The Pesticide Registration Branch

Desk Manual Chapter 6

2013

California Department of Pesticide Regulation

Chapter

6

Label Amendments and Formula Revisions

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I. Introduction

A registrant may choose to amend their product label or formulation on file with DPR after the product has received registration. Although similar, the amendment/notification process at U.S. EPA differs from that at DPR. This chapter provides guidance on processing a label amendment or formula revision at DPR and includes but is not limited to:

- Label amendments requiring data and possibly scientific evaluation
- Non-substantive changes
- Minor changes processed as "File as Latest" (FAL)
- Changes processed as Amendments w/o Notice
- Minor changes processed through the DPR Notification process
- Minor changes not requiring notification to DPR

All label revisions that cannot be processed through notification, or do not require notification to DPR, must be submitted to, and found acceptable by DPR before the revised product containers/labels can be released for sale.

Note: If U.S. EPA assigns a new EPA Reg. No. due to a formulation change, it is considered a new product and must be processed as such. Refer to Chapter 4 for guidance.

II. How to Process a Label Amendment

A. General Guidance

1. Quick Reference - Items that Must Be Submitted by the Applicant to Support a Label Amendment

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

- California Application to Amend a Pesticide Product (if

applicable)

- $25 application fee

- Six copies printer's proof or final printed labels

- A copy of the latest U.S. EPA stamped-accepted accepted label and accompanying letter, or a copy of the U.S. EPA Application for Registration/Amendment form for revisions made by notification to U.S. EPA (if applicable)

- 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 applicable)

2. General Intake Process

Intake

Once the Intake Technician receives the amendment submission in the mail, he/she should proceed as follows:

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

- Assign a sequential tracking ID# with an appropriate prefix or suffix to identify the type of submission

- 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 Indexing Technician

- If there is an attention flag (computer assigned) on the status sheet, give the entire sheet to the designated Program Specialist who will forward the package to the Indexer or the

Memo:
10-25-94

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

Regulatory Scientist (RS)

The procedures in "Intake through Archiving" guidance document should 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.

Indexing

If data are submitted with a registration request, the Indexing Technician will:

- 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 applicant acknowledging receipt of data that includes the assigned tracking ID# and a report of the indexed data
- Forward the registration submission to the RS

Applicants must submit data in the format outlined in "Format Guidelines for All Data Submitted for Pesticide Registration in California (California Notice 2006-6). If an incorrectly formatted data submission is received, the Indexing Technician will contact the applicant and inform them that the data will be shredded. The applicant must resubmit the data properly bound before DPR will 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.

3. Items that should be Included with the Product Submission

a) Status Sheet

A status sheet should accompany all label amendments. 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:

Memo: 10-25-94

Memo of 4-4-91

CA Notice 2006-6

Memos of 1-1-99 6-23-93

- 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 photo copy with corrections highlighted, initialed, and dated to the Intake Technician
- Submit a photo copy with corrections highlighted 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. This is especially important for label amendments because it can provide the RS with a detailed description of the changes being made.

c) Complete Application to Amend a Pesticide Product **form (035)**

The application form must be filled out and signed. The firm name and address shown on the application must be consistent with federal documentation (unless the product is an adjuvant).

3 CCR 6170.1, 6170.5, and 6157

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 97-6 and 99-4

CA Notice 2009-5

The RS must revise the status sheet and any other pertinent documentation before the product is posted 30-to Register.

