevention Act (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested

- The mandatory health affects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA).

To propose a conditional registration the RS will:

- Place the tracking ID# on the weekly action log under "30-to-Registerister"and submit the action log to the appropriate staff person

- Send a letter to the applicant listing the conditions and the time frames, and request a written letter agreeing to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and found acceptable

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E"

and "M".

- Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
- EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
- Section 18s approved by DPR for use in California (Alpha code EE)
- Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- U.S. EPA forms (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation
- A copy of the stamped-accepted, printer's proof, or final printed label.
- Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. If the product contains a fertilizer, a note should be clipped or stuck to the front of the package indicating such, so that the Licensing Technician will know which letter to prepare. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of

the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product is not officially licensed until the product license has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS will:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should

be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
    - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
    - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and

amount on the form.

- U.S. EPA forms (e.g., 8570-1, 8570-5)
- The U.S. EPA stamped-accepted label and accompanying letter
- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation
- A copy of the stamped-accepted, printer's proof, or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license.

If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner

  Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)
- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner
- A copy of the status sheet with all corrections made
- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, conditional binder, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation memo(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the

tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. Issuance has not occurred until the product license has been sent out by PRB.

Yearly Assignments

P/P 2006-6

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on Changing a Conditional Registration to a Full Registration.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The
RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with

corrections made, the evaluation report(s) and the data (in that order)

- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for

registration by submitting the following:

- A new Application for Registration
- The $1,150 application fee
- All data or information identified as lacking in the previous submission

D. Biopesticides (Products that contain active ingredients found in currently registered products)

Biopesticides are certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. There are three major classes of biopesticides: 1) Microbials, 2) Biochemicals, and 3) Plant-Incorporated-Protectants. Biopesticides are often developed as alternatives to synthetic, conventional pesticides.

Microbial pesticides are composed of living entities such as bacteria, fungi, viruses, and protozoans. Also included are killed organisms. Each new variety, subspecies, or strain of an already registered microbial pest control agent must be evaluated and may be subject to additional data requirements. Larger organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA by 40 CFR Part 158.65 and Part 152.20(a)

Biochemical pesticides include, but are not limited to, products such as semio-chemicals (insect pheromones), natural plant and insect hormones and regulators (plant growth regulators, insect growth regulators, insect juvenile growth hormones), and enzymes.

Plant Incorporated Protectants (PIPs) are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance. For example, scientists can take the gene for a specific Bacillus thuringiensis (Bt) pesticidal protein, and introduce the gene into the plant's genetic material. The plant then manufactures the pesticidal protein and as a result, and controls the pest when it feeds on the plant. EPA regulates both the protein and its genetic material; the plant itself is not regulated. They are complex and **DPR does not currently regulate PIPs.**

A biopesticide product may be labeled for either agricultural or home use. This section contains information on how to process both types of submissions.

A supervisor or trainer should be consulted if the RS does not have experience processing biopesticide labels.

For additional information on the federal regulatory history of biopesticides or information on processing a biopesticide at U.S. EPA, please visit their website at http://www.epa.gov/pesticides/biopesticides.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the application to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies printer's proof or final printed labels
- A copy of the U.S. EPA stamped-accepted label and accompanying letter
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (both internal and external)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions
- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the Regulatory Scientist will:

- Make the changes on the original status sheet with the corrections highlighted, initialed and dated

- Submit a photocopy with corrections highlighted to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the licensed issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo of 8-31-98

CA Notice 2009-5

the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

Each active and inert ingredient in the product formulation sheet must be listed. The U.S. EPA Confidential Statement of Formula (CSF), EPA form 8570-4, may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%.

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

1) Are the same chemical composition; or

2) Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental

CA Notice 96-1

3 CCR 6152

40 CFR 156.10 (b()2)(ii)

U.S. EPA Label Review Manual

U.S. EPA Label Consistency Web page

distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must read left to right, top to bottom.

d) Application Fee

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

FAC 12812

3 CCR 6148

e) Proof of Federal Registration

A copy of the U.S. EPA stamped-accepted label and a copy of the accompanying U.S. EPA letter are required. The accompanying letter must be provided because it often contains label revisions that the registrant must conform to before distributing the product. These revisions must be reflected on the label submitted to California.

FIFRA Sec. 3

f) Six Copies of Printer's Proof or Final Printed Labels

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

3 CCR 6170

g) Data

All products must be supported by data. All data submitted to U.S. EPA by the applicant in support of federal registration of their product and required pursuant to 40 CFR, must be submitted to DPR unless the data

3 CCR 6158
6159

is currently on file. For specific data requirements for biopesticide products, please click here.

If the product is a lepidopteron pheromone as defined in P/P 99-3, only chemistry and efficacy data are required. The submission is routed only to these two scientific evaluation stations.

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

FAC 12811.5

h) Miscellaneous Items

Items such as draft labels, irrelevant documents addressed to U.S. EPA, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc. may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, part 156.10, matches the U.S. EPA stamped- accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s). The RS should assume that the EPA label received is the most recent copy. This does not need to be verified. The applicant may choose to delete uses on the proposed label.

Microbial Products[1]

For products containing live microorganisms [in general], U.S. EPA has historically required that the label indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight or volume of product. The OPPTS Harmonized Test Guidelines, Series 885 Microbial Pesticide Test Guidelines address this topic. CSF certified

limits can be expressed for microbial products as:

a. Microbial Pest Control Agents (MPCA) units/unit weight or volume
b. International Units of Potency per unit weight
c. Weight percent of product

Items (a) and (b) may be expressed using biological, genetic, biochemical, serological or other appropriate data. For example:

ACTIVE INGREDIENTS:	
Pseudomonas syringae strain ESC	3.8% (by wt.)
OTHER INGREDIENTS:	96.2% (by wt.)
Total	100.0%
Contains at least 50 million viable cells/lb	_____

ACTIVE INGREDIENTS:	
Trichoderma harzianum (ATCC 20476) *	16.6% W/W
Trichoderma polysporum (ATCC 20475) **	16.6% W/W
OTHER INGREDIENTS:	66.8.% W/W
Total	100.0%
* Contains a Minimum of 4.5 million colony	
** Contains a Minimum of 14 thousand colony	

For **Bacillus thuringiensis (Bt)** products, the percentage of active ingredient for the ingredient statement will be calculated using the dry weight of the fermentor solids and solubles, including the spores and toxins as the amount of the active ingredient. For liquid products, a representative sample of the technical material is to be dried down to determine the dry weight for the purpose of expressing the percentage of active ingredient on the label. The weight of the water is to be included in the inert ingredient percentage on the label. Strain variety must appear on the label. (PR Notice 72-6). The use of potency units expressed in terms of International Units (IU) per milligram of product is not allowed except when standards are obtained from an EPA-recognized international authority. Instead of International Units, company-maintained target insect assay units are acceptable when named after the insect. (e.g. "cabbage looper units") If potency units are used, the designation should appear on the label immediately below the ingredient statement and should be followed by the

statement *"the % active ingredient does not indicate product performance and potency measurements are not federally standardized."*

For example:

ACTIVE INGREDIENTS:	
Bacillus thuringiensis subspecies *kurstaki* strain AB1 *	5.0% w/w
OTHER INGREDIENTS:	95.0% w/w
Total	100.0%
**Potency: 10,000 cabbage looper units per mg of product or 4540 cabbage looper units per a pound of product*	
The % active ingredient does not indicate product performance and potency measurements are not federally standardized	*The % active ingredient does not indicate product performance and potency measurements are not federally*

Biochemicals [2]

The ingredients statement for a product for which the active ingredient is a naturally occurring plant regulator, (such as cytokinins, auxins, or gibberellins) and for which quantitative chemical methods and units are not available, should be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENTS:	
Cytokinin *	3.0%
OTHER INGREDIENTS:	97.0%
Total	100.0%
*equivalent to 200 ppm kinetin activity	

Pheromones

The ingredient statement for pheromone dispenser labels shows the pheromone in mg. per dispenser as a footnote. For example:

ACTIVE INGREDIENTS:	
Pheromone *	1.0%
OTHER INGREDIENTS:	99.0%
Total	100.0%
*x mg per dispenser	

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[1] U.S. EPA Label Review Manual, Chapter 5, Section IX, A

[2] U.S. EPA Label Review Manual, Chapter 5, Section IX, B, C

Home and Garden Products

As a reminder, the following dilution rates, application rates, and use directions are appropriate if the product is labeled for home or household use:

- Rates per square feet/cubic feet
- Spray for complete plant coverage including undersides of leaves
- Wet plants to point of run-off (dripping point)
- Dilution rates using appropriate volumes such as 1 to 10 gallons of water
- Technical terms if they are defined in lay person's language
- Directions to contact the County Agricultural Extension office for preventive spray schedules and timing of applications
- Storage and disposal statements such as "Wrap in newspaper, discard in trash."

The following dilution rates, application rates, and use directions are inappropriate for home or household use:

- Rates per acre
- Dilution rates using large volumes such as 100 gallons of water
- Directions to make a % solution unless the label contains

instructions to use a specified amount of product in a specified amount of water or other diluent

- Terms such as Cover Spray, Delayed Dormant, Early Green Bud, Buckshot, Pre-ping, Popcorn Stage, Shuck Split (stone fruit), Shuck Fall, Layby, Boot, and Tiller, unless they are defined on the label

- Use of specialized equipment (except for swimming pool chemical metering devices)

- Storage and disposal statements such a "triple rinse"

- Graphics which contradict the text

The submission should be returned if the label terms, statements, graphics, designs, etc., are not likely to be understood by the average householder.

Use of Asterisks to Omit Uses

A company may choose to omit use sites, pests, etc. on their pesticide label in California until such uses can be supported by data. It is acceptable for a company to place an asterisk next to the use site, pest, etc. accompanied by a statement that the product may not be used on, or at that use/use site in California (or unless accompanying by a supplemental label). The RS' supervisor can provide additional information on this subject.

When adding asterisks and labeling to omit various uses to the label, the registrant must obtain an amended label from U.S.EPA that reflect these changes.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies

- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.

- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope

- Include a copy of the proposed label highlighting areas of concern if applicable

- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy

- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system

- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant

- Enter the date from the cover letter into the return section on the application form

- Return the surname copy of the letter to the RS

- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)
- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations
- Contain the same or substantially similar inert ingredient(s)
- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)
- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.
- Bear the same or substantially similar method(s) of application.
- Claim to control the same or substantially similar pests or site/pest combination(s)
- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant

Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR within the last 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness (see part 2 of this section), the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable, and data requirements identified, the package should be prepared to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as “Not applicable, AB1011 –

(list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

Use Appendix E "Evaluation Station Responsibilities and Purpose of Review" to determine the appropriate scientific evaluation stations. **It is important to read the Evaluation Station Responsibilities and Purpose of Review section, as most home and garden products need limited review.** If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet. In general, all new products requiring evaluation are routed to chemistry, medical toxicology, and efficacy for review.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring

Branch Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form.
- A second copy of the proposed label
- The U.S. EPA label (if available) and all other pertinent U.S. EPA documentation
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e. med. tox, then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. If you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staffs prepare written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. In rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (e.g., the label was revised and label claims removed

negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (e.g., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- If an adverse effect disclosed by data pertains to any other currently registered products, see Chapter 8 for guidance

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation After the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will post the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period.

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration
- The label mitigates any hazards or possible adverse effects
- No additional data or information are required to support full registration

Concurrent submissions: If the submission is being registered concurrently, the proposed decision to register may be posted for the 30-day comment period. However, the RS must verify receipt of the U.S. EPA stamped-accepted label with the accompanying letter, and must compare the final U.S. EPA label to the proposed label before registration can be granted. Significant changes may require the package to be resubmitted into evaluation. If the U.S. EPA registration has not been granted by the end of the 30-day comment period, The RS may hold the concurrent submission that is proposed for registration for up to six months.

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying them Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Branch Chief for their signature
- Provide a copy of the signed pinky to the evaluator and the Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product

- Acute dermal LD50 data on the product

- Acute LC50 data on products that produce respirable aerosols or gases

- Primary eye irritation data on the product

- Primary skin (dermal) irritation data on the product

- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level or interval, when human contact is likely to occur

- Preliminary efficacy data indicating the effectiveness for the proposed use

- Groundwater protection data as required by the Pesticide Contamination Prevention Act, (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested

- The mandatory health affects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA.). To propose a conditional registration the RS will:

  - Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a

yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and found acceptable

- If the submission was submitted concurrently to U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

- Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
- Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
- EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
- Section 18s approved by DPR for use in California (Alpha code EE)
- Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- U.S. EPA forms (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip

them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.
- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)
- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner
- A copy of the status sheet with all corrections made
- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. If the product contains a fertilizer, a note should be clipped or stuck to the front of the package indicating such, so that the Licensing Technician will know which letter to prepare. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should

place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS will:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)
- If the submission was concurrent with U.S. EPA, verify receipt of the U.S. EPA tamped-accepted label and accompanying letter. Compare the final U.S. EPA label to

the proposed label for any changes.

Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

  - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
  - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
  - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
  - Section 18s approved by DPR for use in California (Alpha code EE)
  - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.
- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.
- Stamp "Conditional" on the top, middle portion of the first

page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- U.S. EPA forms (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, conditional binder, agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation memo(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (e.g., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. Issuance has not occurred until the product license has been sent out by PRB.

Yearly Assignments

P/P 2006-6

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on Changing a Conditional Registration to a Full Registration.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route

sheet

- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration
- The $1,150 application fee
- All data or information identified as lacking in the previous submission

E. Antimicrobial Products (Products that contain active ingredients found in currently registered products)

An antimicrobial pesticide is defined in FIFRA, Section 2mm as a pesticide that is intended to:

FIFRA Sec.2mm

1. Disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms;
2. Protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime. This includes:

   i. Sanitizers and disinfectants used on inanimate surfaces

   ii. Sterilizers intended to kill virus and all bacteria, fungi and their spores, on inanimate surfaces, except liquid sterilants used to sterilize critical and semicritical medical equipment

   iii. Bacteriostats intended to inhibit growth of bacteria

   iv. Fungicides and fungistats intended to inhibit the growth of,

or destroy fungi (including yeasts)

v. Commodity preservatives and protectants intended to inhibit the growth of, or destroy bacteria and fungi

vi. Preservatives and protectants used in manufacturing processes

vii. Pool and spa products

Important Terminology

When reviewing antimicrobial labels, it is important to discern the following terms:

American Type Culture Collection (ATCC) numbers: ATCC is a private, nonprofit biological resource center and research organization whose mission focuses on the acquisition, authentication, production, preservation, development and distribution of standard reference microorganisms, cell lines and other materials for research in the life sciences. In other words, ATCC obtains or produces different strains of microorganisms, cell lines, and other materials such as bacteria, assign them specific numbers (ATCC numbers), and sells them to researchers and other organizations.

ATCC numbers must appear in <u>one</u> of the following locations:

1) On the data matrix provided to U.S. EPA
2) On the master label (as optional text) with the listing of the organisms claimed
3) As the final page of the master label (as optional text).

Thus, ATCC numbers are not required to appear on the final product label.

Bactericide: A bactericide is a substance or mixture of substances used to kill bacteria. This term is normally used on labels for non-health related products.

Bacteriostat: A bacteriostat is a substance or mixture of substances used to inhibit the growth or multiplication of bacteria. The effectiveness of a bacteriostat is normally good for a defined period of time. The term bacteriostat may be used in non-health related or health related pesticidal products. For health related products, the efficacy data normally needs to be generated with repeated wearing of the treated surfaces and in the presence of moisture to simulate the use condition. For industrial use products, in-use studies are required.

Disinfectant: Disinfectants are substances that intend to destroy or irreversibly inactivate infectious or other undesirable vegetative forms of bacteria on surfaces or inanimate objects. A general disinfectant is effective against both Gram

positive bacteria and Gram negative bacteria. A general disinfectant for use in hospitals and medical facilities must also be effective against *Pseudomonas aeruginosa*. A limited disinfectant only has limited effectiveness against a specific group of bacteria, such as Gram negative bacteria.

Disinfectant products must kill the organism being tested, 59 out of 60 times for each test set performed to provide a 95% confidence level.

Fungicide: A fungicide is a substance or mixture of substances used to kill fungi. The term "fungicide" found on a disinfectant label also implies effectiveness against health related fungi.

Fungistat: A fungistat is a substance or mixture of substances used to inhibit the growth or multiplication of fungi. The term "fungistat" is commonly used on labels of industrial microbicides.

Sterilizer or sterilant: A sterilizer is a substance or mixture of substances intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces. Sterilizers must kill 100% of the test organism they are being tested against in laboratory trials.

Sanitizer: A sanitizer is a substance that intends to reduce the number of living bacteria on inanimate surfaces, in water, or in air. To qualify as a sanitizer for use on non-food contact surfaces, a 99.9% reduction of the bacteria is required over a defined contact time. To qualify as a sanitizer for use on food contact surfaces, a 99.999% reduction of the bacteria is required over a defined contact time.

Products that contain at least 5% glycols, may claim to be air sanitizers that temporary reduce bacteria in air but cannot claim to reduce 99.9% of bacteria in air without efficacy data on the formulated product.

This section of Chapter 4 contains information on processing antimicrobial product applications for home use, industrial use, institutional use, and antimicrobial/agricultural dual-use products.

Note: If the product is a bacteriostatic water filter or for use in medical waste treatment, the Regulatory Scientist handling the submission must provide the applicant with a copy of a memorandum from the Department of Health Services on either subject as applicable (see Appendix N & O).

Concurrent Review

FAC section 12836 allows for any pesticide product classified by the United States Environmental Protection Agency (EPA) as a "public health pesticide" or "antimicrobial pesticide" that is determined by U.S. EPA to have human health protection benefits, to be submitted to both U.S. EPA and DPR for concurrent review.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies printer's proof or final printed labels
- A copy of the U.S. EPA stamped-accepted label and accompanying letter (if product has not been submitted concurrently to U.S. EPA)
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the brown folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions

- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the RS will:

- Make the changes on the original status sheet

- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the licensed issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

The application form must be signed and dated by an authorized

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo of 8-31-98

CA Notice 2009-5

representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC).

The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

If the product application is submitted concurrently to DPR and U.S. EPA, the product brand name may change throughout the registration process. Companies will often submit new application forms and final labels before the product is posted 30-to-Registerister. The RS must revise the status sheet and any other pertinent documentation before the product is posted 30-to Register (if possible). All documents must be finalized before the product can be registered.

Each active and inert ingredient in the product formulation sheet must be listed. The U.S. EPA Confidential Statement of Formula (CSF), EPA form 8570-4, may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%.

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different

Memos of
3-24-97
7-30-96

CA Notice 96-1

3 CCR 6152

40 CFR 156.10 (b()2)(ii)

U.S. EPA Label Review Manual

U.S. EPA Label Consistency Web page

registrants to use the same brand name, provided the products:

1) Are the same chemical composition; or

2) Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must read left to right, top to bottom.

d) Application Fee

FAC 12812

3 CCR 6148

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

e) Proof of Federal Registration

FIFRA Sec. 3

A copy of the U.S. EPA stamped-accepted label and a copy of the accompanying U.S. EPA letter are required. The accompanying letter must be provided because it often contains label revisions that the registrant must conform to before distributing the product. These revisions must be reflected on the label submitted to California. If the product is being submitted concurrently to U.S. EPA, proof of federal registration will not be available until the product is federally registered

and must be provided before the product is registered in California.

f) Six Copies of Printer's Proof or Final Printed Labels

3 CCR 6170

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All products must be supported by data. All data submitted to U.S. EPA by the applicant in support of federal registration of their product and required pursuant to 40 CFR, must be submitted to DPR unless the data is currently on file. For specific data requirements for antimicrobial products, please click here.