Memo: 8-31-98

The brand name on the application form must be the same as the name shown on the label and consistent with federal documentation.

d) Application Fee

A $25 application fee, regardless of whether the registrant submits data or the amendment is submitted into evaluation, must accompany label amendments that require the support of scientific data. This includes supplemental distributors who submit label amendments to include label language that has already been approved on the basic's California label, as well as additional brand name 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 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 6148.5

e) The Latest U.S. EPA Stamped-Accepted Label or a Copy of the U.S. EPA Application for Pesticide Registration/Amendment (Notification form) (8570-1)

If U.S. EPA requires the applicant to submit an application for amended registration, they will stamp the accepted label and include an accompanying letter. The registrant is required to submit this label and letter to California when amending their product label. As previously noted, the notification processes at U.S. EPA and DPR differ. A company may be required to submit their label revision to DPR through the label amendment process, even though the company was allowed to submit the same label revision to U.S. EPA through

U.S. EPA PR-Notice 98-10

their notification process. If this occurs, the applicant must submit a copy of the U.S. EPA Application for Pesticide Registration/Amendment (notification) form with their submission. The DPR notification process will be addressed later in this chapter.

The RS should compare the proposed label to the current U.S. EPA label on file to ensure no other changes have been made. If the U.S. EPA label is not provided, the RS should obtain the current label from the product file in the Registration Resource Center.

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 be the same 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 or other U.S. EPA documentation. 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 amendment cannot be completed until the printer's proof or final printed labels have been submitted and approved.

g) Data

3 CCR 6158
6159

Certain label amendments must be supported by data (discussed below). A $25 application fee must accompany all amendments.

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 amendment is approved.

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 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 to amend his/her product by submitting the following:

- A new Application to Amend Pesticide Product

- The $1,125 application fee

- All data or information identified as lacking in the previous submission

follow the procedures in the appropriate section of this chapter.

To confirm that the product does not require data, the RS will:

- Compare the proposed label to the label currently on file. It should be noted that on occasion, a company might choose to add a use or pest to their label that was previously approved, but removed from the label currently on file. This should be noted by the applicant in their cover letter. Should this occur, the RS would need to review previously approved labels for the subject product.

- Compare the proposed label to the U.S. EPA stamped-accepted label/cover letter. U.S. EPA Notification form provided to ensure the amendment has been approved by U.S. EPA or that U.S. EPA have been notified of the change

- If the amendment is submitted to comply with a U.S. EPA PR-Notice or other U.S. EPA guidance, the RS should review the documentation and the proposed label to ensure they are consistent. In most cases, the Registration Branch Chief will inform the RS' and appropriate staff that such revisions shall be accepted without the submission of data. In all other cases, the RS may consult with his/her supervisor to confirm data is not required. If it is determined that the amendment must be supported by data, follow the instructions below for amendments that must be supported by data.

- Confirm that the status sheet has a "PE" (previously evaluated) prefix in front of the tracking ID#. The PE prefix will inform the reviewer that all use sites, pests, etc. for the proposed label amendment have been previously evaluated or do not require the support of scientific data. If the PE prefix must be added, the RS should amend the status sheet and provide a copy to the Intake Technician.

Amendment Not Acceptable

If there are deficiencies in the submission that cannot be reasonably corrected by working with the applicant, the submission should be returned. To return the submission, the RS should:

- Prepare a return letter for the applicant, detailing the deficiencies.

- Print 2 white copies and 1 yellow surname copy. Write "Return

File" in the upper right-hand corner of one white copy and his/her last name in the upper right-hand corner of the yellow copy. The surname copy will be returned to the RS once the process is complete

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign the applicant letter and surname the yellow copy

- Place the letter designated "Return File" *in* the colored folder, on top of all the submitted documents

- Clip the applicant's return letter, envelope, and yellow surname copy to the front cover of the colored folder.

- Submit the package to his/her supervisor

Note: The designated staff person, not the RS, takes the action on a return package. **Return actions do not get placed on the weekly action log by the RS!**

Amendment Acceptable

If the amendment is found to be acceptable, the RS will:

- Stamp 3 labels with the appropriate acceptance stamp (a fourth copy may be retained by the RS). Write "Product File," "Coding," and "Company," along with the tracking ID# in the upper right-hand corner of each label respectively. The added use sites, pests, etc. must be highlighted on the label marked "Coding" in yellow. The product file label will be tagged and placed in the back of the product file in the Registration Resource Center by the appropriate staff member once processed.