FAC
12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

h) Miscellaneous Items

Items such as draft labels, irrelevant documents addressed to U.S. EPA, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc., may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, part 156.10, matches the U.S. EPA stamped-accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s). The RS should assume that the EPA label received is the most recent copy. This does not need to be verified. The applicant may choose to delete uses on the proposed label.

Home and Garden Products

As a reminder, the following dilution rates, application rates, and use directions are appropriate if the product is labeled for home or household use:

- Rates per square feet/cubic feet
- Spray for complete plant coverage including undersides of leaves
- Wet plants to point of run-off (dripping point)
- Dilution rates using appropriate volumes such as 1 to 10 gallons of water
- Technical terms if they are defined in lay person's language
- Directions to contact the County Agricultural Extension office for preventive spray schedules and timing of applications
- Storage and disposal statements such as "Wrap in newspaper, discard in trash"

The following dilution rates, application rates, and use directions are inappropriate for home or household use:

- Rates per acre
- Dilution rates using large volumes such as 100 gallons of water
- Directions to make a % solution unless the label contains instructions to use a specified amount of product in a specified amount of water or other diluent
- Terms such as Cover Spray, Delayed Dormant, Early Green Bud, Buckshot, Pre-ping, Popcorn Stage, Shuck Split (stone fruit), Shuck Fall, Layby, Boot, and Tiller, unless they are

defined on the label

- Use of specialized equipment (except for swimming pool chemical metering devices)
- Storage and disposal statements such a "triple rinse"
- Graphics which contradict the text

The submission should be returned if the label terms, statements, graphics, designs, etc., are not likely to be understood by the average householder.

Criteria for a Germs Claim

In order to use the term “germs” on an antimicrobial label, the product must bear directions for use as a disinfectant. If the disinfectant directions are removed from the label, the term “germs” must also be removed from the label.

1. Unqualified germ claims

Products that make unqualified claims to control germs (in other words, a product label that claims to control germs but does not list specific organisms), must provide DPR with product performance data, developed using current U.S. EPA guidelines, for the following three major classes of organisms:

1) Bacteria – meet the general purpose/broad spectrum disinfectant performance standard per EPA guidelines

2) Fungi – One pathogenic fungi (usually Trichopyton mentagrophyes) that is representative of the use sites listed for the product

3) Viruses – One enveloped and non-enveloped virus that is representative of the use sites for the product

2. Qualified germ claims

Products that make qualified claims (one that clearly describes the type of “germ” the product is efficacious against such as Staphylococcus aureus) to control germs must provide DPR with product performance data, developed using current U.S. EPA guidelines, on all organisms identified in addition to data on bacteria. Note: to make a qualified germ claim, the applicant must list at least one fungus or virus on the label of a broad spectrum disinfectant product and the data must support that organism respectively.

Note: As long as the data required for a qualified or unqualified claim has been provided, DPR may accept a label approved by U.S. EPA that doesn't meet the label guidance in the CSPA letter.

- Viruses - One enveloped and non-enveloped virus that is representative of the use sites for the product. Studies to be conducted according to EPA guidelines

- The claim "germs" can be used without descriptors of the type of organism. No asterisk is required. The claim can appear on the front or back/side panel of a label. However, specific organisms must still be listed on the label

- The claim "germs" can be used if the product is effective against bacteria AND either a virus or fungi or uses all three.

- Examples: Kills Germs, Kills germs in the bathroom and/or kitchen

- Qualified statements are optional and can be added to the product label, if desired

Unacceptable use of the Word Chlorine

Use of the word "Chlorine" alone or in combination with other wording in the name or in labeling text to describe products other than liquefied chlorine under pressure is in violation of FIFRA Section 2(q)(1)(A). For more information, see U.S. EPA Pesticide Registration (PR) Notice 75-5.

Use of Asterisks to Omit Uses

A company may choose to omit use sites, pests, etc. on their pesticide label in California until such uses can be supported by data. It is acceptable for a company to place an asterisk next to the use site, pest, etc. accompanied by a statement that the product may not be used on, or at that use/use site in California (or unless accompanying by a supplemental label). The RS' supervisor can provide additional information on this subject.

When adding asterisks and labeling to omit various uses to the label, the registrant must obtain an amended label from U.S.EPA that reflect these changes.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

Fruit Graphic Symbols

The U.S. EPA allows registrants to add fruit graphics that depict the fragrance in existing antimicrobial product labels by Notification. However, unlike traditional Notifications, U.S. EPA must review and approve the graphic before it is acceptable. Before accepting an amendment to an antimicrobial label to add or revise a fruit graphic in California, DPR must have a copy of the Notification to the U.S. EPA showing a picture of the graphic and proof of the U.S. EPA approval of the federal Notification before accepting the fruit graphic on an antimicrobial label in California. See U.S. EPA's letter on the subject at http://www.epa.gov/oppad001/fruitgraphic.htm .

Certain fruits should not appear on pesticide labels, i.e., fruits that are frequently eaten by children in the form depicted such as cherries, grapes, and watermelon slices. Such fruits and thus any graphics representing them may be inherently more attractive to children.

For additional information on acceptable labeling, see **Chapter 2** of this manual.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.
- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope
- Include a copy of the proposed label highlighting areas of concern if applicable
- Clip all items listed above to the outside of the brown folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the RS
- Attach the remaining copy of the letter to the front of the package inside the brown folder. The brown folder and accompanying data should be placed in the "return package" cabinet.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)
- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations
- Contain the same or substantially similar inert ingredient(s)
- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)
- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.
- Bear the same or substantially similar method(s) of application.
- Claim to control the same or substantially similar pests or site/pest combination(s)
- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR in the past 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the registrant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness, the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable, and data requirements identified, the package should be prepared to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

Use Appendix E "Evaluation Station Responsibilities and Purpose of Review" to determine the appropriate scientific evaluation stations. **It is important to read the Evaluation Station Responsibilities and Purpose of Review section, as most home and garden products need limited review.** If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously

evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet. In general, all new products requiring evaluation are routed to chemistry, medical toxicology, and efficacy for review.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Brown Folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.

- A copy of the status sheet (with correct information)

- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members.

Inside the Brown Folder

- A copy of the status sheet/route sheet filled out

- The applicant's cover letter (if provided)

- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form.

- A second copy of the proposed label

- The U.S. EPA label (if available) and all other pertinent U.S. EPA documentation

- If data waiver requests were submitted, include this documentation when entering the package into evaluation

Behind Brown Folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed

sequentially to each individual evaluation station (i.e., med. tox, then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. In rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the

physical data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the TC will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

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- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- If an adverse effect disclosed by data pertains to any other currently registered products, see Chapter 8 for guidance

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation after the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will post the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration
- The label mitigates any hazards or possible adverse effects
- No additional data or information are required to support full registration

Concurrent submissions: If the submission is being registered concurrently, the proposed decision to register may be posted for the 30-day comment period.

However, the RS must verify receipt of the U.S. EPA stamped-accepted label with the accompanying letter, and must compare the final U.S. EPA label to the proposed label before registration can be granted. Significant changes may require the package to be resubmitted into evaluation. If the U.S. EPA registration has not been granted by the end of the 30-day comment period, The RS may hold the concurrent submission that is proposed for registration for up to six months if the U.S. EPA registration has not been granted.

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the
Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and the Program Manager of Evaluation

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product

- Acute dermal LD50 data on the product

- Acute LC50 data on products that produce respirable aerosols or gases

- Primary eye irritation data on the product

- Primary skin (dermal) irritation data on the product

- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level

or interval, when human contact is likely to occur

- Preliminary efficacy data indicating the effectiveness for the proposed use

- Groundwater protection data required by the Pesticide Contamination Prevention Act (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested

- The mandatory health effects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA.)

To propose a conditional registration the RS will:

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should process the package as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and acceptable

- If the submission was submitted concurrently to U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

- Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are

assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

  - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
  - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
  - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
  - Section 18s approved by DPR for use in California (Alpha code EE)
  - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- U.S. EPA forms (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo), if

the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof, or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. If the product contains a fertilizer, a note should be clipped or stuck to the front of the package indicating such, so that the Licensing Technician will know which letter to prepare. Include the brown folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the brown folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product is not officially licensed until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)

- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)

- If the submission was concurrent with U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

  Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

- Verify that the EPA Reg. No., company name, and product name written on the company letter, license, and documentation are consistent

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

  - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
  - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
  - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)

- Section 18s approved by DPR for use in California (Alpha code EE)
- Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.
- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation memo(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write “Product File” in the upper right-hand corner of the application. Verify that there is an RC# on the form (discussed in Part 1)

- The U.S. EPA stamped-accepted label and accompanying letter

- A copy of the stamped-accepted, printer’s proof or final printed label. Write “Product File” and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with “Company” written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. **Do not include the folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation reports(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly with the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Yearly Assignments

P/P 2006-6

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on "Changing a Conditional Registration to a Full Registration."

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation reports, and a label. Mark the package "Denial File" and

submit to the Registration Resource Center.

- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature

- Record the tracking ID# as "Final to Deny" on his/her weekly action log

- Give the data package, original status sheet, and route sheet to the Archiving Technician for processing. Use the "Intake through Archiving" manual on-line for instructions on archiving

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet

- Arrange the data by volume (if more than one volume)

- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)

- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration

- The $1,150 application fee

- All data or information identified as lacking in the previous submission

F. Adjuvants (New active ingredients and products that contain active ingredients found in currently registered products)

FAC 12753 12758

A spray adjuvant is defined as a pesticide under California law as, "...any wetting agent, spreading agent, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier, or similar agent, with or without toxic properties of its own, which is intended to be used with another pesticide as an aid to the application or effect of the other pesticide and sold in a package that is separate from that of the pesticide other than a spray adjuvant with which it is to be used."

In other words, an adjuvant is a product sold in a separate package, with or without toxic properties of its own, that is intended to be used with another pesticide to aid the application or enhance the activity of the pesticide. The Department regulates adjuvants that are to be used with other pesticides. It does not regulate adjuvants that are to be used with non-pesticides (i.e., adjuvants used to enhance the effectiveness of fertilizers).

This includes antifoam/defoaming agents. Products may or may not mention that they are intended for use with a pesticide, although they commonly state "for agricultural applications." It has been determined that antifoam/defoamers "aid in the application" of a pesticide product and therefore are considered spray adjuvants.

DPR does not require the registration of adjuvants that are solely for manufacturing or repacking into spray adjuvant end use products. If a spray adjuvant label includes **both** manufacturing/repacking and end use directions, registration is still required.

The assigned Regulatory Scientist (RS) for the applying company processes adjuvant applications. **This includes spray adjuvants that contain new active ingredients.** Adjuvants containing new active ingredients will first be routed to the designated Program Specialist and flagged before they will be given to the RS for processing. This flag will appear on the status sheet and removed from the system if the product is registered. It should also be noted that adjuvants containing new active ingredients **do not** require chronic toxicity data.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies printer's proof or final printed labels
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

2. Detailed Description of Items that should accompany the Product Submission (internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the RS. It should be reviewed for accuracy and if needed, corrections should be made.
It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions
- The active ingredients listed are consistent with the label, application, and other documentation
- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the Regulatory Scientist will:

- Make the changes on the original status sheet
- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

3 CCR 6170.1, 6170.5, and 6157

CA Notice 2009-5

CA Notice 97-6 and 99-4

Memo of 8-31-98

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

CA Notice 96-1

Section 09 of the application (U.S. EPA Registration Number) may be left blank by the applicant and filled in by the RS. Since the product will not be federally registered, the product will be issued a California Registration Number prior to licensing and should be written on the application form by the RS when registered. A copy of the product label with the correct CA Reg. No. must be submitted to DPR within 6 months from the date the license is issued.

Each active and inert ingredient in the product formulation must be listed. Since the product will not be federally registered, the company will not submit a U.S. EPA Confidential Statement of Formula

(CSF), EPA form 8570-4. Therefore, they must fill out completely and accurately page 3 of the DPR application. All ingredients must total 100%.

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

3 CCR 6152

1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)
2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a\ master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

d) Application Fee

FAC 12812

3 CCR 6148

A $1,150 application fee is required for all new products. **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the

RS. This process may take 1-2 weeks.

e) Six Copies of Printer's Proof or Final Printed Labels

3 CCR 6170

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e., Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All products must be supported by data. For specific data requirements for adjuvants, please click here. **It should be noted that chronic toxicity data is not required for adjuvants.** The chronic toxicology studies mandated by the Birth Defects Prevention Act of 1984 (SB 950) were based on, and subject to, the standards and protocols established by FIFRA. Since adjuvants are not recognized by FIFRA as pesticides, they're not subject to the SB 950 data requirements.

Process for pre-determining data requirements

3 CCR requires certain data be submitted for all pesticide products in California. However, certain data requirements may be waived and an applicant can 1) submit their application and request a waiver for one or more specific studies; or 2) if they are unsure which data to develop or how to develop the data, provide a copy of the draft label and the product formulation to his/her RS.

Once received, the RS will informally route the documents to a predetermined point person for each appropriate evaluation station, and the point person will provide a written summary of the data requirements specific to that product. The informal summary should be provided to the applicant within 60 days. For companies that have no RS assigned, the request will be routed to the ombudsman.

FAC 12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the

ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements. Although it is unlikely there would be data currently on file for new active ingredients, all staff should be familiar with this law.

h) Miscellaneous Items

Items such as draft labels, MSDS sheets (not specifically referenced on the product label), Letters of Authorization, etc. may be retained by the RS but should not be placed in the product file once the product is registered.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with labeling requirements outlined in Title 3 of the California Code of Regulations, Article 10, sections 6235-6243.

Minimum Label Requirements

Adjuvants are not subject to U.S. EPA labeling requirements unless such requirements are also required under California laws/regulations, since adjuvants are not considered pesticides under federal law. At a minimum, the following items must be included on all adjuvant labels:

- Name, brand, or trademark
- Name and address of manufacturer, distributor, packer, formulator, or registrant
- California Registration Number
- Warning or Caution Statement

DPR may require additional label language or label revisions as appropriate.

California's alpha code after the U.S. EPA registration's number is considered optional language.

Tank Mixes

Since adjuvants are used in conjunction with other pesticide products, it is common to find tank mixes instructions on adjuvant labels. DPR does not require compatibility data to support label instructions for tank mixes on adjuvant labels. If the company has knowledge of a compatibility issue, it is their responsibility to provide appropriate label language. DPR does not assume liability for tank mix compatibility complications.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the product formulation sheet as it contains confidential business information that could be lost in the mail.
- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope
- Include a copy of the proposed label highlighting areas of concern if applicable
- Clip all items listed above to the outside of the colored folder (application package) and submit it to his/her supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the RS
- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified in the original return letter within 6 months, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)

- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations

- Contain the same or substantially similar inert ingredient(s)

- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)

- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.

- Bear the same or substantially similar method(s) of application.

- Claim to control the same or substantially similar pests or site/pest combination(s)

- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The

30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR within the past 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness, the label reviewed, and the data requirements identified, the RS should be prepare the package to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

Use Appendix E "Evaluation Station Responsibilities and Purpose of Review" to determine the appropriate scientific evaluation stations. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet. In general, all new products requiring evaluation are routed to chemistry, medical toxicology, and efficacy for review.

DPR review stations are as follows:

Pesticide Registration Branch
- Chemistry
- Microbiology

Pest Disease and Prevention
Fish and Wildlife
Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC

committee members

Inside the Colored folder

- A second copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the product formulation sheet
- A second copy of the proposed label
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluator's decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e. Med. Tox, then Chemistry, then Efficacy). Unlike federally registered products, adjuvants that contain new active ingredients are routed sequentially, not concurrently, through the evaluation process. The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should the RS have questions about a certain package in evaluation, they may ask the Tracking Coordinator to review the binder.

Our evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration

decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all

evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the

signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed
- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant
- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted
- If an adverse effect disclosed by data pertains to any other currently registered products, see Chapter 8 for guidance
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

3 CCR 6253

P/P 2007-1

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends and; 2) DPR responds to any comments received during the comment period on that product.

If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the

date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation After the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will repost the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard

copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period.

Meeting an Evaluator's Concern without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature
- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet
- Give the package to the Tracking Coordinator who will revise the registration decision in the database
- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration
- The label mitigates any hazards or possible adverse effects
- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the
Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and the Program Manager of Evaluation

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our

scientific staff.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product
- Acute dermal LD50 data on the product
- Acute LC50 data on products that produce respirable aerosols or gases
- Primary eye irritation data on the product
- Primary skin (dermal) irritation data on the product
- Preliminary efficacy data indicating the effectiveness for the proposed use

To propose a conditional registration the RS will:

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person
- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS verifies that all items have been received and will:

- Verify that final printed, or printer's proof labels were submitted and acceptable

If all items are submitted and acceptable, the product can be licensed. The RS will:

The RS must assign a firm number for CA only products, if the company does not already have one assigned my U.S. EPA and if intake has not already done so (check the application form to see if Intake has written in a firm number). To assign a firm number, the RS must refer to the California Firm/Product Number Assignment binder that can be found in the licensing area. Firm numbers are assigned in numerical sequence. Write the new company name and the firm number that you are using in the binder.

When ready to register an adjuvant, the RS must assign the new product a 50000 (California) product number. The product number immediately follows the firm number and precedes the alpha code. To assign a California only product number, the RS must use the California Firm/Product Number Assignment binder that can be found in the licensing area. Product numbers are assigned in numerical sequence by company. Each company's new adjuvant product receives a new product registration number (i.e., 50001, 50002, 50003, etc.). For example, the first product registered to a California only company (not currently registered by U.S. EPA) would read "California Registration Number 1052203-50001-AA." The same company's second product would be assigned "California Registration Number 1052203-50002-AA." When assigning the product number, write the brand name and product number that you are assigning to the product in the binder on the sheet for the company.

NOTE: All additional brand names for registered adjuvant products should be assigned to unique product number rather than a new alpha code. An alpha code other than "AA" should only be used in unique situations and then only after consultation with his/her supervisor.

Also, supplemental distributors that re-pack products are assigned their own product numbers. They treated as independent registrations. For example, if a company is currently registered under the firm number 123 at U.S. EPA, their product registration may read CA Reg. No. 123-50001-AA (**not** XXX-50001-AA-123 as it would for a federally registered product).

- Completely fill out the upper right-hand portion of the Application for
- Registration form

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula.

Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the product formulation sheet). Write "Coding" in the upper right-hand corner.

  Note: Additional copies of alternate formulas should not be included (i.e., the company has submitted one basic product formulation sheet and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (such as new products that did not enter scientific evaluation). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product is not officially licensed until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with

corrections made, the evaluation reports(s) and the data (in that order)

- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required data, the RS will:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Assign a firm number if the company does not already have one assigned by U.S. EPA and if intake has not already done so (check the application form to see if Intake has written in a firm number). To assign a firm number, the RS should use the California Firm Number Assignment binder that can be found in the licensing area. Upon issuance, adjuvants are assigned a 50000 California Registration Number that immediately follows the company number and precedes the alpha codes. For example, a California only registration for a company not currently registered by U.S. EPA may read California Registration Number 1052203-50001-AA.