- If the RS chooses to highlight the new material on the amended label, the highlighting must be in yellow

- Prepare a letter to the registrant (using the correct, full company name) accepting the label amendment. If the company agent has requested a copy of the label and approval letter, include a copy with the word "Agent" written in the upper right-hand corner. At the bottom of the letter, add "cc: <NAME OF AGENT>, <AGENT'S COMPANY NAME> (w/ enclosure)

- Print 3 copies on white paper and 1 copy on the yellow surname paper.

- Write "Product File" on the yellow copy, "Coding" and "Cover Letter File" on two of the white copies respectively. Provide and additional white paper copy for the agent if applicable.

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign one copy of the letter. This copy will be sent to the registrant.

- Surname the yellow copy and write "Product File" in the upper right-hand corner.

Assemble for the Registrant

- Clip together the signed copy of the letter, envelope, and the approved label designated "Company." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Product File

- Pertinent documents including but not limited to the U.S. EPA stamped accepted label, U.S. EPA notification forms, application forms, etc.

- 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.

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

Assemble for Coding

Clip together a copy of the letter designated "Coding," a copy of the label (**with amended areas highlighted in yellow**), and a copy of the status sheet, in that order. **Include only** a representative label if there are multiple labels submitted (colors, sizes, graphics, etc.).

Assemble for the Cover letter file

Clip together a copy of the letter designated "Cover Letter File" and the original cover letter (or a copy)

Assemble for the Registrant's Agent (if applicable)

Clip together a copy of the letter, envelope, and the approved label designated "Agent." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Note: If someone other than a company representative (such as a consultant) submits the product for amendment, a duplicate copy of the letter and an envelope should be prepared. **It is important that the original company letter reflect the correct company name** because it directs the designated staff person to file the information in the appropriate product file. Use of a consultant's company name on the main letter misleads the person filing the paperwork.

Once complete, the RS should clip together all individual sections listed above (registrant, product file, coding, cover letter - in this order) and submit to his/her supervisor (do not include the colored folder) and record the tracking ID# on his/her action log in the **"File as Latest"** (FAL) column. The colored folder should be returned to the designated folder area.

C. Amendments that Must Be Supported by Scientific Data

Some label or formula changes require the submission of data. If the amendment(s) has not been previously approved by DPR, scientific evaluation is required. Examples of label amendments requiring data, include, but are not limited to:

- Addition of a crop or a use site
- Addition of an indoor use
- Adding the first agricultural use for the active ingredient to the label
- Adding pests or types of pests not already on the label
- Reducing the signal word or the precautionary statements
- Revising the ingredient statement on the label (provided the revision is approved by U.S. EPA and DPR and is determined

to be significant but not significant enough to classify the product as "new")

Due to the passage of AB 1011, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support amendments to pesticide products (use sites, pests, precautionary language, etc.). A $25 application fee, regardless of whether the registrant submits data or the amendment is submitted into evaluation, must accompany label amendments that require the support of scientific data. This includes supplemental distributors who submit label amendments to include label language already been approved on the basic's California label and additional brand names.

To determine if the label amendment must be submitted into scientific review, the RS should:

- Review the cover letter (if submitted) to determine if the applicant has identified the additions or revisions being made, referenced similar products, and if data have been submitted to support all of those additions

- If the applicant has identified that the amended label language was previously approved on a similar product(s), the RS should obtain a copy of the cited product label and CSF

- If the applicant has not identified that the amended label language was previously approved on a similar product(s), the RS will attempt to identify one or more previously approved products containing the same active ingredient(s) and bearing the same or similar uses as the proposed label amendment

- If there are previously approved products on file, compare the proposed amended label (and/or CSF where applicable) with the previously approved product label(s) (and/or CSF) and determine whether the proposed use sites, pests, etc. were previously approved

  To assist in determining similarity, the RS should confirm that the proposed and the 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 a 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 all items being added or revised were previously approved by DPR, add a "PE" (previously evaluated) prefix to the hard copy of the status sheet. The PE prefix will inform the viewer that all use sites, pests, etc. for the proposed label amendment have been previously evaluated or do not require the support of scientific data. Make a copy of the amended status sheet and place in the Intake Technician's box.

- If some of the amendments were previously approved by DPR, add an "SPE" (some previously evaluated) prefix to the hard copy of the status sheet. The SPE prefix will inform the viewer that some of the use sites, pests, etc. for the proposed label amendment have been previously evaluated, but that certain revisions must be submitted into scientific evaluation for review. Make a copy of the amended status sheet (sign and date the change) and place in the intake technician's box.

Amendment Not Acceptable

If there are deficiencies in the submission that cannot be reasonably corrected by working with the applicant, the submission should be returned. To return the application, the RS should:

- Prepare a return letter for the applicant, detailing the deficiencies.

- Print 2 white copies and 1 yellow surname copy. Write “Return

File" in the upper right-hand corner of one white copy and the RS' last name in the upper right-hand corner of the yellow copy. The surname copy will be returned to the RS once the process is complete

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign the applicant letter and surname the yellow copy

- Place the letter designated "Return File" *in* the colored folder, on top of all the submitted documents

- Clip the applicant's return letter, envelope, and yellow surname copy to the front cover of the colored folder.

- Submit the package to his/her supervisor

Note: The action on a return package is taken by a designated staff person, not the RS. **Return actions do not get placed on the weekly action log by the RS!**

Amendments that Require the Support of Data but Do Not Require Submission into Scientific Evaluation (Amendment w/o Notice)

If it is determined that all amended items on the proposed label have been previously evaluated and approved, the amendment can be processed without entering scientific evaluation. Although the amended required the support of scientific data, the RS determined that the data had previously been previously evaluated and approved, regardless of the data owner, and supported the proposed amendment(s).

To process the amendment, the RS should:

- Stamp 3 labels with the appropriate acceptance stamp (a fourth copy may be retained by the RS). Write "Product File," "Coding," and "Company," along with the tracking ID# in the upper right-hand corner of each label respectively. The added use sites, pests, etc. must be highlighted in yellow on the label marked "Coding." The product file label will be tagged and placed in the back of the product file in the Registration Resource Center by the appropriate staff member once processed.

  If the RS chooses to highlight the new material on the amended label, the highlighting must be in yellow

- Fill out the upper right-hand portion of the application

- Prepare a letter to the registrant (using the correct, full company name) accepting the label amendment. If the company agent has requested a copy of the label and approval letter, include a copy with the word "Agent" written in the upper right-hand corner.

- Print 3 copies on white paper and 1 copy on the yellow surname paper: Write "Product File" on the yellow copy, "Coding" and "Cover Letter File" on two of the white copies respectively. Provide and additional white paper copy for the agent if applicable.

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign one copy of the letter. This copy will be sent to the registrant. Surname the yellow copy and write "Product File" in the upper right-hand corner.

Assemble for the Registrant

- Clip together the signed copy of the letter, envelope, and the approved label designated "Company." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Product File

- The 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.

- Other pertinent documents including but not limited to the U.S. EPA stamped accepted label, U.S. EPA notification forms, application forms, etc.

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

Assemble for Coding

- Clip together a copy of the letter designated "Coding," a copy of the label (**with amended areas highlighted in yellow**), and

a copy of the status sheet, in that order. **Include only** a representative label if there are multiple labels submitted (colors, sizes, graphics, etc.).

Assemble for the Cover letter file

- Clip together a copy of the letter designated "Cover Letter File" and the original cover letter (or a copy)

Assemble for the Registrant's Agent (if applicable)

- Clip together a copy of the letter, envelope, and the approved label designated "Agent" If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Note: If someone other than a company representative (such as a consultant) submits the application, a duplicate copy of the letter and an envelope should be prepared. **It is important that the original company letter reflect the correct company name** because it directs the designated staff person to file the information in the appropriate product file. Use of a consultant's company name on the main letter misleads the person filing the paperwork.