  Note: In general, additional brand names for registered adjuvants should be assigned a unique product number rather than a new alpha code. However, should a unique situation arise, there is nothing in regulation to prevent us from using an alpha code for a new product. **An alpha code other than AA should only be used except in unique situations.** All new adjuvant products should receive new product registration numbers (i.e., 50001, 50002, 50003, etc.). In the case of a unique situation, the RS should consult with his/her supervisor.

  Also, supplemental distributors that re-pack products are assigned their own product numbers. They are treated as independent registrations. For example, if a company is currently registered under the firm number 123 at U.S. EPA, their product registration may read CA Reg. No. 123-50001-AA (not XXX-50001-AA-123 as it would for a federally registered product).

- Completely fill out the upper right-hand portion of the Application for Registration form.

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write “Product File” in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer’s proof or final printed label. Write “Product File” and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with “Company” written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.), clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the product formulation sheet). Write "Coding" in the upper right-hand corner.

  Note: Additional copies of alternate formulas should not be included (i.e. the company has submitted one basic product formulation sheet and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, conditional binder, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 or 7 copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder

1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation report(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Yearly Assignments

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

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If the time frame cannot be met, the company should be informed that their product will not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on "Changing a Conditional Registration to a Full Registration."

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.

- Write “Denied” in the lower right-hand corner of the route sheet, with the date and his/her signature

- Record the tracking ID# as “Final to Deny” on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The
RS should:

- Write “Archive” on the lower right-hand portion of the route sheet

- Arrange the data by volume (if more than one volume)

- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration

- The $1,150 application fee

- All data or information identified as lacking in the previous submission

G. Supplemental Distributor Products

40 CFR 152.132

A registrant may distribute or sell a registered product under another person’s name and address instead of (or in addition to) their own. This is referred to as supplemental distribution, subregistration, or distributor registration. The term “supplemental registration” is also used to refer to products that are registered and sold under the distributor's name, address, and brand name. The product must have the same formulation, label, and packaging as the currently registered product.

Supplemental distribution requires an agreement between the basic

(primary) registrant and the distributor's company. This agreement is confirmed when both companies submit a completed Notice of Supplemental Distribution of a Registered Pesticide Product form (U.S. EPA Form 8570-5) for each distributor product to the U.S. EPA. The distributor is considered an agent of the registrant for all purposes under FIFRA and both the distributor and the primary registrant can be held liable for violations pertaining to the distributor product.

Before a subregistration/distributor product can be sold or used in California, a certificate of registration (license) must be obtained. Supplemental distributor products may include agricultural, structural, biopesticide, antimicrobial, or industrial products. Companies that repackage adjuvant products under a distributor brand name are not considered supplemental distributor products. See Section F for information on processing adjuvant applications. To add a supplemental distributor to a Special Local Need section 24(c), see Section I. For all other use classifications, follow the instructions under the appropriate section of this chapter for processing (i.e., biopesticide, agricultural/structural, etc.), but note the following:

- The applicant must submit a copy of the U.S. EPA Notice of Supplemental Distribution of a Registered Pesticide Product form (8570-5), signed and dated by both the basic registrant and the distributor/subregistrant. This form is required whether or not the basic registrant is registered in California.

- The content on the label of the distributor product must be the same as that of the registered product, except that:

    - The product name of the distributor product may be different (but may not be misleading)

    - The name and addresses of the distributor may appear instead of that of the basic registrant

    - Use sites or pests may be deleted

- The registration number of the basic registrant's product must be followed by the distributor firm number (obtained from U.S. EPA)

    - For example, EPA Reg. No. 1234-123-345, where 1234 is the basic registrant's firm number, 123 is the product number, and 345 is the supplemental distributor's firm number.

- The establishment number must be that of the final establishment at which the product was produced

- The CSF will likely not be submitted with the application because the basic registrant's product formulation information is often kept from the supplemental distributor. The basic company will generally submit the CSF independently. The applicant should identify this in their cover letter. If it's not submitted, and the basic company's product is on file, the RS may retrieve the CSF(s) from the basic file.

- If the basic product is not registered with DPR, the RS may use another distributor file to review the label and CSF, as long as the basic registrant's product is the same

Quick Reference - Items that must be submitted by the Applicant to Support the Supplement Distributor Request

The following items must be submitted by the applicant in order for the application to be processed:

- California Application for Pesticide Registration

- $1,150 application fee

- A copy of the basic company's U.S. EPA stamped-accepted label and accompanying letter (if this has not been submitted, the RS may obtain a copy on-line if available or from the basic company's file)

- A copy of the U.S. EPA Notice of Supplemental Distribution of a Registered Pesticide Product form (8570-5)

- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)

- **If** a distributor registration is based on a primary's conditional registered product, the RS must send a letter proposing the same conditions to the distributor registrant. The RS must receive a letter from the distributor registrant agreeing to the conditions **before** the RS can register the distributor's product. The distributor's product will be registered under the same conditions and time frames as compare to the primary registrant's prodouct.

H. Section 18 Emergency Exemptions

FIFRA Section 18

3 CCR 6206

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes U.S. EPA to allow an unregistered use of a pesticide for a limited time if U.S. EPA determines that an emergency condition exists. The regulations governing section 18 of FIFRA (found in Title 40 of the Code of Federal Regulations, Part 166), define the term "Emergency Condition" as an urgent, non-routine situation that requires the use of a pesticide(s). It allows for the time-limited use of a pesticide product (registered or unregistered) to control an urgent, non-routine pest problem. Such uses are often referred to as "emergency exemptions," "Section 18s," or simply "exemptions."

Emergency exemptions may be requested by a state or federal agency. The issuance of a Section 18 is not the same as the issuance of a product license.[1]

[1] U.S. EPA website on Section 18s

Note: The applicant for a Section 18 must be someone other than the product registrant. Examples include farm advisors, County Agricultural Commissioners, grower groups, etc. It is recommended that the applicant contact the designated Section 18 staff person at DPR prior to submitting an application, to ensure all requirements are clearly understood.

All Section 18 applications are handled by a designated staff person, who will be referred to as the DSP throughout this section.

There are four types of emergency exemptions:

1. ***Specific Exemption*:**

   - Majority of requests are for specific exemptions
   - Requested when an emergency condition exists, in order to avert a significant economic loss, or a significant risk to endangered or threatened species, beneficial organisms, or the environment
   - Growers or agricultural research scientists identify a pest situation which registered pesticides cannot control
   - Specific exemptions may be authorized for up to one year

2. *Quarantine Exemption*:

- Requested to control the introduction or spread of an invasive pest species not previously known to occur in the United States

- "Emergency" rests on the potential of an invasive species to cause a significant economic loss

- Quarantine exemptions may be authorized for up to 3 years

3. *Public Health Exemption*:

- Requested to control a pest that will cause a significant risk to human health

- "Emergency" based upon the risk to human health presented by the pest to be controlled

- Public health exemptions may be authorized for up to one year

4. *Crisis Exemption*:

- May only be issued when there is an immediate need for a specific, quarantine, or public health exemption in situations involving an unpredictable emergency situation when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of an exemption through normal means

- DPR must confer with, and receive verbal authorization from, U.S. EPA prior to issuance. U.S. EPA performs a cursory review to ensure there are no concerns, and whether the appropriate safety findings required by the Food Quality Protection Act of 1996 can be made. If authorized by U.S. EPA, a state or federal agency may issue a crisis exemption allowing the use for up to 15 days.

- Applicant may follow up the crisis with, unless already submitted, a specific, quarantine, or public health emergency exemption request, which allows the use to continue until U.S. EPA makes a decision on the corresponding exemption requested. This is usually done simultaneously in California.

Emergency exemptions are for food uses for which no tolerance or exemption from tolerance has already been established. Food uses with existing residue tolerances or exemption from the requirement of a tolerance are processed under FIFRA section 24(c). If the emergency use involves the treatment of a food crop, U.S. EPA will establish a temporary tolerance (maximum allowable residue levels) to cover any pesticide residues that may result. These are usually granted for 2-3 years.

The following items should also be noted:

- All uses under an emergency exemption require a restricted materials permit from the appropriate agricultural commissioner's office prior to purchase and use

- Product uses issued under Section 18 cannot be advertised unless criteria outlined in 40 CFR 168.22 are met

1. Quick Reference - Items that must be submitted by the Applicant to Support the Section 18 Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Section 18 Emergency Exemption that includes but is not limited to:

  a. A complete description of the emergency pest problem
  b. The contact information for knowledgeable experts
  c. The emergency use instructions needed to apply the product in order to control the pest problem
  d. Information to support the argument that a significant economic loss (SEL) has occurred or is about to occur, due to a pest problem
  e. The economic history (typically 3-years worth of information) of the crop including information on annual production, price of commodity, and cost of production before the pest problem occurred or became significant

- Data to support the Section 18

- A letter of authorization from the product registrant

- A draft product label and product formulation sheet if the product has not been registered federally, or a copy of the U.S. EPA stamped-accepted label and confidential statement

of formula (CSF) if the product is not currently registered in California

2. Pre-application Meeting

It is recommended that the applicant contact the DSP before submitting their application. This informal meeting can be conducted in person or via telephone to aid the applicant in preparing the application and required documents.

3. Receipt of Application and other Documents

Once the Mail Technician receives the application and related documents, they are forwarded directly to the DSP. The DSP is responsible for creating a draft status sheet, based on the information received. The draft status sheet should include information about the product (such as the active ingredient(s), DPR chemical codes, applicant, etc.). Once the status sheet is drafted, the following steps are taken:

- The DSP will deliver the draft status sheet and all documents obtained to the Intake Technician

- The Intake Technician will generate a formal status sheet. In addition to the information provided by the DSP, the status sheet will include an assigned, sequential, tracking ID# that will also be placed on an accompanying colored folder. He/she will submit the package to the designated Indexing Technician so the data can be cataloged into the database.

- The Indexer will return the package to the DSP once the indexing process is complete

4. Processing the Application

Once the DSP has received the colored folder, relevant documents, and accompanying data, he/she should proceed as follows:

a) Review the status sheet

The status sheet should be the first item reviewed by the DSP. It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The DSP should verify the following:

- The tracking ID# matches the ID# on the colored folder

- The applicant or organization's name is correctly stated and

is consistent with the application and other documentation

- Special flags/instructions
- The active ingredients listed are consistent with the label, application, and other documentation
- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the DSP will:

- Make the changes on the original status sheet
- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The DSP should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Review the Cover Letter (if submitted)

Section 18 applications may be accompanied by a cover letter that identifies the applicant's intention. The DPS should review the cover letter if submitted.

c) Verify there is No Tolerance or Exemption

To verify that a tolerance has or has not been established for the active ingredient on the commodity (or the chemical is exempt from the requirement of a tolerance), the DSP should use the Pesticide Chemical News Guide (binder is housed in Chemistry) and 40 CFR, part 180. Included in Part 180 are crop definitions used for purposes of a tolerance, regional tolerances, crop groupings, and exemptions from tolerance.

d) Confirm the Letter of Authorization is Submitted

A letter of authorization from the company whose product is proposed for use must be submitted before the application can be processed.

e) Review the Application for Section 18 Emergency Exemption

The application should be reviewed for completeness and a list of deficiencies should be noted (if any). It is important that the DSP comprehensively review the proposed use section because this information will be used to draft the emergency use instructions.

f) Data

The DSP should informally review the data and/or summaries to make an initial determination that there are no major deficiencies. If the product is currently registered in California, the following data are generally required:

- Residue data sufficient for U.S. EPA to establish a time-limited tolerance
- Efficacy data to support the emergency use instructions
- Phytotoxicity data to support the emergency use instructions
- In cases where pest resistance is the basis for the emergency exemption, field data to demonstrate resistance to currently registered products should be submitted. It's important that the data be collected in the region that the pest problem is occurring.

If the product is not currently registered in California, the product manufacturer (not the applicant) must also submit acute toxicology and both product and residue chemistry data, adequate to support the emergency use instructions. This data is processed by the DSP, not the Regulatory Scientist assigned to that company.

g) Consult with U.S. EPA

The DSP should informally consult with the Section 18 contact at U.S. EPA to discuss the application and make a preliminary determination as to whether or not the emergency exemption will satisfy the U.S. EPA guidelines for a Section 18.

h) Contact the Applicant

The applicant should be contacted and any deficiencies identified in the review should be discussed. The Description of Proposed Use section on the application should be reviewed with the applicant to ensure the proposed emergency use instructions are complete. The DSP may revise the original application to reflect any changes. However, changes must be initialed and dated by the DSP. Additional data/information should be requested at this time.

i) Additional Data/Information

Any additional information submitted by the applicant will be processed by the Mail Technician and submitted to the DSP for review. This information will be linked to the original package submitted and given the same tracking ID#. The DSP may assist the applicant by gathering additional information necessary to support the submission. Internal sources of information may include Pesticide Use Reports (PURs), the Agricultural Commissioners' reports, The California Agricultural Resource Directory, grower group annual reports, etc. This information is generally used to support the economic history of the crop.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the DSP will contact the applicant to obtain the missing items. If the deficiencies cannot be resolved or the significant economic loss claim can't be supported, the package should be returned.

The DSP will:

- Prepare a return letter to the applicant that identifies all deficiencies. The original letter, a copy of the application, and the data summaries (not the data itself) will be returned to the applicant.

- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the DSP once processed), and a return envelope

- Clip all items listed above to the outside of the colored folder (application package) and submit it to his/her supervisor for sign off

  Note: The DSP should retain a copy of the return letter and the application and place them in his/her personal denial file. These files are categorized by calendar year and are kept in the DSP's office.

The Supervisor will:

- Review the return letter and surname the yellow copy

- Route the package with signed letters to the designated "out box" for distribution

The Designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the application, and data summaries to the applicant
- Return the surname copy of the letter to the DSP
- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, the package and data will be shredded unless otherwise noted.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Preparing the Data Package for Scientific Evaluation

If the DSP has determined that the emergency exemption request has merit, he/she should prepare the package to enter scientific evaluation.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet.

If the product is registered in California, the request should be routed to:

- Chemistry
- Efficacy
- Plant Physiology (if use on a new crop)

If the product is not registered in California and does not contain a new active ingredient, **the request should also be routed to**:

- Medical Toxicology

In addition, if the product is not registered in California but does contain a new active ingredient, it should be routed to:

- Fish and Wildlife

Note: If there are potential environmental hazards or groundwater issues associated with the product, it should **always** be routed to Environmental Monitoring for review.

The evaluation scientists will:

- Determine if data supports the emergency use instructions
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Inside the Colored folder

- 2 copies of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- The original application

- The data summaries

Note: If the product is not currently registered in California, a copy of the product label and CSF provided by the registrant should also be placed in the colored folder.

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

7. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the DSP's binder, and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e., med. tox, then chemistry, then efficacy) unless the product is expedited.

Expedited packages are considered urgent and are given priority over other packages in evaluation. If the DSP feels the package warrants an expedited review, he/she will prepare and submit a Tracking Documentation Memo (pinky) justifying the need for an expedited review. The pinky must be submitted to the Pesticide Registration Branch Chief for his/her signature. A copy of the pinky should be included with the package when it's submitted to the Tracking Coordinator.

The Tracking Coordinator maintains a binder for the DSP that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the DSP. The DSP is responsible for reviewing the evaluation reports to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before

releasing the report, the DSP shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the DSP must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the DSP should check with his/her supervisor for guidance. On rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The DSP must fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the DSP should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The DSP should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the DSP to finalize the process. A hard copy of the revised evaluation report will be sent to the DSP with the package.

DPR's Request to U.S. EPA

DPR must prepare and submit an application to U.S. EPA requesting acceptance of the emergency use instructions. Although not submitted until the emergency use instructions receive acceptance from DPR, the DSP should prepare this application before the package exits evaluation. The application form is not publicly available but can be accessed internally. A more detailed description of the application to U.S. EPA is described below.

Note: **It is the DSP's responsibility to monitor the package as it proceeds through the registration process. Although no regulatory standards are in place, the target date for completion is a few weeks to one month. Because the package was submitted for an emergency problem, it's important for the DSP to periodically check on the package's progress.**

8. Exiting Scientific Evaluation and the 30-day Comment Period

Once the package has completed the evaluation process, the DSP will review the evaluation reports to determine if the emergency exemption use instructions are supported and a time limited tolerance has been recommended for the active ingredient.

When the scientific evaluation process is completed, the Program Manager indicates if the product application should be approved or denied (based on the evaluators' decisions), by signing the route sheet. Once the package is returned, the DSP should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed
- Communicate any deficiencies to the applicant
- Place the tracking ID# on the weekly action log as 30-to-Registerister or 30-to-Deny and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30- day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Registration

Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

The DSP may not issue the emergency use instructions until:

1) The day after the 30-day posting period ends
2) DPR responds to any comments received during the comment period on that product; and
3) U.S. EPA has approved the request.

If DPR receives a comment(s) on a product during the 30-day posting period, the DSP will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The DSP must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised. If this occurs, the DSP should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The DSP should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the DSP. A hard copy of the revised evaluation report will be sent to the DSP with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the DSP with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

9. Submitting an Application and Supporting Documentation to U.S. EPA for approval

When the package exits scientific evaluation with a recommendation to approve the emergency use instructions, the product is posted 30-to-Registerister and the DSP will submit an application to U.S. EPA for approval. The original U.S. EPA application, two copies, and all supporting documents are sent through Federal Express to the designated contact person at U.S. EPA. The application should include:

- The nature, scope, and frequency of the pest problem. This includes a description of the pest, when and where it occurs, and when the treatment is necessary.

- The crop that is affected

- A discussion of the currently registered products or available alternative control methods, and a description of why each cannot be used

- The proposed emergency use instructions, which include but are not limited to the chemical, application rate, precautions, limitations, and an analysis of any acute hazard to man and the environment

- Risk information regarding the Food Quality Protection Act and a discussion on potentially effected endangered species

- The names, addresses, and organizations of knowledgeable experts on the subject matter

- Economic effects including projected crop and economic losses, both with and without the proposed exemption

In addition, DPR must submit:

- Data, including both efficacy and residue data, and

accompanying DPR evaluation reports

- In cases where pest resistance is the basis for the Section 18, field data to demonstrate resistance to currently registered products should be submitted. It's important that the data be collected in the region that the pest problem is occurring.

- The evaluation reports generated by DPR's scientific staff

Note: Once the package is submitted, the DSP should contact U.S. EPA to inform them that an application has been sent.

10. Issuance or Denial of the Section 18

Issuance of the Section 18

U.S. EPA will e-mail the DSP to confirm the emergency exemption request has been granted, or that they are returning the application request unapproved. If approved, the e-mail will include the emergency use instructions, will provide additional guidance as appropriate, and will often note that the active ingredient in the product is acceptable for re-certification (explained in part 11). If the Section 18 has been requested on a new crop, the emergency use instructions will be effective immediately, but the time-limited tolerance may not be issued for several weeks. In such cases, the emergency use instructions should bear a warning that the time-limited tolerance has not yet been issued for the treated crop. Residues detected by Enforcement staff could be considered illegal. It is advised that the DSP consult with his/her supervisor for guidance in such cases.