Once complete, the RS should clip together all individual sections listed above (registrant, product file, coding, cover letter, and agent - in this order) and submit to his/her supervisor (do not include the colored folder) and record the tracking ID# on his/her action log in the **"Amendment w/o Notice"** column. The colored folder should be returned to the designated folder area.

Amendments that Require Scientific Evaluation

If it is determined that a label amendment requires scientific evaluation, the RS should prepare the package for scientific evaluation.

1. Preparing the 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. 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.

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 revisions, additions, 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 the 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 with the new use sites/pattern/rates highlighted in yellow. 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 application (and CSF if applicable)

- A second copy of the proposed label with the tracking ID# written on the top, right-hand corner with the new use sites/pattern/rates highlighted in yellow.

- The U.S. EPA label and/or all other pertinent U.S. EPA documentation

Behind Colored folder

- Data submitted by the applicant (if provided)

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

2. 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). 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 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/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 printed 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 on the weekly action log, 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 "Amendments that Require the Support of Data but Do Not Require Submission into 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 for processing 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.

3. 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 RS receives the package, he/she should proceed as follows:

- Review the Program Manager's decision 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 under the appropriate section (30-to-Registerister or 30-to-Deny) 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

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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 approve the amendment 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 Label Amendment Back into Evaluation After Scientific Review is Complete but before the Product is posted for the 30-day Public Comment Period

If the label amendment 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 Label Amendment 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. 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

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

4. Propose to Approve, Conditionally Approve, or Deny a Label Amendment

Propose to Approve a Label Amendment

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 (rare): If the submission is being amended at both U.S. EPA and DPR 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 the label amendment 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:

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

Propose to Approve a Label Amendment when an Evaluation Station has recommended denying the Application

If the RS wishes to approve a label amendment 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

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

Propose to Conditionally Approve a Label Amendment

If during the scientific evaluation process, DPR's evaluation staff finds that an applicant submitted sufficient data to approve the label amendment, but additional data are need, the evaluation scientist can recommend that the amendment be accepted with conditions. California Code of Regulations, Title 3 (3 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.

Acceptance of amendments with conditions 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 amending a product with conditions at DPR.

Acceptance of an amendment with conditions 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 3 CCR Sections 6181 and 6182, 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 acceptance of an amendment with conditions, 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, 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 amendment can be registered conditionally, after the 30-day posting period.

If the agreement is not received, the decision to deny the amendment 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 Label Amendment

If any evaluator finds the data/information does not support the amendment, the proposed decision to deny the application for amendment 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 Denial of Label Amendment" letter to the applicant (it 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 necessary to remove the deficiency(s) is submitted during the 30-day comment period, the RS should process the package as described in the section above.

5. Final Decision to Accept or Deny

After the 30-day public comment period is complete, final decisions to accept, conditionally accept, or deny acceptance is taken.

Process for Registering a Label Amendment (non-conditional)

If the label amendment is supported, the RS should:

- Verify that all items have been received

- 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 concurrently submitted to DPR and 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 re-submitted into evaluation. If additional data are required, post the registration "30-to Deny."

If all items are submitted and acceptable, the amendment can be accepted. The RS should:

- Stamp 3 labels with the appropriate acceptance stamp (a fourth copy may be retained by the RS). Write "Product File," "Coding," and "Company," along with the tracking ID# in the upper right-hand corner of each label respectively. The added use sites, pests, etc. must be highlighted in yellow on the label marked "Coding." The product file label will be tagged and placed in the back of the product file in the Registration Resource Center by the appropriate staff member once processed. An additional copy should be made if requested by the company agent.

- If the RS chooses to highlight the new material on the amended label, the highlighting must be in yellow.