The DSP will draft the official emergency use instructions based on the information provided in the e-mail from U.S. EPA, including any additional instructions. Once complete, the DSP should:

Prepare a cover letter addressed to the appropriate County Agricultural Commissioner(s)

E-mail to the County Agricultural Commissioner(s)

- A copy(s) of the cover letter and the emergency use instructions

Assemble for the Registrant (not the Section 18 applicant!)

- A hard copy of the cover letter and the emergency use instructions

Assemble for the Section 18 File

- A hard copy of the cover letter and emergency use instructions. If the product is not registered for use in California or the emergency use instructions are to be used on a newly approved use site, a copy of the draft label (do not stamp-accept) and CSF are also placed in the Section 18 file.

Assemble for the Product File

- A hard copy of the form letter and the emergency use instructions

Assemble for Coding

- A hard copy of the form letter and emergency use instructions

Assemble for Archiving

- Give the data volumes, copy of the status sheet, and route sheet to the Archiving Technician for processing

Assemble for DSP File

- A hard copy of the original application, data summaries, supporting documentation (non-data), original status sheet, etc. These items are retained by the DSP indefinitely. They are kept in a file in the DSP's office.

Denial of the Section 18

U.S. EPA can deny an emergency exemption request by returning it or asking DPR to withdraw the application. If this occurs, the proposed decision to deny the application is posted for the 30-day public comment period. Once the 30-day period has ended, the DSP will:

- Prepare a letter to the applicant notifying them that the application denial is final, surname copy, and envelope and submit to his/her supervisor

- Place the tracking ID# on the weekly action log under "Final-to Deny" and submit the action log to the appropriate staff person

- Give any data volumes submitted on behalf of the emergency exemption request, a copy of the status sheet,

and the route sheet to the Archiving Technician for processing.

The original application, supporting information, status sheet, data summaries, etc. is retained by the DSP indefinitely. They are kept in a file in the DSP's office.

11. Re-certification

Applicants for specific emergency exemptions may submit new applications, relying on previously submitted information, to re-certify (renew) the Section 18 if the pest problem continues to be an emergency past the expiration date of the original Section 18. The emergency exemption may be renewed on an annual basis.

U.S. EPA will often note in their e-mail to the state granting the emergency exemption, that the active ingredient in the product is acceptable for re-certification. At the end of each calendar year, the U.S. EPA will prepare a re-certification list, categorized by state, identifying which active ingredients are eligible for re-certification. The list is generally available at the early part of the next calendar year.

If the applicant submits the same emergency exemption request for a second, third, etc. time, and the active ingredient is identified on the re-certification list, the application process at U.S. EPA is expedited. If it is not on the list, DPR must completely re-apply to U.S. EPA.

To re-certify a specific Section 18 emergency exemption, the DSP will:

- Send U.S. EPA a re-certification request via Federal Express once the new application has been received from the applicant. The re-certification should consist of a short letter summarizing that the emergency exemption continues to exist. It should include updated crop or economic loss information and a copy of the proposed emergency exemption use instructions.

- Inform the appropriate contact person at U.S. EPA that a re-certification request has been submitted

- Post the product 30-to-Registerister

U.S. EPA will review the letter and e-mail the DSP their decision. Follow the instructions listed above to re-issue the emergency exemption to the appropriate counties or deny the request.

12. Pesticide Use Reporting

In accordance with 40 CFR, part 166.32, the DSP must submit a final report to U.S.

EPA, summarizing the pesticide use under the emergency exemption within 45 days after its expiration. The DSP should send a report form to the appropriate County Agricultural Commissioners, requesting information on use of the applicable product under the Section 18. The form is then mailed or e-mailed back to the DSP within 1 month (or other time frame determined by the DSP). The DSP should compile the information and present it to U.S. EPA in a final report. This report should be sent via regular mail.

I. 24(c) Special Local Need (SLN)

To address a pest situation that is existing or imminent, and that a section 3 product cannot mitigate, the Department of Pesticide Regulation, under the authority of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) section 24(c), and Title 40 Code of Federal Regulations, Part 162.152, may register a new end-use product or an additional use of a federally registered pesticide product, provided there is a special local need within the State and the following conditions exists:

- The use is covered by the necessary tolerances or exemption from tolerance if the pesticide is to be used on a food or feed commodity
- Registration for the same use has not previously been denied, disapproved, suspended or cancelled by U.S. EPA, or voluntarily cancelled by the registrant
- The pesticide does not contain a new active ingredient not registered by U.S. EPA
- There is no other federally-registered pesticide for the specific use or no federally registered product available to address the special local need

A special local need (SLN) may address a new pest, method or timing of application, different use rate, new crop/ use site, and Integrated Pest Management in certain crops.

There are two types of SLNs: A first-party SLN in which the applicant is the manufacturer of the pesticide, and a third-party SLN in which the applicant is someone other than the manufacturer, such as a grower, grower association, or UC Extension.

1. Quick Reference - Items that must be submitted by the Applicant to Support a Special Local Need Application

The following items must be submitted by the applicant in order for the submission to be processed:

- The California Request for a Special Local Need Registration (SLN), section 24(c) form

- Efficacy, phytotoxicity and residue data to support the SLN use pattern

- For a first-party SLN, six copies of the proposed label that address the SLN use pattern. Third-party SLN labels are developed from state application form.

- A letter of authorization from the manufacturer of the pesticide supporting the use of their product as an SLN
- A U.S. EPA SLN form (Form 8570-25, rev.1-94) titled "Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need," filled out and signed

- Detailed letters or documentation from experts such as UC Farm Advisors or UC Extension Specialists demonstrating the SLN pesticide/ use pattern has been shown to address an existing or imminent pest problem, and no federally registered pesticide product is sufficiently available

2. Pre-application Meeting

It is strongly suggested that the applicant contact the Regulatory Scientist (RS) before submitting their application. This is an informal meeting that can be conducted in person or over the phone, to aid the applicant in preparing the application and required documents.

3. Receipt of Application and other Documents

Once the Mail Technician receives the application and related documents, they are forwarded directly to the RS. The RS is responsible for creating a draft status sheet based on the information received. The draft status sheet should include information about the product (such as the active ingredient(s), DPR chemical codes, applicant, etc.). Once the status sheet is drafted, the following steps are taken:

- The RS will deliver the draft status sheet and all documents obtained to the Intake Technician

- The Intake Technician will generate a formal status sheet. In addition to the information provided by the RS, the status sheet will include an assigned, sequential, tracking ID# that will also be placed on the accompanying brown folder.

He/she will submit the package to the Indexer to catalog the data into our database.

- The Indexer will return the package to the RS

4. Detailed Description of Items that should accompany the Product Submission (both internal and external)

a) Review the status sheet

The status sheet should be the first item reviewed by the RS. It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process, including the public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the brown folder
- The correct prefix FP (for first-party) or 3P (third-party)
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions
- The active ingredients listed are consistent with the label, application, and other documentation
- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the Regulatory Scientist will:

- Make the changes on the original status sheet with the corrections highlighted
- Submit a photocopy with corrections highlighted to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Review the Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Review the California Request for a Special Local Need Registration (SLN), section 24(c) Application form (PR-REG-004, Est. 7/91, Rev. 05/02)

3 CCR 6170, 6170.1, 6170.5, and 6157

> The application form must be filled out in detail by the applicant and signed by a County Agricultural Commissioner. The Agricultural Commissioner's signature is an acknowledgement he/she will issue a permit if required. It is important that the name and address of the registrant is accurate because it will be printed on the SLN label issued by DPR. The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file.

The application form must incorporate detailed letters or documentation from experts such as UC Farm Advisors or UC Extension Specialists, demonstrating the SLN pesticide/ use pattern has been shown to address an existing or imminent pest problem, and a federally registered pesticide product is not sufficiently available. A letter of authorization from the manufacturer of the pesticide product supporting the use of their product in the SLN is very important to justify the need for the SLN.

d) Review the federal Special Local Need registration form titled "Application for/Notification of Sate Registration of a Pesticide to Meet a Special Local Need" EPA Form 8570-25

The application form needs to be completely filled out and signed by the section 24(c) applicant.

e) Application Fee

3 CCR 6148.5

There are no California registration fees for SLNs, but the applicant of the SLN is responsible for the Federal Maintenance Fee. There are provisions for the SLN applicant to request a waiver of this fee (Fee Waiver for Minor Agricultural Use).

For more detailed information on the Federal Maintenance Fee or Fee

Waiver for Minor Agricultural Use, contact U.S. EPA at 1-800-444-7255.

f) Six copies of the proposed label

3 CCR 6170

For a first-party SLN, the applicant must submit 6 copies of the proposed SLN label. Third party labels are generated by the RS from information on the application form once the submission is approved.

g) Data

3 CCR 6158 6159

All 24(c) applications must be supported by efficacy, phytotoxicity, and chemistry (residue) data.

If the SLN use pattern is considered a food/feed use, residue data must be submitted to demonstrate the SLN use pattern will not exceed the established tolerances on the food/feed commodity, for which the SLN will be used upon. If the active SLN use pattern is exempt from a tolerance, the applicant must provide documentation.

5. Verification for Completeness

Review the package to determine if it is complete, has all the required items listed above, and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

6. Review of the Label

Review the label to determine if the SLN use pattern conflicts with the section 3-product label. If any conflicts arise during the label review process, these concerns must be corrected before the RS can proceed with processing the submission. Labeling problems generally arise when the proposed SLN label conflicts with a prohibition or restriction on the section 3 product label. If these concerns cannot be corrected, the SLN should be returned to the applicant. To help resolve these conflicts, the RS should consult the "U.S. EPA 24(c) Guidance Document," dated February 9, 1996, and/or communicate with the appropriate U.S. EPA Product Manager.

The following items should appear on the proposed label:

- Brand name of the pesticide
- U.S. EPA Reg. No.

- Manufacturer of the pesticide
- Location (such as county specific or statewide)
- Crop/commodity/site
- Pest(s)
- Dosage/ dilution rate
- Method of application
- Frequency/timing of application
- Restricted Entry Interval (REI)
- Pre-harvest Interval (PHI)
- Any other special requirements

If the applicant is applying for a third-party SLN, the information listed above (identified on the application) should be used to create a draft label. The RS is responsible for drafting a third-party SLN label. The label should be drafted at this stage of the registration process.

7. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, the RS should consult with his/her supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the California application form. This copy will be sent to the applicant along with the return letter.
- Make one copy of the letter for the "return package," and a yellow surname copy (this will be returned to the RS once processed)
- Include a copy of the proposed label highlighting areas of concern if applicable

- Clip all items listed above to the outside of the brown folder (application package) and submit to his/her supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters back to the designated RS

The RS will:

- Place the return letter, application, label (if applicable), copies of the content of the brown folder and brown folder into the "return" basket.
- Place a copy of the return letter, application, and label, along with the original contents of the brown folder in the SLN/Deny folder for that given year. The SLN/Deny files are located in the common work area.

The designated Technician will:

- Enter the tracking ID# and date of the return letter into the tracking system
- Mail original letter, copy of the application, and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the RS
- Attach the remaining copy of the letter to the front of the package inside the brown folder. The brown folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months, the application will be shredded.

8. Preparing the Data Package for Scientific Evaluation

If it is determined that the label is acceptable (or generated by the RS in the case of a third-party SLN), and the appropriate documents are submitted, the RS will prepare the SLN application package for scientific evaluation.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

The type of SLN use pattern will determine which evaluation stations the package will be routed to. Appendix E should be used as a guide to help the RS determine the appropriate review stations, depending on the SLN use pattern. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet. In general, all SLN applications that require evaluation are routed to Chemistry, Worker Health & Safety, Phytotoxicity, and Efficacy for review. See Appendix E for information on evaluation station responsibilities.

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the

package must be assembled for evaluation. The package should be assembled as follows:

Front of Brown Folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections
- A copy of the status sheet (with correct information)

- One copy of the proposed SLN label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members.

Inside the Brown Folder

- A properly filled out copy of the status sheet/route sheet

- A second copy of the proposed SLN label

- A copy of the section 3 product label

Behind Brown Folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

9. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e,. med. tox, then chemistry, then efficacy). The Tracking
Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s)

to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back to an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any

necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the

signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.

10. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the SLN application should be approved or denied (based on the evaluator's decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

DPR posts publicly for 30 calendar days, all proposed decisions for SLN applications that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30- day notice is to allow for public comment of the proposed SLN application and the Department's decision to accept or deny the SLN application. The Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

3 CCR 6253

P/P 2007-1

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate documentations to register the SLN. However, the RS may not register the SLN until 1) the 30-day posting period ends and; 2) DPR responds to any comments received during the comment period relating to the 24(c). If DPR receives a comment(s) during the 30-day posting period, the RS will be immediately informed.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the SLN is posted for the 30-day Public Comment Period

If the SLN application has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible
- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation After the Product is posted for 30- day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will repost the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period.

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If the evaluators concerns are met by submission of a revised label or corrected application after the SLN is posted 30-to-Deny, the package can be posted 30-to-Registerister without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature
- Provide a copy of the signed pinky along with the SLN package to the Program Manager who will revise the registration action and re-sign/date the route sheet
- Give the package to the Tracking Coordinator who will revise the registration decision in the database
- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

11. Propose to Register, Conditionally Register, or Deny a SLN Application

Propose to Register a SLN

If all evaluators find the data/information acceptable, the SLN is posted 30-to-Registerister for the public comment period. A proposed decision to register means:

- The data supported the registration
- The label mitigates any hazards or possible adverse effects
- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the applicant, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled “30 to Reg”and submit the action log to the appropriate person

Propose to register a SLN when an Evaluation Station has recommended denying the Application

If the RS wishes to register a SLN when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action to the Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a “Propose to Register” letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled “30 to Reg” and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product
- Acute dermal LD50 data on the product
- Acute LC50 data on products that produce respirable aerosols or gases
- Primary eye irritation data on the product
- Primary skin (dermal) irritation data on the product
- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level or interval, when human contact is likely to occur
- Preliminary efficacy data indicating the effectiveness for the proposed use
- Groundwater protection data required by the Pesticide Contamination Prevention Act (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested
- The mandatory health affects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA.)

To propose a conditional registration the RS will:

- Place the tracking ID# on the weekly action log under "30-to- Register" and submit the action log to the appropriate staff person
- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions. If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support the SLN registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny indicates one or all of the following:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label
- Label claims were not supported by the information/data submitted
- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the SLN applicant (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should process the package as described above

12. Final Decision to Register or Deny

After the 30-day public comment period is complete, a final action to register is taken.

Note: In most cases, a SLN is an amendment to a currently registered product, and not a new product. Unless the SLN is for a new end-use product, a license is not issued.

Registering a Special Local Need (SLN)

If the SLN is supported, the RS verifies that all items have been received and will:

- Verify the federal and DPR application forms are properly filled out

- Fill out the appropriate areas on the federal application form

- Attach appropriate documentation to the application if the SLN is a food/ feed use, supporting a residue tolerance or exemption for the active ingredient in the SLN use pattern

- Generate a letter to the applicant accepting the SLN registration. The letter format may be obtained from the designated RS.

- Stamp six labels with the "Label Acceptable Stamp" for distribution to the product file, coding, SLN file, U.S. EPA, and the applicant. The "Label Acceptable Stamp" will include the required date, reviewer's signature, and U.S. EPA registration number. Additionally, a SLN number will **also** be incorporated on the stamp.

- The SLN number is a six-digit numerical number in which the first two numbers represent the year in which the SLN was issued, followed by a four-digit number that represents the numerical sequence of the SLN for that calendar year. The six-digit number is preceded by the abbreviation of the issuing state. For example, an SLN with the number CA-080003 would reflect this is the third SLN issued in the state of California during 2008.

The RS should assemble and clip together (in this order) the following items

Assemble for the SLN Applicant

- A copy of the SLN approval letter
- A copy of the U.S. EPA application form
- A copy of the stamped-accepted SLN label

Assemble for the RS

- A yellow surname copy of the letter

Assemble for the Product File

- A copy of the SLN approval letter and stamped-accepted SLN label. Clip or staple together and write "Product File" and the tracking ID# on the upper right-hand corner of the approval letter.

Assemble for Coding (in this order)

- A copy of the SLN approval letter
- A stamped-accepted SLN label with "Coding" written in the upper right- hand corner
- A copy of the status sheet with all corrections made
- Clip or staple together and write "Coding" on the upper right-hand corner of the approval letter

Assemble for U.S. EPA

- A copy of the SLN approval letter
- A copy of the U.S. EPA application form
- A stamped-accepted SLN label

Assemble for the Assigned RS SLN File

- A copy of the SLN approval letter, **original** federal and state application forms (including **original** supporting documents), and a stamped-accepted SLN label

  Note: These documents will be filed in the assigned RS' SLN file cabinet.

Once the package is properly assembled, the RS must submit the package to his/her supervisor for their approval.

To approve the SLN, the supervisor must sign the federal application form and surname the yellow copy of the letter. Once complete, the supervisor will give the package back to the assigned RS, who will remove the RS SLN File component and place the rest of the package into the tray labeled "Production Request, section 18s, SLNs, and misc."

The RS should immediately make a copy of the SLN approval letter and label, and deliver them to the SLN basket located in the Registration Resource Center.

Once the RS receives his/her copy of the company letter back from the support staff affirming that the SLN has been processed, they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the SLN. A SLN is not officially licensed until the approval letter has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS will:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Conditionally Registering a SLN

The process for conditionally registering a SLN is identical to that of a full registration. However, a SLN with conditions is generally assigned an expiration date to aid in enforcing the time frame or requirements.

Denying a SLN

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, federal and state application forms, copies of the evaluation reports, and the label. Mark the package "Denial File" and file the "Denial File" in the RS' SLN File cabinet for the appropriate year. The RS' SLN cabinet is located in the common work area.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature

- Record the tracking ID# as “Final to Deny” on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS will:

- Write “Archive” on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)
- Place the entire package in the designated area to be archived

J. Experimental Use Permits (EUPs) (Products that contain active ingredients found in currently registered products)

40 CFR 172

FIFRA Sec 5

(There are few if any references in FAC or 3 CCR to EUPs)

An Experimental Use Permit (EUP) is a permit issued by U.S. EPA that allows a person to test an unregistered pesticide product (may or may not contain a new active ingredient) or a currently registered pesticide product for an unregistered use, to accumulate the data necessary to register the product under section 3 of FIFRA. A EUP is not required when (1) the experimental use of the pesticide is limited to (i) Laboratory or greenhouse tests or (ii) Limited replicated field trials as described in part 172.3 (c) of 40 CFR; and (2) the producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the pesticide's use. A EUP is not defined as a “registration” under FIFRA, but it is considered a “license” to sell and use the product.

Neither U.S. EPA nor DPR require EUPs for research done on 10 or less acres. However, researchers must apply for a research authorization for research not approved under a EUP in California (some exceptions).

Note: 40 CFR, Parts 172.20-172.25 allows states to issue EUPs under their own authority (this is not the same as our process for research authorizations). In other words, DPR would have the authority to issue

its own unique experimental use permits (though such permits are much more limited than those allowed under the federal program) in place of the federal EUPs. To date, DPR has not decided to pursue this course of action but instead allows for use of the federal EUP by conditionally registering the federal EUP or allowing the product's use under a California Research Authorization. See Section P of this chapter for detailed information on research authorizations.