- Fill out the upper right-hand portion of the application

- Prepare a letter to the registrant (using the correct, full company name) accepting the label amendment. If the company agent has requested a copy of the label and approval letter, include a copy with the word "Agent" written in the upper right-hand corner. At the bottom of the letter, add "cc: <NAME OF AGENT>, <AGENT'S COMPANY NAME> (w/ enclosure)

- Print 3 copies on white paper and 1 copy on the yellow surname paper.

- Write "Product File" on the yellow copy, "Coding" and "Cover Letter File" on two of the white copies respectively. Provide

and additional white paper copy for the agent if applicable.

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign one copy of the letter. This copy will be sent to the registrant.

- Surname the yellow copy and write "Product File" in the upper right-hand corner.

Assemble for the Registrant

- Clip together the signed copy of the letter, envelope, and the approved label designated "Company." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Product File

- The application form and new/revised CSF (if applicable). 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.

- Other pertinent documents including but not limited to the U.S. EPA stamped accepted label, U.S. EPA notification forms, application forms, etc.

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

Assemble for Coding

- Clip together a copy of the letter designated "Coding," a copy of the label (**with amended areas highlighted in yellow**), a copy of the CSF (if applicable) and a copy of the status sheet - in that order. **Include only** a representative label if there are multiple labels submitted (colors, sizes, graphics, etc.).

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

Assemble for the Cover letter file

- Write "Cover Letter File" in the upper right-hand corner of the original cover letter (or a copy) and clip together with a copy of the company letter

Assemble for the Agent (if applicable)

- Clip together a copy of the letter, envelope, and the approved label designated "Agent." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Note: If someone other than a company representative (such as a consultant) submits the application, a duplicate copy of the letter and an envelope should be prepared. **It is important that the original company letter reflect the correct company name** because it directs the designated staff person to file the information in the appropriate product file. Use of a consultant's company name on the main letter misleads the person filing the paperwork.

Once complete, the RS should clip together all individual sections listed above (registrant, product file, coding, cover letter, and agent – in this order), submit to his/her supervisor (do not include the colored folder) and record the tracking ID# on his/her action log in the "**Final Register**" column. The colored folder should be returned to the designated folder area.

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

Process for Accepting a Label Amendment Conditionally

After posting the label amend for public comment, and upon receipt of written agreement from the applicant agreeing to conduct the required data, the RS should:

- 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 re-submitted into evaluation. If additional data are required, post the registration "30-to- Deny."

If all items are submitted and acceptable, the amendment can be accepted. The RS should:

- Stamp 3 labels with the appropriate acceptance stamp (a fourth copy may be retained by the RS). Write "Product File," "Coding," and "Company," along with the tracking ID# in the upper right-hand corner of each label respectively. The added use sites, pests, etc. must be highlighted in yellow on the label marked "Coding." The product file label will be tagged and placed in the back of the product file in the Registration Resource Center by the appropriate staff member once processed. An additional copy should be made if requested by the company agent.

- If the RS chooses to highlight the new material on the amended label, the highlighting must be in yellow

- Fill out the upper right-hand portion of the application and stamp "Conditional" on the top, middle section

- Prepare a form letter to the registrant (using the correct, full company name), identifying each of the conditions and timeframe(s). Attaching copies of the evaluation report(s) is not a substitute for listing the conditions and timeframes in the letter. If the company agent has requested a copy of the label and approval letter, include a copy with the word "Agent" written in the upper right-hand corner. At the bottom of the letter, add "cc: <NAME OF AGENT>, <AGENT'S COMPANY NAME> (w/ enclosure)

- Print 4 copies on white paper and 1 copy on the yellow surname paper. Write "Product File" on the yellow copy, "Coding," "Cover Letter File," and "Licensing" on the white copies respectively. Provide an additional white paper copy for the agent if applicable.

- Sign one copy of the letter. This copy will be sent to the registrant. Surname the yellow copy. This copy remains in the product file.

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

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

Assemble for the Registrant

- Clip together the signed copy of the letter, envelope, and the approved label designated "Company." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Assemble for the Product File

- The application form and new/revised CSF (if applicable). 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.