Time frames

EUPs are effective for a specified period of time (noted by U. S. EPA upon issuance), normally one year, depending upon the crop or site to be tested and the requirements of the testing program submitted. Permits may be renewed, extended, or amended upon request and approval.

Use Restrictions

EUPs are issued for test areas greater than ten acres for terrestrial use, and one surface acre of water per pest for aquatic use. When testing more than one target pest at the same time and in the same locality, the one-acre limit shall encompass all of the target pests. Waters, which are involved in or affected by such tests, are not used for irrigation purposes, drinking water supplies, or body-contact recreational activities.

Testing cannot be conducted in waters that contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed, unless an appropriate temporary tolerance or exemption from a tolerance has been established. This is also true for animal treatment tests.

Pesticides used under a EUP may not be sold or distributed other than to participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the EUP. Product uses issued under section 5 EUPs cannot be advertised.

Tolerance Requirements

If use of the product is on a food or feed crop (including animal treatments), and there is no tolerance, U.S. EPA may establish a temporary time-limited residue tolerance or exemption from tolerance before issuing the EUP. If there is no tolerance or temporary time-limited tolerance (or exemption from tolerance), the food or feed derived from the experimental program must be destroyed or fed only to experimental animals. Temporary time limited tolerances have become difficult to obtain, requiring crops to be destroyed, and lessening the likelihood of a person obtaining a EUP.

Use of a EUP in California

To use a federal EUP in California, a company must either register the EUP in

California or use the EUP under a research authorization. This section only covers registration of a EUP (non-new active ingredient). For information on processing a EUP under a research authorization, please see Section P of this chapter.

Note: EUPs may be submitted concurrently to DPR and to U.S. EPA for review. Once registered by DPR, the EUP label is treated the same as any other registered label in the state. The product is registered in terms of the parameters and restrictions of the EUP, such as amount of active ingredient to be used, acres to be treated, and expiration date.

EUPs will only be registered as a "conditional registration" if they evaluation memos require the registrant to submit additional data.

The information for use in California are the same as those placed on the federal EUP by U.S. EPA:

- Expiration date
- Total amount of product to be used
- Total number of acres to be treated
- Quarterly reports

Stop! If the product contains a new active ingredient, follow Section A of this chapter for processing the application. If the applicant has requested the EUP be processed under DPR's research authorization process, our Plant Physiology staff is responsible for processing the package.

1. Quick Reference - Items that must be submitted by the Applicant to Support the EUP Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Method of analysis and analytical sample (if the product contains a new active ingredient)
- A copy of the U.S. EPA approved EUP label and accompanying letter (if the product has not been submitted to U.S. EPA concurrently)

- A copy of the time-limited tolerance approval letter (if applicable)

- All data submitted by the applicant to U.S. EPA in support of the federal EUP request, including a copy of the experimental program approved by U. S. EPA (Section G -described in detail below).

- All data required for an EUP pursuant to 40 CFR

2. Detailed Description of Items that <u>Should</u> Accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder

- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation

- Special flags/instructions

- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the RS will:

- Make the changes on the original status sheet

- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation and will be used on the licensed issued by DPR. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

If the product contains a fertilizer, the components (generally NPK or nitrogen, phosphorus, and potassium) should be identified on the CSF.

3 CCR
6170.1, 6170.5, 6157

CA Notice
97-6
99-4

Memo:
8-31-98

CA Notice
2009-5

The brand name on the application form must be the same as the name shown on the label and consistent with federal documentation. The RS should confirm that the brand name is consistent on all documents before the package is submitted to licensing.

40 CFR 156.10 (b()2)(ii)

U.S. EPA Label Review Manual

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

3 CCR 6170.1, 6170.5, 6157

CA Notice 97-6 99-4

Memo: 8-31-98

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same EPA Reg. No. and are considered the same product, the products may bear the same brand name.

Federal law does not prohibit two different registrants from using the same product brand name. California regulations allow two different registrants to use the same brand name, provided the products:

CA Notice 2009-5

1) Are the same chemical composition; or

2) Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

Brand names must also read left to right, top to bottom.

If the EUP is for a new product not currently registered with DPR, the applicant must include the product's formulation with the submission. The U.S. EPA Confidential Statement of Formula (CSF), EPA form 8570-4 may be submitted in lieu of filling out page 3 of the DPR application form. The CSF must be filled out completely and accurately and the percent by weight of the listed ingredients must total 100%. If the product is currently registered with DPR and the company does not provide the CSF, the RS should obtain the CSF from the product file in the Registration Resource Center.

CA Notice 96-1

d) Application Fee

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

FAC 12812

3 CCR 6148

e) U.S. EPA Stamped-Approved Label and Approval Letters

A copy of the U.S. EPA stamped-approved EUP label and approval letter (if issued), and the time-limited tolerance approval letter (if applicable) must be submitted. If the applicant applied to U.S. EPA concurrently, a copy of the stamped-approved label and letter(s) must be submitted before the conditional license can be issued.

f) Six Copies of Printer's Proof or Final Printed Labels

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. Submitted labels must have the same content as the U.S. EPA label, although uses may be deleted. The label must comply with any revisions identified in the letter accompanying the U.S. EPA label. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration

3 CCR 6170

process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All products must be supported by data. All data submitted to U.S. EPA by the applicant in support of the EUP and required pursuant to 40 CFR, must be submitted to DPR unless the data is currently on file.

U.S. EPA requires companies to submit selected Experimental Use Permit in a specific format, which differs from the typical format required for section 3 registrations. It is divided into sections A-G (see U.S. EPA form 8570-17 for further detail):

- Section A - A data sheet giving the chemical and physical properties of the active ingredient
- Section B - A copy of the proposed label including all items included in 40 CFR part 172.6
- Section C - Toxicity data or reference to data currently on file including fish and wildlife toxicity data
- Section D - Residue data/analytical method
- Section E - Effectiveness data
- Section F - Tolerance information (where applicable)
- Section G - Proposed Experimental Program

The Proposed Experimental Program (Section G) is a key element in the issuance of a EUP. No person, other than those specified in the approved program can sell or distribute the EUP product once approved, and the product may only be used at the application site of a cooperator in accordance with the permit. The following items must be documented in the program:

- Names, addresses, and phone numbers of the individuals who will supervise the experimental work

- The states in which the EUP product will be used and the acreage to be treated in each state

- Details of the proposed program including target pests, crops, animals, surfaces, and sites of applications

- Objectives of the proposed program (i.e., types of data to be collected)

- An explanation to justify the quantity of the material requested

- Time frames for completion
- Method of disposal for unused product

DPR's chemists evaluate only the EUP-required data listed in 40 CFR and any environmental fate AB2021-type data that are submitted. They do not evaluate any other submitted data such as residue data for crops not listed on the EUP, storage stability data or other product chemistry studies not required for the EUP. Review of these types of data is deferred until the section 3 submission is received. The chemistry evaluator will indicate the record numbers of those studies or tests for which a complete evaluation was done on the Data Index Report accompanying the package. This report will be attached to the evaluation report.

U.S. EPA Application Form 8570-17 for EUPs

When the Section 3 request is later submitted, both the chemist and the RS will be able to identify which studies have already undergone complete evaluation and will not have to be re-reviewed. The RS will attach a copy of the chemist's original report and the Data Index Report to the section 3 package when it is submitted into evaluation.

FAC 12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, Part 172**.** U.S. EPA may permit a pesticide to be used under a EUP with supplemental labeling but such supplemental labeling must be approved. If the product is currently registered and the company has submitted the EUP as a

supplemental label, compare the proposed supplemental label to the U.S. EPA stamped-accepted EUP supplemental label and ensure it complies with any modifications identified by U.S. EPA in the accompanying letter(s). If the EUP application was submitted to DPR and U.S. EPA concurrently, ensure the required label elements are on the label before routing it for evaluation. Once the U.S. EPA label is available, it should be compared to the proposed label submitted to DPR. If the product is for a new active ingredient, follow instructions outlined in Section A of this chapter.

The following items must appear on a EUP label:

- The statement, "For Experimental Use Only"
- The Experimental Use Permit number
- The statement, "Not for sale to any person other than a participant or cooperator of the U.S. EPA-approved Experimental Use Program"
- The name, brand, or trademark
- The name and address of the permittee, producer, or registrant
- The net contents
- An ingredient statement
- Warning or caution statements
- Any appropriate limitations on entry of persons into treated areas
- The establishment registration number, except in those cases where application of the pesticide is made solely by the producer
- The directions for use, except that U.S. EPA may approve the use of the experimental program (see above) as labeling provided that such program is to be distributed with the product

Tank Mixes

The EUP may allow use for a tank mix. DPR will accept U.S. EPA approved tank mix label claims without supporting compatibility and residue data if the following conditions are met (meeting these conditions are the responsibility of the company,

not the RS reviewing the package):

- The pesticide product to be mixed with the product that is the subject of the application, does not contain a label prohibition against such mixing

- The label contains the following statement:

  - "This product can be mixed with (chemical name, including percentage of active ingredient and type of formulation, or specific product name, or both) for use on (crop/sites) in accordance with the more (most) restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing. Where a specific product name is recommended for the tank mix, the label statements shall be more explicit, including such information as specific dilution and dosage rates."

It is acceptable for a label to mention an unregistered product in a tank mix, provided:

- The statements are permissive rather than mandatory and,

- The product is effective without the unregistered product and,

- The label does not require use of the unregistered product

Note: The RS may notify the registrant that it is illegal to sell or use the unregistered product in California.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies

- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the CSF as it contains confidential business information that could be lost in the mail.

- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope

- Include a copy of the proposed label highlighting areas of concern if applicable

- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy

- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system

- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant

- Enter the date from the cover letter into the return section on the application form

- Return the surname copy of the letter to the RS

- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that Do Not Require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)
- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations
- Contain the same or substantially similar inert ingredient(s)
- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)
- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.
- Bear the same or substantially similar method(s) of application.
- Claim to control the same or substantially similar pests or site/pest combination(s)
- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant

Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR within the last 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness, the label has been reviewed and compared to the U.S. EPA stamped label and found acceptable, and data requirements identified, the RS should prepare the package to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each

station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

In general, EUPs are routed to Chemistry and Medical Toxicology. To determine if the product should be routed to Fish and Wildlife, the RS should consult informally with a Fish and Wildlife scientist. If the product is to be applied directly or indirectly to water, it should be routed to Environmental Monitoring (note: there are limitations to products applied to water outlined in 40 CFR, Part 172). Appendix E, "Evaluation Station Responsibilities and Purpose of Review" should be used as a secondary aid to determine the appropriate scientific evaluation stations. If the RS is not sure which evaluation stations the product should be routed to, he/she should consult with a supervisor.

If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet.

DPR review stations are:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.

- Determine if any required data have not been submitted

- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the CSF, which may be substituted for page 3 of the form
- A second copy of the proposed label
- The U.S. EPA label (if available) and all other pertinent U.S. EPA documentation
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e., med. tox, then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation reports are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet (refer to sample) and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible

adverse effects, recommendations for conditional registration, or recommendation for risk assessment not already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- If an adverse effect disclosed by data pertains to any other currently registered products, contact the Reevaluation Coordinator and see Chapter 8 for guidance on Reevaluation

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30-days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet

and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation after the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information

located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will post the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period.

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to

the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

10. Propose to Conditionally Register or Deny the EUP Product

All EUP registrations are conditional in California under California Code of Regulations (CCR) section 6200.

Propose to Conditionally Register the Product

To propose a conditional registration the RS will:

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted for 30 more days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should process the package as described above.

11. Final Decision to Conditionally Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register conditional or deny is taken.

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS will:

- Verify that final printed, or printer's proof labels were submitted and acceptable (Master labels don't require final printed labels)

- If the submission was concurrent with U.S. EPA, verify receipt of the U.S. EPA stamped-accepted label and accompanying letter. Compare the final U.S. EPA label to the proposed label for any changes.

Significant changes mean that the package must be sent to the applicable evaluation station. If additional data are required, post the registration "30- to Deny."

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Completely fill out the upper right-hand portion of the

Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names. When issuing a EUP, the RS will assign a number in the following way:

- Firm number - 55000 (the last digits are assigned from the USEP assigned EUP number) – EX. For example, the Reg. No. may read 123-55001-EX.

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation reports(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write “Product File” in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form

- U.S. EPA forms (e.g., 8570-1, 8570-5)

- The U.S. EPA stamped-accepted label and accompanying letter

- The Memorandum of Registration (blue or green memo) if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer’s proof or final printed label. Write “Product File” and the tracking ID# in the upper right-hand corner. It will be tagged and placed in

the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. . If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding (in this order)

- A copy of the full application form (including the CSF). Write "Coding" in the upper right-hand corner.

  Note: Additional copies of alternate formulas should not be included (i.e., the company has submitted one basic CSF and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, conditional binder, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (if applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation memo(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent,
or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. Issuance has not occurred until the product license has been sent out by PRB.

P/P 2006-6

Yearly Assignments

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product would not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on "Changing a Conditional Registration to a Full Registration."

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted

- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor

- Stamp the first page of the original application form "Denied"

- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.

- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature

- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet

- Arrange the data by volume (if more than one volume)

- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)

- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration

- The $1,150 application fee

- All data or information identified as lacking in the previous submission

K. Interim Registration

FAC 13161-13170

An Interim Registration may be issued for an agricultural use product that contains an active ingredient subject to the environmental fate data (AB 2021) requirements. It is similar to a typical agricultural registration. However, up to 3 specified data requirements may be deferred to a later date and are not required for submission. DPR may issue a certificate of interim registration allowing the sale and use of a pesticide that otherwise meets the requirements of normal registration guidelines, if all of the following conditions are met:

- The certificate stipulates which of the California data requirements listed in Food and Agriculture Code section 13163 are being deferred for completion during the time of interim registration
- The certificate stipulates a period of time, not to exceed three years, for each deferral determined by the director as reasonably sufficient for the generation, submission, and review of the data
- The certificate stipulates any limitations on the use of the pesticide that the director may deem appropriate pursuant to Food and Agriculture Code section 13166 or on the sale of the pesticide

In granting a certificate of interim registration, DPR may defer no more than three of the following registration data requirements:

- Efficacy studies pursuant to section 12824
- KOW (octanol water partition coefficient) pursuant to paragraph (3) of subdivision (a) of section 13143
- Soil photolysis pursuant to paragraph (6) of subdivision (a) of section 13143
- A field dissipation study pursuant to paragraph (6) of subdivision (a) of section 13143
- A study pursuant to subdivision (a) of section 13143 that will be redone to correct errors or a study conducted under California conditions or guidelines, if the weight of evidence from all other submitted data support a scientific judgment in favor of interim registration

Since interim registrations are issued for conventional products for agricultural use, the Regulatory Scientist (RS) should follow the instructions under Section B of this chapter to process an application, but should note the following:

- The applicant must provide information that the product is part of a pest management system as outlined in CA Notice to Registrants 94-7 (notes: this document is not online and the general application fee it referred to has since increased from $200 to $1,150)

- The applicant must commit in writing to submitting the deferred data, including a schedule of quarterly progress reports

- The application fee for an Interim Registration is $6,150

- The Pesticide Registration and Evaluation Committee (PREC) must be consulted before the application can be approved. After a consultation set up by the RS, a written finding is prepared for the director's signature. This is placed in the file with the appropriate paperwork if the application is approved and the product licensed.

- The Certificate of Interim Registration (license) must specify which data are being deferred, the time frame for submission not to exceed three years, and any limitations on the use deemed appropriate. The RS should submit this information to the Licensing Technician before the license is prepared. It is the RS' responsibility to assure the 3-year time limit is adhered to.

It should also be noted that an Interim Registration is not synonymous with a conditional registration. These are two different processes under California law.

L. Emergency Registration

An Emergency Registration may be issued for products previously allowed for use under a section 18 emergency exemption as allowed by the Food and Agricultural Code FAC section 12833. The most significant aspect of an emergency registration is that the evaluation process need not be completed prior to issuance. If the pesticide product is not currently registered by DPR, the applicant or another party must submit an application for full registration of the product concurrently, or shortly after the application for emergency registration is filed. The two applications should be processed

together, as it will be necessary to review the data simultaneously for both products. The Regulatory Scientist assigned to that company should follow the appropriate section within this chapter (conventional product, antimicrobial, etc.) for instructions on processing the full product registration.

The criteria for issuance of an Emergency Registration are as follows:

- The product is currently registered by U.S. EPA as a Section 3
- The active ingredient was previously allowed for use under a Section 18 emergency exemption, but does not need to have been issued in California or for the same crop/pest combination presently being requested
- The applicant has submitted all data required for registration pursuant to Division 7 of the Food and Agricultural Code and the regulations adopted pursuant to Division 7
- The applicant demonstrates that the product qualifies for registration pursuant to FAC section 12815 and the Department determines that it is probable the product will receive California registration within one year
- Use of the pesticide during the period of emergency registration will not pose a potential significant risk to humans or the environment
- Use of the pesticide is necessary to respond to an emergency pest control problem as outlined in the FAC section 12833
- The certificate of registration may be issued for up to one year, may be renewed one time only, and may be revoked at any time if deemed necessary

An Emergency Registration is separate and independent of a Section 18 emergency exemption, although a previous Section 18 is one of the criteria. An emergency registration may not be issued for more than one year and may only be renewed one time, provided certain conditions are met pursuant to FAC section 12833. No fees are required for emergency registrations. The designated staff person assigned to Section 18s should process the submission. **That person will be referred to as the DSP (designated staff person) throughout this section.**

1. Quick Reference - Items that should be submitted by the Applicant to Support the Product Application

Note: With the exception of data, California law does not <u>require</u> the applicant to submit the following information/documentation to support the emergency registration request. However, in order to meet the requirements outlined in FAC section 12833, it is strongly suggested that the applicant provide the information to aid DPR in determining whether or not the requirements have been met.

It is suggested that the following items be submitted by the applicant in writing:

- California Application for Pesticide Registration or Application to Amend a currently registered product

- Data to support the registration (or waiver requests)

- A copy of the pesticide product label listing only the crop and pest that are the subject of the emergency, or a copy identical to the currently registered federal label with "not for use in California" designations on all crops or pests for which the pesticide has not been approved for use in California. The labels should also provide a space for an expiration date that will occur one year from the date the emergency registration is granted.

- Proof of federal registration

- Documentation that confirms the U.S. EPA previously granted a Section 18 for a product containing the same active ingredient, if the previous Section 18 was not obtained in California

- Any information that would be useful in enabling DPR to make the determination that use of the pesticide during the period of emergency registration will not pose a potential significant risk to public health, safety, or the environment

- Information that would be useful in enabling DPR to make the determination that an emergency pest control problem exists for which there is not reasonable alternative including identification of all pest control alternatives and documentation of ineffectiveness

- Information that would aid DPR in determining that the product qualifies for registration pursuant to FAC section 12815

2. Detailed Description of Items that should accompany the Emergency Registration (both internal and external documents)

Since the applicant must demonstrate that the product qualifies for registration pursuant to FAC Section 12815, and the Department must determine that it is probable the product will receive California registration within one year, the application for emergency registration should be accompanied by a complete application for full registration. Therefore, the two packages should be separate registration actions and separate status sheets, tracking ID#s, etc., but processed together. This part of the chapter documents those items that should accompany the emergency registration portion of the package.

a) Status sheet

The status sheet should be the first item reviewed by the DSP. It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The DSP should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The tracking ID# on the status sheet is preceded by the prefix "EMER"
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation
- Special flags/instructions
- The active ingredients listed are consistent with the label, application, and other documentation
- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the DSP will:

- Make the changes on the original status sheet
- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed,

and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The DSP should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Emergency Registration form

To date, the Department does not have an application form for emergency registrations. If an applicant wishes to apply for emergency registration, they should contact the Registration Branch Ombudsman or their DSP.

The law states that the applicant must demonstrate to the department that the pesticide [product] qualifies for registration pursuant to FAC section 12815 and the department determines that it is probable that the pesticide will receive registration within one year. An Application for Pesticide Registration form must be filed with DPR as a condition of full registration. Without the application form, we cannot make a determination that the product will be registered within one year. Therefore, the applicant or another party must submit (or have already submitted) an application form and all other appropriate documents necessary for registration if the product is not currently registered in California. Please see the appropriate section within this chapter (conventional product, antimicrobial, etc.) to process a full product registration.

d) Proof of Federal Registration

The product proposed for use under the emergency registration must be federally registered. Therefore, the applicant should provide a copy of the U.S. EPA stampeded-accepted label and accompanying letter.

If the U.S. EPA label is not provided, the DSP may obtain the current label from the U.S. EPA website (if available), or from an available file in the Registration Resource Center.

e) A Copy of the Proposed Label

It is suggested that the applicant submit a copy of the proposed label that includes only those use sites, crops, pests, etc. that pertain to the emergency registration request. Any additional sites, crops, etc. on the label that are not

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo of 8-31-98

currently approved for use in California, must be designated as such (i.e., "not for use" or "not approved in California"), the law does not specify labeling guidelines for emergency registrations. Therefore, such labels will be developed and reviewed on a case-by-case basis.

f) Data

Since the applicant must demonstrate that the product submitted for emergency registration qualifies for full product registration in California, all data to support the full registration of the product must be submitted before the emergency registration can be processed. The data will be simultaneously reviewed to support the emergency registration and the application for full pesticide registration. Therefore, the data requirements will vary based upon the type of product submitted (i.e., antimicrobial, agricultural, industrial, etc.).

All data submitted to U.S. EPA by the applicant in support of federal registration of their product and required pursuant to 40 CFR, must be submitted to DPR unless the data is currently on file. For specific data requirements, click here.

3 CCR 6158 6159

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

FAC 12811.5

3. Verification for Completeness

Review the package to determine if it is complete, has all the required items listed above, and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the Label

Review the label to determine if it is in compliance with the federal labeling requirements outlined in 40 CFR, Part 156.10, matches the U.S. EPA stamped-accepted label and complies with modifications required by U.S. EPA in the accompanying letter(s).

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The DSP will:

- Prepare a return letter to the applicant that identifies all deficiencies
- Make a copy of the first page of the original application form (if applicable). This copy will be sent to the applicant along with the return letter.
- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the DSP once processed), and a return envelope
- Include a copy of the proposed label highlighting areas of concern if applicable
- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy
- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system
- Mail original letter, copy of the first page of the application (if available) and product label (if applicable) to the applicant
- Enter the date from the cover letter into the return section on the application form
- Return the surname copy of the letter to the DSP
- Attach the remaining copy of the letter to the front of the

package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months from the date of the original return submission, the application is still considered incomplete.
A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another the submission will be shredded.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Preparing the Data Package for Scientific Evaluation

Selecting Evaluation Review Stations

To determine that the emergency registration will not pose a potential significant risk to public health or safety or to the environment, it will likely require scientific review. Studies may include acute toxicology, environmental fate data, etc. Each case is unique and should be handled on a case-by-case basis. The Pesticide Registration Branch Chief should be consulted to determine which evaluation stations are required. If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. If U.S. EPA data waivers were granted, they should be submitted by the applicant and routed with the package.

DPR review stations are:

Pesticide Registration Branch
- Chemistry
- Microbiology
- Pest Disease and Prevention
- Fish and Wildlife
- Plant Physiology

Medical Toxicology Branch

Worker Health and Safety Branch

Environmental Monitoring Branch

Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.
- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)

- A copy of the proposed label
- If data waiver requests were submitted, include this documentation when entering the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

7. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the DSP's binder and electronic tracking system database. The package is routed sequentially to each evaluation station unless the product is expedited. Expedited packages are considered urgent and are given priority over other packages in evaluation. If the DSP feels the package warrants an expedited review, he/she will prepare and submit a Tracking Documentation Memo (pinky) justifying the need for an expedited review. The pinky must be submitted to the Branch Chief for his/her signature. A copy of the pinky should be included with the package when it's submitted to the Tracking Coordinator.

The Tracking Coordinator maintains a binder for the DSP that contains copies of the status sheet/route sheet, and evaluation memos that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the DSP. The DSP is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the DSP shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification.

Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the DSP should check with his/her supervisor for guidance. On rare occasions, the evaluation memos are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To route a package back to a specific evaluation station, the following should occur:

- The DSP must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible.

- If additional data were submitted, informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The DSP should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the DSP to finalize the process. A hard copy of the revised evaluation report will be sent to the DSP with the package.

8. Exiting the Scientific Evaluation Process and the 30-Day Comment Period

It should be noted that the application for full registration of the product might not be complete at the same time it is determined that the criteria to fulfill the emergency registration has been met. The emergency registration package may exit scientific evaluation once this determination has been made (case-by-case basis). It is also possible for both the emergency registration and the application for full registration submissions to receive negative scientific reviews and require additional data or label revisions be submitted to mitigate a hazard.

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. Products are posted "30-to- Register" or "30-to-Deny" based on the proposed evaluation decisions and DPR's overall assessment. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to accept or deny the product application. The Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the DSP may gather and prepare the appropriate registration documents for submission to Licensing. However, the DSP may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends and; 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the DSP will be informed immediately.

The information in this section applies to both the emergency registration and the application for full registration packages since the data submitted will likely be documented on both route sheets and will be routed concurrently.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the emergency registration package has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The DSP must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the physical data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.
- The DSP should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet(s) The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet(s) and the package will be returned to the DSP to finalize the process (this may not apply to the application for full registration if the review process is not yet complete). A hard copy of the revised evaluation report(s) will be sent to the DSP with the package(s).

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet(s). The Tracking Coordinator will revise the date on the route sheet(s), and return the package(s) to the DSP with a hard copy of the revised evaluation report(s). The Program Manager does not re-sign the route sheet(s).

Submitting a Data Package Back into Evaluation after the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the DSP will:

- Informally route the package with all data submitted with the

package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet(s) (refer to sample) and provide as much detail to the evaluation staff as possible

- Submit the package(s) to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package(s) is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report(s) is sent to the DSP with the package.

- The RS will repost the package(s) 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet(s), and return the package(s) to the DSP with a hard copy of the revised evaluation report(s). The Program Manager does not re-sign the route sheet(s).

- The decision to deny registration stays in effect until the end of the original 30-day comment period. For information on completing a final action, see instructions below.

9. Propose to Register or Deny an Emergency Registration

Propose to Register

Prior to approving the emergency registration, the director's findings will be drafted and state the following:

- The conditions of FAC section 12833 (a) (1)-(4) have been met
- There is substantial evidence to meet subsection (a)(5)(A) and (B)
- Any limitations placed on the use of the pesticide
- Allowance for the product to be used during the 30-day comment period

Again, it should be noted that the evaluation process for full product registration might not be complete prior to the approval of an emergency registration. The Pesticide Registration Branch, acting on behalf of the Director, will make this determination on a case-by-case basis.

The DSP will:

- Prepare a "Propose to Register" letter for the applicant, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg." and submit the action log to the appropriate person

Propose to Register the Emergency Registration when an Evaluation Station has recommended denial of the Application

If the DSP wishes to propose registration of an emergency registration when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The DSP will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Pesticide Registration Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the applicant, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg." and submit the action log to the appropriate person

Propose to Deny

If it has been determined that the emergency registration cannot be supported by the information provided, the DSP is responsible for aiding the applicant in obtaining the necessary documentation. If the deficiencies cannot be corrected, the product should be posted "30-to-Deny."

The DSP will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the DSP should process the package as described above.

10. Final Decision to Issue or Deny the Emergency Registration

After the 30-day public comment period is complete, a final action to register or deny is taken.

Issuing the Emergency Registration

If the registration is supported, the DSP will:

- Verify that final printed, or printer's proof labels were submitted and acceptable and all other items have been received

If all items are submitted and found acceptable, the product can be licensed. The DSP will:

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The DSP may retain an additional copy for his/her file.

Assemble for the Product File

- The original copy of the director's findings
- A copy of the stamped-accepted label with the words "Product File" and the tracking ID# written in the upper right-hand corner
- All other documentation submitted by the applicant or obtained by the DSP to process the registration

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license.

Assemble for Coding (in this order)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner
- A copy of the status sheet with all corrections made

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper - right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. Do not include the colored folder.

The package will be processed by licensing and returned to the DSP for final review. The
RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy.

The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the DSP receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Denying the Emergency Registration

If the data do not support registration or the criteria outlined in FAC section 12833 have not been met, the DSP will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the emergency registration has been denied, a surname copy, and an envelope and submit to his/her supervisor
- Staple together a copy of the final denial letter (placed on top), all documents submitted by the applicant or obtained by the DSP to support the registration, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

After the final denial action has been taken, the applicant may reapply for registration by submitting all data or information identified as lacking in the previous submission.

M. Structural Devices

California Food and Agricultural Code (FAC) sections 15300-15340 require DPR to regulate specific types of structural pest control devices. Such devices include those used to control wood destroying insects such as termites, carpenter ants, and powder post beetles. The law excludes those devices that are manufactured solely for export outside of California.

A structural pest control device is defined as, "...any method, instrument, or contrivance intended to be used to prevent, eliminate, destroy, repel, attract, or mitigate any wood destroying pest, but does not include firearms, pesticides as defined in FAC Section 12753, or equipment used for the application of pesticides when sold separately from a pesticide."

It should also be noticed that labels and documents related to structural devices may or may not be releasable as public documents! For information, consult with the Pesticide Registration Branch Chief.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for a Structural Pest Control Device
- $200 application fee
- A copy of the device product labeling (not required to be printer's proof or final printed labels)
- Valid data supporting each claim on the proposed label and supporting the safety of the device for each proposed labeled use

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder
- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation

- Special flags/instructions

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the RS will:

- Make the changes on the original status sheet

- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Each package should be accompanied by a cover letter that identifies the applicant's intention

c) Complete Application for Structural Pest Control Device (form DPR-032

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents.

CA Notice 2009-5

The firm name and address shown on the application must be consistent with other documentation and will be used on the licensed issued by DPR.

A registrant may not have the same brand name for two different products, even if those products are being supplementally distributed from different basic manufacturers.

Brand names must also read left to right, top to bottom with nothing in-between (though the brand name may contain graphics.

The graphics are not part of the brand name for purposes of licensing).

d) Application Fee

FAC 15308

A $200 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting. A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

e) Six Copies of the Product Label

FAC 15325

Registrants must submit at least one copy (although 6 are recommended) of the product label. The label must contain the following items:

- Printed directions for use on the label. If the directions for use are not on the label, they must be enclosed with the device.
- The name, brand, or trademark, if any, under which the device will be sold
- The name and address of the device manufacturer, dealer, importer, or vender
- Any necessary safety precautionary statements associated with the use of the device

FAC 15305, 15315

The label may also contain a warranty statement, provided it does not exclude or waive the following:

FAC 15326

- The device corresponds to all claims and descriptions that the registrant has made in print regarding the device

FAC 15308

- The device is reasonably fit for use for any purpose for which it is intended according to any printed statement of the registrant

f) Data

All products must be supported by safety and efficacy data. There are no test guidelines for devices. If the registrant needs guidance on developing the data, the RS should have them contact DPR's efficacy scientists for efficacy questions and Harvard Fong or current Industrial Hygienist in the Worker Health and Safety Branch for safety questions. For data requirements, click here.

FAC 15308

Safety Data

The registrant must identify any hazard(s) to applicators, bystanders, or animals associated with the use of the device. Information/data/studies supporting how the identified safety hazards are mitigated should be included.

Efficacy Data

The registrant must provide data/studies that support the efficacy of the device as claimed on the device label and device promotional materials.

Other

Registrants must also submit structural integrity data including a wood damage study generated using their device.

3. Verification for Completeness

Review the package to determine if it is complete, has all the required items listed above, and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with the labeling requirements listed above.

5. Deficiencies

If there are deficiencies in the application or product labeling, the RS should contact the applicant to determine if the issues can be resolved. If they cannot, the RS should proceed to part 9 of this section and propose to deny the product.

6. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness and the label has been reviewed, the RS should prepare the package to enter scientific evaluation. The package should be routed to WH&S and Efficacy.

The data submitted to support registration of a device cannot be used to support the registration of another company's device unless the data owner provides DPR with a letter or authorization to do so.

If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated.

The evaluation scientists will:

- Determine if data supports the label
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application
- A second copy of the proposed label

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

7. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e., WH&S, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns or inconsistencies.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. The evaluation reports may be considered "working documents" and therefore not releasable.

Submitting a Data Package Back into an Evaluation Station during Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database.

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing

the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

Prepare and submit the appropriate letter to the registrant (propose registration or denial) **Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.**

8. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is completed, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, or recommendation for risk assessment not already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the registration request has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician.

This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation after the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re-sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will repost the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period.

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg." and submit the action log to the appropriate person

9. Propose to Register or Deny a Product Application

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration

- The label mitigates any hazards or possible adverse effects

- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg." and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Pesticide Registration Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and the

Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data submitted

- Required data was not submitted

The RS will

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# under "30-to Deny" on the weekly action log and submit the action log to the appropriate staff person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

Note: Structural device products cannot be conditionally registered.

10. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register or register conditional is taken.

Registering a Product

If the registration is supported, the RS will:

- Verify that all items have been submitted
- Check the database to determine which alpha code should be assigned.
- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.
- Alpha Codes for new products and additional brand names are to be assigned in order as follows:
    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
    - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
    - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)
- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form. Write "Product File" in the upper right- hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.
- A copy of the stamped-accepted label. This should be placed

behind the product file documents but not clipped to them. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license.

Assemble for Coding (in this order)

- A copy of the application form. Write "Coding" in the upper right-hand corner.
- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner
- A copy of the status sheet with all corrections made

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

Licenses are sent to the company address entered in the Pesticide Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing those additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-

to-deny letter, copies of the evaluation reports (if applicable), and a label. Mark the package "Denial File" and submit to the Registration Resource Center.

- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature

- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet

- Arrange the data by volume (if more than one volume)

- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)

- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new California Application for a Structural Pest Control Device

- $200 application fee

- Six copies of the device product labeling (not required to be printer's proof or final printed labels)

- All data or information identified as lacking in the previous submission

N. California Master Labels

California Master Label – A California master label is defined by DPR as a pesticide product label bearing most or all U.S. Environmental Protection Agency (EPA) accepted uses for that product, but that the company does not intended to market for sale or use in

California. **California master labels cannot be sold, used, or distributed in California. They are for reference only! They are not considered registered product labels.** If it is the registrant's intent is to distribute or sell the end use product in California, even if the container label for the end use product is identical to the "California master label," the registrant must seek an additional, separate registration for the end-use product.

It should be noted that DPR and U.S. EPA's definitions of a "California master label" differ. As defined by U.S. EPA, the "California master label" is the label that contains all of the approved uses for a given product and all associated required labeling (see Label Review Manual). Federal California master labels may or may not be synonymous with the end use label. They are **never** considered end-use labels in California.

Historical information

DPR began accepting California master labels for antimicrobial products in the early to mid 1980s. Many large antimicrobial manufacturing firms (basic manufacturers) developed their products to be sold and marketed solely by supplemental distributors. Registering the basic manufacturer's product in California enabled DPR to review the data to support all use sites, rates, etc. at one time, rather than individually for each end use product. This was done despite the fact that the basic manufacturer's product would never be sold or used in California because it reduced the processing time and streamlined the registration process both internally and for the supplemental distributors.

Since the basic manufacturers did not sell or distribute their registered products in California, the labels were considered reference or "Master" labels. Over time, many companies (antimicrobial and non-antimicrobial manufacturers) elected to keep a "California master label" on file with DPR in addition to their end use label. This included those that chose to split their "California master labels" and market their products under sub-labels (a label which bears claims and directions for only a portion of the approved label). This is common for agricultural use products sold in different markets.

Until 2006, there was no internal policy or procedure for accepting California master labels. In general, California master labels submitted in addition to end use labels on file would be placed in the same product file as the end use label. No registration fees were charged. Other California master label submissions were issued separate registrations. The internal label stamp used to approve both end-use labels and California master labels was identical until approximately 2003, making it difficult to decipher those labels that were end-use and those that were for reference only.

In addition, DPR's Product Compliance Branch received Mill Assessment Reports for reference only products, indicating that certain products with no end-use labels on file were being sold and used in California.

CA Notice 2006-10

To provide consistency to our stakeholders and allow for better identification of reference-only labels by our Product Compliance Branch, the Pesticide Registration Branch began segregating California master labels by placing them in separate product files and providing both a "California master label" prefix to the product name and a "ML" alpha code to the registration number in 2006. Previously approved California master labels were removed from end-use product files, stamped-approved as California master labels, and placed in separate files reflecting the new prefix/alpha code. Files containing only California master labels were stamped-approved as California master labels and revised to reflect the new prefix/alpha code. All impacted companies were informed of our decision in writing and our decision was posted on-line under California Notices to Registrants 2006-10.

Companies that wish to convert their California master label files to end-use product files must apply for new product registration. The grace period given after 2006 has expired.

Registering a California master label

Once a California master label is reviewed and approved in California, a license is issued, the label stamped-accepted, and all relevant documents are placed in a file in the Registration Resource Center. California master labels may be submitted for any type of product such as agricultural, structural, biopesticide, antimicrobial, adjuvant, etc. California master labels are processed identical to other product registrations with the following exceptions:

- The applicant is not required to submit printer's proof or final printed labels
- Labels may include optional language or multiple sets of directions for use for various container sizes
- The license received does not entitle the user to sell, use, or distribute the product in California
- The product name can be identical to that of the end-use label because the California master label cannot be sold, used, or distributed in California.

For processing a California master label submission, follow the instructions under the appropriate section(s) within this chapter (i.e., biopesticide, conventional, antimicrobial, etc.).

Quick Reference - Items that must be submitted by the Applicant

to Support the Registration Request

The following items must be submitted by the applicant in order for the submission to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Six copies of the proposed label
- A copy of the U.S. EPA stamped-accepted label and accompanying letter (non-adjuvants)
- Data to support registration (or identification of a product(s) previously approved by the Director that would be subject to the same data requirements as applicable to the applicant's product)
- If the California master label is submitted by a supplemental distributor (rare), a copy of U.S. EPA Notice of Supplemental Distribution of a Registered Pesticide Product form (8570-5)

O. 25(b) Products

FIFRA Sec. 25

40 CFR 152.20-30

3 CCR 6147

Both federal and state laws exempt certain pesticide products from the requirement to obtain registration, provided they meet certain criteria. These products are still pesticides and individuals in the business of pest control for hire who apply exempt products, are subject to DPR's licensing requirements but are exempt from pesticide use reporting.

The criteria and label requirements for products that are exempt from registration are outlined in DPR's California Notice to Registrants 2000-6. Because California exemption criteria are linked closely to U.S. EPA exemption criteria, U.S. EPA's PR Notice 2000-6 should also be used in conjunction with California's Notice 2000-6 as a reference. Where U.S. EPA criteria and California criteria differ, the California criteria must be followed. At a minimum, all products must meet the following requirements:

- The active ingredient(s) must be listed by name and percentage (by weight) on the label. To qualify for an exemption as a minimum risk pesticide, each active ingredient in the pesticide product must be listed in 40CFR 152.25(f)(1). The approved list of active ingredients can also

be found in 3 CCR section 6147(a)(5).

- List all inert ingredients by name on the label. All inert ingredients must be on U.S. EPA's most current Minimum Risk FIFRA Section 25(b) Inert Ingredient list (formerly List 4A). **These two lists are not interchangeable.**

- The total percentage by weight must equal 100%

- The label must not contain false or misleading statements as defined in 40 CFR part 156.10(a)(5)(i) through (viii)

- Additionally, products must also meet a series of exemption conditions described in 40 CFR 152.25 and 3CCR 6147

In some cases, a company will choose to register a product, even if it is exempt from federal or state registration. Companies that choose to register their products in California, even though they qualify for exemption, must first register their product federally. If the product does not require federal registration but does require registration in California, the company is required to apply for registration with DPR.

Note: If a product is exempt from federal registration, but requires registration under California law, the product is considered a pesticide under FAC section 12753 and all California regulations and registration requirements apply.

Spray Adjuvants that Qualify for Exemption from Registration

The following guidelines have been written to clarify how we handle spray adjuvants that qualify for exemption from registration:

A. Exemption Allowance for Spray Adjuvants

Spray adjuvants can qualify for exemption from registration provided the product meets all of the criteria outlined in 3 CCR section 6147.

B. Active Ingredients vs. Principle Functioning Agents.

It is acceptable for the active and inert ingredients in a spray adjuvant to be listed as "Principle Functioning Agents" and "Constituents Ineffective as a Spray Adjuvant," respectively, on a spray adjuvant label. DPR considers the term "principle functioning agent" to be synonymous with the term "active ingredient," and the term "constituents ineffective as a spray adjuvant" to be synonymous with "inert ingredient," for purposes of exemption under 3 CCR section 6147. To be exempt from registration, all

principal functioning agents in the spray adjuvant product must be listed in 3 CCR section 6147(a)(5), and all constituents ineffective as a spray adjuvant must be listed by name and be on U.S. EPA's Minimum Risk FIFRA Section 25(b) Inert Ingredient list (formerly List 4A)

C. Labeling of a Spray Adjuvant for Exemption.

All general labeling requirements as outlined in 40 CFR, Part 152.25, and 3 CCR section 6147 must be followed in order for a spray adjuvant to qualify for exemption. This means that spray adjuvant products must list all active ingredients (or principle functioning agents) by name and percentage (by weight), and all inert ingredients (or constituents ineffective as a spray adjuvant) by name on the product label. In addition, the product label must not include any false and misleading statements.

If the 25(b) product qualifies for exemption under federal law but does not qualify for exemption under California law, the company must apply for registration with DPR. Follow the instructions below to process such products.

1. Quick Reference - Items that must be submitted by the Applicant to Support the Product Application

The following items must be submitted by the applicant in order for the application to be processed:

- California Application for Pesticide Registration
- $1,150 application fee
- Data to support the registration (or waiver requests)
- Six copies printer's proof or final printed labels

2. Detailed Description of Items that should accompany the Product Submission (both internal and external documents)

a) Status sheet

The status sheet should be the first item reviewed by the Regulatory Scientist (RS). It should be reviewed for accuracy and if needed, corrections should be made. It is very important to make corrections! The status sheet is used throughout the evaluation process and public postings. It must contain accurate and complete information. The RS should verify the following:

- The tracking ID# matches the ID# on the colored folder

- The company name/firm number are correctly stated and are consistent with the label, application, and other documentation

- Special flags/instructions

- The active ingredients listed are consistent with the label, application, and other documentation

- The General Use and Added Use sections are considerably detailed so that the information is accurate when transferred to the public Notice of Decisions (NODs) and Materials Entering Evaluation (MEEs) on-line and viewed by the public

To correct a status sheet, the RS will:

- Make the changes on the original status sheet

- Submit a photocopy with corrections highlighted, initialed, and dated to the Intake Technician

Note: If data were submitted, submit a photocopy with corrections highlighted, initialed, and dated along with the data to Indexing. Indexing must formally index the data before it can be returned to the RS.

For certain active ingredients, an attention flag with instructions will appear on the status sheet. The RS should follow the instructions. See the "Intake through Archiving" manual on-line for a list of attention flags.

b) Cover Letter

Though not required by law, each package should be accompanied by a cover letter that identifies the applicant's intention.

c) Complete Application for Pesticide Registration form (39-030)

The application form must be filled out and signed. The RS should confirm that the application is completely and correctly filled out including designations of container type, density, type of pesticide, application method, type of formulation, use of pesticide, and signal word. If the information is incorrect or incomplete it will result in errors or deficiencies in DPR's product label database.

3 CCR 6170.1, 6170.5, and 6157

CA Notice 97-6 and 99-4

Memo: 8-31-98

The application form must be signed and dated by an authorized representative. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file. See CA Notice to Registrants 2009-5 for restrictions and limitations regarding authorized agents. All letters shall be place in a designated binder located in the Registration Resource Center (RRC). The Regulatory Scientist is responsible for placing the original letter in the appropriate bin located in the RRC, to be filed by RRC staff. The Regulatory Scientist is responsible for ensuring that the letters for their assigned companies are updated and correct.

CA Notice 2009-5

3 CCR 6152

A registrant may not use the same brand name for two of its registered pesticide products. This includes:

1) Registrants that supplementally distribute products from different basic manufacturers (e.g., Company X supplementally distributes a 41% glyphosate product from basic manufacturer A and another almost identical 41% glyphosate product from basic manufacturer B)

2) Registrants assigned more than one company number (e.g., 1234 and 567 both issued to Company X)

Note: this does not apply to a registrant that registers both a master label and an end-use label for the same product. Since both products are registered under the same CA Reg. No. and are considered the same product, the products may bear the same brand name.

California regulations allow two different registrants to use the same brand name, provided the products:

1) Are the same chemical composition; or

2) Do not have different physical conditions sufficient to affect their pesticidal properties

In other words, per 3 CCR 6152, two products registered in California to two different companies can have the same product name, as long as those two products are basically identical. **This regulation applies to California master labels!**

Acceptable – Two 41% glyphosate products of substantially similar formulation, registered by two different registrants under the same brand name

Acceptable – A basic manufacturer and their supplemental

distributor register their products under the same brand name

Not acceptable – One 41% glyphosate product registered to Company A and one 20% glyphosate product registered to Company B, both registered under the same brand name

d) Application Fee

FAC 12812

A $1,150 application fee is required for all new products (including additional brand names). **This is an application-processing fee and is non-refundable.** DPR's accounting office is responsible for processing these fees. When the Registration Branch Mail Intake Technician receives a submission, the original application, and the registrant's check are clipped together and sent to accounting.

3 CCR 6148

A copy of the application and the check stub is forwarded to the RS with the package. Once the check is processed, a receipt code (RC code) is stamped on the front of the application and returned to the RS. This process may take 1-2 weeks.

e) Six Copies of Printer's Proof or Final Printed Labels

3 CCR 6170

Registrants must submit 6 copies printer's proof, final printed labels, or copies thereof. The address on the label may differ from the application form and the license. If the proposed labels are not final printed or printer's proof (i.e. Word® documents), the RS should contact the applicant and inform him/her that the package will be reviewed, but the registration process cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

All products must be supported by data. In general, 25(b) products require medical toxicology, chemistry, and efficacy data. If the product is to be used on commercial crops, phytotoxicity data may also be required. It is common for the applicant to request a data waiver for the toxicology and chemistry data (phytotoxicity data when applicable). An applicant may submit public literature as "data" but there is no guarantee it will be sufficient. The RS should work with both the applicant and the scientific staff to determine the appropriate data requirements on a case-by-case basis.

FAC 12811.5

In lieu of submitting data with an application, the law states that DPR "may rely upon any evaluations of previously submitted data to determine whether to accept an application for registration of a new

pesticide product, an amendment to a registered product, or to maintain the registration of a pesticide product regardless of the ownership of the data previously evaluated." This section of law does not change or reduce DPR's data requirements.

3. Verification for Completeness

Review the package to determine if it is complete and can be processed. This does not include any review of the data as this is left to the evaluation scientists. If the package is incomplete, it should be returned to the applicant. Details on returning a package are listed below.

4. Review of the label

Review the label to determine if it is in compliance with Title 3, California Code of Regulations, sections 6235-6543.

Minimum Label Requirements

At a minimum, the following items must be included on all 25(b) product labels that require registration in California:

- Name, brand, or trademark
- Name and address of manufacturer, distributor, packer, formulator, or registrant
- Registration Number
- Warning or Caution Statement

DPR may request additional label language or label revisions as appropriate.

Tank Mixes

DPR does not require compatibility data to support label instructions for tank mixes on adjuvant labels. If the company has knowledge of a compatibility issue, it is there responsibility to provide appropriate label language. DPR does not assume liability for tank mix compatibility complications.

5. Return to Applicant, Incomplete Submission

If any of the required items listed in the preceding sections are missing, incomplete, or unacceptable, the submission should be returned to the applicant. For exceptions, speak with your supervisor.

The RS will:

- Prepare a return letter to the applicant that identifies all deficiencies

- Make a copy of the first page of the original application form. This copy will be sent to the applicant along with the return letter. Do not return the product formulation sheet as it contains confidential business information that could be lost in the mail.

- Make one copy of the letter for the "return package," a yellow surname copy (this will be returned to the RS once processed), and a return envelope

- Include a copy of the proposed label highlighting areas of concern if applicable
- Clip all items listed above to the outside of the colored folder (application package) and submit it to your supervisor

The Supervisor will:

- Review the return letter and surname the yellow copy

- Route the package with signed letters to the designated "out box" for distribution

The designated Technician will:

- Enter the tracking ID# and date of return letter into the tracking system

- Mail original letter, copy of the first page of the application, and product label (if applicable) to the applicant

- Enter the date from the cover letter into the return section on the application form

- Return the surname copy of the letter to the RS

- Attach the remaining copy of the letter to the front of the package inside the colored folder. The colored folder and accompanying data should be placed in the "return package" designated area.

If the applicant provides only some, but not all of the missing items within 6 months

from the date of the original return letter, the application is still considered incomplete. A package may be returned multiple times. If the applicant does not provide all items identified within 6 months of the date of the original return letter, another $1,150 processing fee is required.

For more details on the tracking and processing of returned packages, see the Intake through Archiving manual online.

6. Products that do not require Scientific Evaluation

DPR may rely upon the evaluations of previously submitted data to support an application for registration or amendment. If the applicant does not identify an identical or substantially similar product(s) previously approved by DPR, the RS will attempt to identify one or more similar products previously approved by DPR. If the applicant identifies one or more products previously approved by DPR or the RS has identified one or more previously approved products, the RS will:

- Compare the proposed product label and product formulation sheet to the label and product formulation sheet of the product or products identified by the applicant or the RS as being identical/substantially similar (see below).

In order to be considered substantially similar, the RS must confirm that the proposed and previously approved product(s):

- Contain same active ingredient(s)
- Contain the same or a substantially similar percentage of active ingredient(s) or when calculated out, the amount of active ingredient(s) as applied is the same or substantially similar for all labeled pest/site combinations
- Contain the same or substantially similar inert ingredient(s)
- Contain the same or a substantially similar percentage of each type(s) of inert ingredient(s)
- Bear the same label language with regard to signal word, human hazard and environmental precautionary statements, worker protection statements, storage and disposal, statement of use classification, first aid statement, etc.
- Bear the same or substantially similar method(s) of application.
- Claim to control the same or substantially similar pests or site/pest combination(s)

- Bear the same or substantially similar application rates and frequency and timing of applications for each pest or site/pest combination

If the RS cannot determine similarity between the product formulation sheets, they should consult with a chemist and/or toxicologist within the Department. If the RS cannot determine whether a plant pest is similar, they should consult with Plant Physiology. If the RS cannot determine whether a plant pathogen, nematode or insect pest is similar, they should consult with PDP. If the RS cannot determine whether a vertebrate pest is similar, they should consult with F&W. If the RS cannot determine whether a microbial pest is similar, they should consult with Microbiology.

If the RS determines that the proposed and previously approved product(s) is/are identical or substantially similar, the RS must revise the status sheet to include a PE (previously evaluated) prefix next to the tracking ID#. This indicates that all use sites, pests, etc. on the label have been previously evaluated by DPR and supported by data. The 30-day posting period is not required.

If the RS determines that the proposed and previously approved product(s) are identical or substantially similar with regard to some, but not all of the items listed above, the RS must revise the status sheet to include a SPE (some previously evaluated) prefix next to the tracking ID#. This indicates that some of the use sites, pests, etc. on the label have been previously evaluated by DPR. The RS must then submit the proposed product to the appropriate stations for scientific evaluation. The 30-day posting period is required.

If the RS determines that the proposed label and product formulation sheet are not identical or substantially similar to any products currently or previously registered with DPR in the last 10 years, and the submission was accompanied by all appropriate supporting scientific data, the RS should submit the proposed product/amendment to the appropriate stations for scientific evaluation. If the package is not accompanied by appropriate supporting data, the RS should return the package to the applicant.

7. Preparing the Data Package for Scientific Evaluation

After the package has been verified for completeness, the label has been reviewed and found acceptable, and data requirements identified, the RS should prepare the package to enter scientific evaluation.

If the applicant does not believe a required study is necessary, they can request that the data be waived. Such requests must be in writing and must provide reasoning for the request. The waiver request is submitted with the package into evaluation.

Selecting Evaluation Review Stations

It is important to indicate the appropriate review stations on the route sheet, depending on the type of product, use patterns, and claims being made. Regardless of which station the package is being routed for review, each station needs to be addressed. Regardless of which station the package is being routed for review, each station needs to be addressed. Using descriptors such as "Not applicable, AB1011 – (list reference product registration number), list policy/procedure memo number, ok-talked to evaluators name plus date."

In general, 25(b) products are routed to Chemistry, Efficacy, and Medical Toxicology. To determine if the product should be routed to Fish and Wildlife, the RS should consult informally with a Fish and Wildlife scientist. If the product is to be applied directly or indirectly to water, it should be routed to Environmental Monitoring. Appendix E "Evaluation Station Responsibilities and Purpose of Review" should be used as a secondary aid to determine the appropriate scientific evaluation stations. If the RS is not sure which evaluation stations the product should be routed to, he/she should consult with a supervisor.

If referencing previously evaluated data on file with DPR, include the volume numbers in the appropriate section of the route sheet. Data volumes submitted with the package should also be referenced on the route sheet, though in a different location than data previously evaluated. Data volumes that are part of a very large submission remain in the Registration Resource Center but should be referenced on the route sheet.

DPR review stations are:

Pesticide Registration
Branch Chemistry Microbiology
Pest Disease and Prevention
Fish and Wildlife
Plant Physiology

Medical Toxicology Branch
Worker Health and Safety Branch
Environmental Monitoring Branch
Enforcement Branch

The evaluation scientists will:

- Determine if data supports the label including the signal words, precautionary statements, protective clothing, worker or public reentry intervals, pre-harvest intervals, etc.

- Determine if any required data have not been submitted
- Determine if additional testing is needed
- Determine if there is evidence of an adverse effect or a potential adverse effect
- Determine if potential hazards are mitigated by the label

Arrangement and Content of Package Entering Scientific Evaluation

Once the evaluation stations have been selected and recorded on the route sheet, the package must be assembled for evaluation. The package should be assembled as follows:

Front of Colored folder

- The route sheet (the back side of the status sheet) with the evaluation stations selected and specific instructions to the evaluators written in the proper sections. If a data waiver was requested, this information must also be provided to the appropriate evaluation station.
- A copy of the status sheet (with correct information)
- One copy of the proposed label with the tracking ID# written on the top, right-hand corner. The Tracking Coordinator retains this label, and forwards it in a report to the PREC committee members

Inside the Colored folder

- A copy of the status sheet/route sheet filled out
- The applicant's cover letter (if provided)
- A copy of the complete application, including the product formulation sheet
- A second copy of the proposed label
- If data waiver requests were submitted, include this documentation when submitting the package into evaluation

Behind Colored folder

- Data submitted by the applicant

Once the package is assembled, it is submitted to the Tracking Coordinator to be routed and tracked through scientific evaluation.

8. Entering the Scientific Evaluation Process

Tracking and Routing the Data Package

Once the package has been prepared, the designated Tracking Coordinator is responsible for routing the package, recording the evaluators' decisions, etc. in the RS' binder and electronic tracking system database. The package is routed sequentially to each individual evaluation station (i.e., med. tox, then chemistry, then efficacy). The Tracking Coordinator maintains a binder for each RS that contains copies of the status sheet/route sheet, and evaluation reports that are completed as the package is reviewed. Should you have questions about a certain package in evaluation, you may ask to review the binder.

DPR's evaluation staff prepares written evaluation reports after reviewing the data. These reports are linked to the tracking ID# on-line, and hard copies of the evaluation reports are sent to the RS. The RS is responsible for reviewing the evaluation report(s) to ensure there are no concerns.

To track the progress of a submission, use the internal tracking system report database available on the PRB internal home page. The tracking ID# can provide received and release dates by the evaluation stations, proposed registration decisions, etc.

Note: Evaluation reports may be released to the applicant, data holder, or other authorized party, prior to public posting. This may be done without a written request while the registration application is still in the evaluation process. However, before releasing the report, the RS shall read the evaluation report for any trade secret or protected information such as manufacturing process or inert ingredient identification. Although this type of information is not expected to appear in the report, the RS must verify that it is not.

When the registrant, applicant, or authorized party (such as a consultant) **is not the data holder,** the RS should check with his/her supervisor for guidance. On rare occasions, the evaluation memos are considered "working documents" and may not be released.

Submitting a Data Package Back into an Evaluation Station During Scientific Review

Packages that exit an evaluation station, but are still in the evaluation process, occasionally need to be submitted back into an evaluation station. This is based on receipt of new or corrected information or data. To submit a package back into evaluation, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met or not:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. Once all evaluation stations have completed their reviews, the Tracking Coordinator will instruct the Program Manager to sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

Withdrawing the Data Package from the Evaluation Process

If the **applicant** requests withdrawal of an application after the data package has entered evaluation, the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- Prepare a letter for the company and state the reason for denial as "Application withdrawn by the applicant"

- Post the action Final-to-Deny, write "Application withdrawn by the applicant" on the action log, and follow the procedures

for denying an application

Note: In certain circumstances, the applicant will request that the product not be posted to deny but be returned instead. The RS should speak with his/her supervisor should this occur.

If the **RS (not the applicant)** requests withdrawal of an application after the package has entered evaluation (i.e., the label was revised and label claims removed negating the need for review by a certain station), the following actions should be taken:

- Submit a Tracking Documentation Memo (pinky) describing the intent or reason for withdrawal to the Program Manager for their approval

- If the product was submitted to only one evaluation station, the product does not require posting. Follow the procedures outlined above under "Products that Do Not Require Scientific Evaluation."

- If the product was submitted to other evaluation stations, post the action as appropriate (30-to-Deny or 30-to-Registerister), state the reasoning on the action log, and follow the procedures below for proposing registration or denial of the application. The route sheet may require the signature of a Program Manager.

- Prepare and submit the appropriate letter to the registrant (propose registration or denial)

Note: for exceptions to the rule (i.e., the registrant requests the package be returned), a supervisor should be consulted.

9. Exiting Scientific Evaluation and the 30-day Comment Period

When the scientific evaluation process is complete, the Program Manager indicates if the product application should be approved or denied (based on the evaluators decisions), by signing the route sheet. Once the package is returned, the RS should proceed as follows:

- Review the Program Manager's decision and any evaluation reports that have not been previously reviewed

- Communicate any deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registration, or recommendation for risk assessment not

already discussed to the applicant

- If the final printed or printer's proof labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration will be granted

- If an adverse effect disclosed by data pertains to any other currently registered products, contact the Reevaluation Coordinator and see Chapter 8 for guidance on Reevaluation

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person.

Requirement to Post for Public Comment

3 CCR 6253

P/P 2007-1

DPR posts publicly for 30 calendar days, all proposed decisions for products that enter scientific evaluation. These decisions can be found on our website under Notice of Decisions. The public comment period fulfills an essential role in DPR's certification for functional equivalency under the California Environmental Quality Act. The purpose of the 30-day notice is to allow for public comment of the proposed product and the Department's decision to register or deny the product application. The Pesticide Registration Branch responds to all public comments received within the 30-day public comment period before a final action can be taken.

During the 30-day public comment period on a "30 to Register" posting, the RS may gather and prepare the appropriate registration documents for submission to Licensing. However, the RS may not give the prepared registration package to Licensing until: 1) the day after the 30-day posting period ends; and 2) DPR responds to any comments received during the comment period on that product. If DPR receives a comment(s) on a product during the 30-day posting period, the RS will be informed immediately.

Submitting a Data Package Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the submission has exited scientific evaluation with a negative review, but has not been posted for the 30-day public comment period, the following should occur:

- The RS must fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- If additional data were submitted, informally route the package with all data submitted to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- The RS should submit the package to the Tracking Coordinator who will route the package back into evaluation and enter the information in the database

If the **evaluator's concerns are met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The TC will instruct the Program Manager to re-sign and date the route sheet and the package will be returned to the RS to finalize the process. A hard copy of the revised evaluation report will be sent to the RS with the package.

If the **evaluator's concerns are not met:**

- The Tracking Coordinator will enter the information in the internal tracking system report database and record any necessary information on the route sheet. The Tracking Coordinator will revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

Submitting a Data Package Back into Evaluation After the Product is posted for 30-day Public Comment Period

During the 30-day public comment period, the applicant may submit additional data to meet deficiencies identified during the evaluation.

If this occurs, the RS will:

- Informally route the package with all data submitted with the package to the Indexing Technician. This may require the retrieval of data currently in evaluation. The data must be formally entered into the database and the information

located on the front of the data volumes may need to be revised. If this occurs, the RS should consult with his/her supervisor for guidance. The new data/information is not given a new tracking ID# or a new status sheet.

- Fill out the re-entry section on the route sheet and provide as much detail to the evaluation staff as possible

- Submit the package to the Tracking Coordinator, with the evaluation stations indicated

The Tracking Coordinator enters the new receipt date, generating a new target date in the database. The package is then submitted back into evaluation.

If the **evaluator's concerns are met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database and instruct the Program Manager to re- sign and date the route sheet. A hard copy of the revised evaluation report is sent to the RS with the package.

- The RS will repost the package 30-to-Registerister

If the **evaluator's concerns are not met**:

- The Tracking Coordinator will enter the information in the internal tracking system report database, revise the date on the route sheet, and return the package to the RS with a hard copy of the revised evaluation report. The Program Manager does not re-sign the route sheet.

- The decision to deny registration stays in effect until the end of the original 30-day comment period. For information on completing a final action, see part 10 of this section.

Meeting an Evaluator's Concerns without Submitting the Package Back into Evaluation

If an evaluator's concerns are met by submission of a revised label or corrected application after the product is posted 30-to-Deny, the package can be posted 30-to-Register without submitting it back into evaluation. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to his/her supervisor for their signature

- Provide a copy of the signed pinky along with the package to the Program Manager who will revise the registration action and re-sign/date the route sheet

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Place the tracking ID# on the weekly action log and submit the action log to the appropriate staff person

10. Propose to Register, Conditionally Register, or Deny a Product Application

Propose to Register a Product

If all evaluators find the data/information acceptable, the product is posted 30-to-Register for the public comment period. A proposed decision to register means:

- The data supported the registration

- The label mitigates any hazards or possible adverse effects

- No additional data or information are required to support full registration

The RS will:

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Register a Product when an Evaluation Station has recommended denying the
Application

If the RS wishes to register a product when there is a recommendation to deny, he/she must obtain approval from the Pesticide Registration Branch Chief. The RS will:

- Prepare and submit a Tracking Documentation Memo (pinky) describing the action, to the Pesticide Registration Branch Chief for their signature

- Provide a copy of the signed pinky to the evaluator and Evaluation Program Manager

- Give the package to the Tracking Coordinator who will revise the registration decision in the database

- Prepare a "Propose to Register" letter for the company, a yellow surname copy, and an envelope, and submit them to his/her supervisor

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

Propose to Conditionally Register a Product

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to make a registration decision, but additional data are needed for full registration, the scientist can recommend that the product be conditionally registered. California Code of Regulations (CCR) section 6200 allows the director to waive certain data requirements for a period reasonably sufficient, not to exceed a maximum of three years, for the generation and submission of the required data.

Conditional registrations may only be granted if certain data required under California laws and regulations are found to be acceptable, but insufficient by our scientific staff. The fact that a product may be conditionally registered with U.S. EPA is not grounds for conditional registration in California.

Conditional registration can be granted only if the following data are submitted and found acceptable. A more complete list is in 3 CCR Section 6200.

- Acute oral LD50 data on the product

- Acute dermal LD50 data on the product

- Acute LC50 data on products that produce respirable aerosols or gases

- Primary eye irritation data on the product

- Primary skin (dermal) irritation data on the product

- Foliar and soil residue data as specified in Section 6181 and 6182 of CCR, sufficient to establish safe reentry level or interval, when human contact is likely to occur

- Preliminary efficacy data indicating the effectiveness for the proposed use

- Groundwater protection data required by the Pesticide Contamination Prevention Act (AB2021 data), for the first agricultural use of an active ingredient, unless Interim Registration is requested

- The mandatory health affects data required by the Birth Defects Prevention Act, (SB950) (may be waived after consulting with OEHHA.).

To propose a conditional registration the RS will:

- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Reg" and submit the action log to the appropriate person

- Send a letter to the applicant listing the conditions and the time frames, requesting a written agreement to the conditions within 30-days. The RS may contact the applicant in advance to advise them of the conditions.

If the agreement is received, the product can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny registration is posted 30-to-Deny for an additional 30 calendar days to allow for comment. Denial is finalized after the posting period.

Propose to Deny a Product

If any evaluator finds the data/information does not support registration, the proposed decision to deny registration is posted for the 30-day public comment period. A proposed decision to deny means:

- The evaluator determined the submitted data indicate a potential hazard not mitigated by the label

- Label claims were not supported by the information/data

submitted

- Required data was not submitted

The RS will:

- Prepare a "Propose to Deny" letter to the company (this should include the reason for the proposed decision, specific information or data required to complete the deficient application, and a copy of the evaluation report), a yellow surname copy, and an envelope, and submit them to his/her supervisor
- Post the action on his/her weekly action log by placing the tracking ID# in the column titled "30 to Deny" and submit the action log to the appropriate person

If the data or information is submitted during the 30-day comment period, the RS should route the data and proceed as described above.

11. Final Decision to Register or Deny

After the 30-day public comment period is complete, or if the product did not require scientific evaluation, a final action to register, register conditional, or deny is taken.

Registering a Product (non-conditional)

If the registration is supported, the RS will:

- Verify that all items have been received

- Verify that final printed, or printer's proof labels were submitted and found acceptable

- Verify that the CA Reg. No., company name, and product name written on the company letter, license, and documentation are consistent

If all items are submitted and acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:

    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
    - Master Labels (Alpha codes assigned ML, MM, MN, MO, MP…MA, MB, MC, MD…MK)
    - EUPs (Alpha codes assigned EX, EY, EZ, EA, EB, EC…EW)
    - Section 18s approved by DPR for use in California (Alpha code EE)
    - Section 18s approved by a federal agency (but not DPR) will be applied in California (Alpha code EU)

- Stamp three labels with the appropriate stamp (Section 3, Master Label, etc.) for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- If there is no U.S. EPA-assigned firm number and the company has not been assigned a company number by Intake, the RS will assign a firm number using the California Firm Numbers Assignment binder in the Licensing area. 25(b) products are assigned a 30000-product number in numerical sequence.
  For example, the CA Reg. No. should read XXX-30001-AA.

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date, and amount on the form.

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof, or final printed label.

- Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license. If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for Coding

- A copy of the full application form (including the product formulation sheet). Write "Coding" in the upper right-hand corner.

- Note: Additional copies of alternate formulas should not be included (i.e., the company has submitted one basic product formulation sheet and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written in the upper right-hand corner

- A copy of the status sheet with all corrections made

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper - right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. Include the colored folder if the tracking ID# will be removed from the tracking system by the licensing technician (examples include company ownership change, new products that did not enter scientific evaluation, company name change). It should be clipped to the bottom of the package. Do not include the colored folder for all other actions (such as new products that were sent to evaluation).

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet

- Arrange the data by volume (if more than one volume)

- Clip together the original route sheet, the status sheet with corrections made, the evaluation reports(s) and the data (in that order)

- Place the entire package in the designated area to be archived

Conditionally Registering a Product

After posting the product for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required studies, the RS will prepare the following:

- Verify that final printed, or printer's proof labels were submitted and found acceptable (Master labels don't require final printed labels)

If all items are submitted and found acceptable, the product can be licensed. The RS will:

- Check the database to determine which alpha code should be assigned.

- Completely fill out the upper right-hand portion of the Application for Registration form. Alpha codes are assigned to all new products because our database software does not recognize registration numbers with multiple brand names.

- Alpha Codes for new products and additional brand names are to be assigned in order as follows:
    - Regular products (alpha codes assigned AA, ZA, ZB, ZC…ZZ, AB, AC, AD…AZ, BA, BB, BC, ETC.) If DPR ever gets that far, it will skip over "E" and "M".
- If there is no U.S. EPA-assigned firm number and the company has not been assigned a company number by Intake, the RS will assign a firm number using the California Firm Numbers Assignment binder in the Licensing area. 25(b) products are assigned a
- 30000-product number in numerical sequence. For example, the CA Reg. No. should read XXX-30001-AA.

- Stamp three labels with the appropriate stamp for distribution to the product file, coding, and the company, and fill in the appropriate information. The RS may retain an additional copy for his/her file.

- Prepare a form letter to the company, identifying each of the conditions and timeframe(s) for submission. Attaching copies of evaluation reports is not a substitute for listing the conditions and timeframes in the letter. E-mail the draft letter to Licensing. Licensing will prepare the final letter.

- Stamp "Conditional" on the top, middle portion of the first page of the application

- Make a copy of the conditional evaluation report(s) for the conditional binder

Assemble for the Product File

- The original application form including the product characterization information and statement(s) of formula. Write "Product File" in the upper right-hand corner of the application. Verify that there is an RC#, fee, date and amount on the form.

- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

- A copy of the stamped-accepted, printer's proof, or final printed label. Write "Product File" and the tracking ID# in the upper right-hand corner. It will be tagged and placed in the back of the product file in the Registration Resource Center.

Assemble for the Registrant

- A copy of the stamped-accepted label with "Company" written in the upper right-hand corner. This copy will be sent to the company with the letter of registration and the product license.

Assemble for Coding

- A copy of the full application form (including the product formulation sheet). Write "Coding" in the upper right-hand corner.

  Note: Additional copies of alternate formulas should not be included (i.e., the company has submitted one basic product formulation sheet and 3 alternates)

- A copy of the stamped-accepted label with "Coding" written

in the upper right-hand corner

- A copy of the status sheet with all corrections made
- The Memorandum of Registration (blue or green memo), if the product was not routed for full evaluation

Assemble for the Cover Letter File

- A copy of the cover letter (or a copy) submitted by the applicant and write "Cover Letter File" in the upper right-hand corner

Assemble for the Conditional Binder

- A copy of the conditional evaluation memo(s) and write "Conditional Binder" in the upper right-hand corner

Assemble for the Registrant's Agent (if applicable)

- If the company agent has requested a copy of the label, include a copy with the word "Agent" written in the upper right-hand corner.

Clip together the individual sections listed above (product file, registrant, coding, cover letter, and agent - in that order) and place in the correct basket in licensing. **Do not include the colored folder.**

The Licensing Technician will prepare 6 (or 7) copies of the conditional letter:

1 original letter for the company
1 copy for the agent (f applicable)
1 surname copy for the product file
1 copy for coding
1 copy for the company licensing binder
1 copy for the Conditional Binder
1 copy for the RS

The Conditional Binder is located on the shelf with the other product license binders. It contains a copy of the letter, license, and conditional evaluation report(s) and is filed in order by the RS' last name.

Licenses are sent to the company address entered in the Registration Branch database. They are not sent to the company agent or other interested party (i.e., the applicant who is not employed directly by the company). If the applicant, agent, or other interested party would like a copy of the product license, the RS should

place a sticky note on the front of the package or indicate to licensing that additional copies of the license and letter should be printed. The RS must include the name of the person, the company they work for, and the company address.

The package will be processed by licensing and returned to the RS for final review. The RS should verify that the EPA Reg. No., company name, and product name written on the company letter, license and other documentation are consistent. Once the final review is complete, the RS should sign the company letter and the yellow surname copy. The letters, license, and package should be submitted to his/her supervisor for final sign off.

Once the RS receives his/her copy of the company letter back from licensing (affirming that the license has been sent to the registrant), they must place the tracking ID# on the action log under "Final to Register." **Do not take this action until you receive the company letter.** Pursuant to 3 CCR section 6255, each product must be posted "Final to Register" within one week of the issuance of the product's license. A product license is not official until it has been sent out by PRB.

Yearly Assignments

P/P 2006-6

In early October of each year, each RS will review the Conditional Binder to see if there are any outstanding conditional registrations that will expire before December 31st of that year. The RS will contact all companies with outstanding conditions, to determine if the deadline can be met. Time frames may be extended no more than 3 years from the initial date of the conditional registration. The RS should consult with the evaluation scientist who recommended the conditional registration, to determine if an extension is warranted. If the evaluation scientist feels that an extension of time should be granted, he/she should request a reasonable time frame for completion of the studies. Consult with your supervisor before extending the time for the conditional registration.

If the time frame cannot be met, the company should be informed that their product would not be renewed for the upcoming year. They should be advised to line out the product on their renewal form before submitting it to the Department. See Chapter 8 for more information.

If an extension is granted, the RS is to prepare the appropriate letter to the registrant indicating that we have extended the time frame for completing the required data. Include the new target date and a copy to Licensing.

A conditional registration is converted to a full registration upon acceptance of the required data. See Chapter 8 on "Changing a Conditional

Registration to a Full Registration."

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write "Archive" on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

Denying a Product

If the data do not support registration, the RS will:

- Verify that the deficient items have not been submitted
- Prepare a letter to the applicant notifying them that the registration denial is final, surname copy, and envelope and submit to his/her supervisor
- Stamp the first page of the original application form "Denied"
- Staple together a copy of the final denial letter (placed on top), a copy of the denied application, a copy of the propose-to-deny letter, the U.S. EPA documents, copies of the evaluation reports, and a label. Mark the package "Denial File" and submit to the Registration Resource Center.
- Write "Denied" in the lower right-hand corner of the route sheet, with the date and his/her signature
- Record the tracking ID# as "Final to Deny" on his/her weekly action log

Assemble for Archiving

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write “Archive” on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation report(s) and the data (in that order)
- Place the entire package in the designated area to be archived

After the final denial action has been taken, the applicant may reapply for registration by submitting the following:

- A new Application for Registration
- The $1,150 application fee
- All data or information identified as lacking in the previous submission

P. Research Authorizations

3 CCR 6260-6272

With the exception of those persons exempted by 3 CCR section 6268 (see below), a written authorization for research must be obtained from the director prior to any experimental, unregistered use of a pesticide. A research authorization (RA) allows a company to gather data on efficacy, phytotoxicity, residue, environmental effects, methods of application, or other field data to support California registration under California use conditions.

RAs are limited by federal regulations to 10 acres or less if the product or proposed use is not federally registered (40 CFR, Part 172). If the product and the proposed use are federally registered, there is no limitation set in California law or regulations, prohibiting DPR from issuing a RA for any size test plot.

In addition to a RA, a person must obtain a federal Experimental Use Permit for use of an unregistered pesticide/use on 10 or more acres. A company may choose to pursue registration of the EUP in California or apply for use of the product under a RA. These are separate processes with different requirements and limitations. See Part J of this chapter for

information on processing a EUP application.

A RA is a permit and not a registration. A company may request a RA by submitting a completed RA application form. There are no application fees for a RA.

A RA is not routed through the evaluation process. Applications for permits are made directly to DPR's designated scientist who is responsible for issuing RAs. The designated scientist will determine the parameters of use such as number, size, location of trials, etc.

Under a RA, the product cannot be sold for the experimental use, but must be provided free of charge to any cooperator whose property is being used for experimental trials. If there is no residue tolerance or exemption from a tolerance, the treated commodity cannot be used for food or feed.

RAs are not processed by the Registration Branch Regulatory Scientists and are therefore not covered in detail in this manual. However, the following items should be noted:

- A special number is assigned to each permit
- The pesticide product used under the RA may not be sold
- Commodities treated with the product may not be used for food or feed unless EPA has established a residue tolerance for the pesticide on the commodity and that tolerance has been met or the pesticide is exempt from a tolerance.
- All commodities treated with a product for which a tolerance has not been established must be destroyed
- A RA is not under the jurisdiction of U.S. EPA
- A RA does not require an application fee
- Certain information must be provided by the researcher to the appropriate agricultural commissioners office at least 24 hours prior to a RA product application
- Registrants may conduct research without obtaining a RA, provided the registrant is the operator of the property upon which the research is to be conducted and continues to be the operator of the property until the treated commodity is destroyed or harvested
- Personnel employed by colleges and universities and engaged

in pesticide research may conduct research without obtaining a RA if they are operating according to the current established policy of the college or university which covers pesticide use and experimentation

It should also be noted that parameters of use are regulated by U.S. EPA regulation and DPR policy (e.g., number, size, and location of trials, total acreage, expiration date, disposition of treated commodity, use reports, etc.).

Detailed questions involving RAs should be referred to DPR's designated scientist.