- Other pertinent documents including but not limited to the U.S. EPA stamped accepted label, U.S. EPA notification forms, application forms, etc.

- 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.

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

Assemble for Coding

- Clip together the copy of the letter designated "Coding," a copy of the label (**with amended areas highlighted in yellow**), a copy of the CSF (if applicable) and a copy of the status sheet - in that order. **Include only** a representative label if there are multiple labels submitted (colors, sizes, graphics, etc.).

  Note: Additional copies of alternate formulas should not be

included (i.e. the company has submitted one basic CSF and 3 alternates)

Assemble for Conditional Binder

- Clip together the copy of the letter designated "Licensing" and the evaluation report(s). This letter will indicate to Licensing that a new conditional license needs to be produced. The letter, license, and evaluation report will eventually be placed into the Conditional Binder.

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)

- Clip together a copy of the letter, envelope, and the approved label designated "Agent." If there are multiple labels (colors, sizes, graphics, etc.) clip them together.

Note: If someone other than a company representative (such as a consultant) submits the application, a duplicate copy of the letter and an envelope should be prepared. **It is important that the original company letter reflect the correct company name** because it directs the designated staff person to file the information in the appropriate product file. Use of a consultant's company name on the main letter misleads the person filing the paperwork.

Once complete, the RS should clip together all individual sections listed above (registrant, product file, coding, conditional binder, cover letter, and agent – in this order), submit to his/her supervisor (do not include the colored folder) and record the tracking ID# on his/her action log in the "**Final Register**" column. The colored folder should be returned to the designated folder area.

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.

The Licensing Technician will amend the current license to identify that the product no longer has full registration but a conditional registration

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.

.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. The colored folder should be returned to the designated folder area.

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

Process for Denying a Product

If the data do not support the amendment, the RS should:

- Verify that the deficient data/items have not been submitted
- Prepare a letter to the applicant notifying them that the amendment has been denied, a surname copy, and an envelope, and submit to his/her supervisor
- 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 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 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 to amend his/her product by submitting the following:

- A new Application to Amend Pesticide Product

- The $25 application fee

- All data or information identified as lacking in the previous submission

III. How to Process a Formula Revision (Non-Substantive Change)

Some formula changes do not require data or scientific review, but cannot be processed through the notification process. These are processed as non-substantive changes. The following are examples of non-substantive changes:

- Minor revision or restatement of an ingredient on the CSF
- Change of percentage of active ingredient to the nominal concentration (see PR-Notice 91-2 for information on nominal concentrations) on the CSF

To determine if the revision is non-substantive, the RS should submit the package to the Tracking Coordinator. The Tracking Coordinator will informally route the package to the chemistry evaluation scientists, who will determine if the revisions are non-substantive and document their decision on the route sheet. The package will be submitted back to the Tracking Coordinator, to be signed off on by a Program Manager.

Non-Substantive Change Acceptable

If the change is determined to be non-substantive, the RS should:

- Prepare a letter to the applicant accepting the formula change and identify the date the CSF was stamped-accepted by U.S. EPA, or the date of the application, if the applicant submitted a Product Formulation Sheet (PFS)
- Print an envelope with the appropriate company information on it
- Print 2 copies of the letter and 1 yellow surname copy.
- Clip together the yellow surname copy, the new confidential statement(s) of formula or product formulation sheet(s) and any U.S. EPA documentation if submitted, in that order. Write "Product File" and the tracking ID# in the upper right corner of the CSF and the yellow copy of the letter.
- For the cover letter file, staple a copy of the company letter to the cover letter submitted by the applicant (if received). Write "Cover Letter File" in the upper right hand corner of the letter.

- Record the tracking ID # on the weekly action log under "Non-Substantive Change, FAL, and Notification" column

Non-Substantive Change Not Acceptable

The evaluator may find that the formulation revision is too significant to be accepted as a non-substantive change. U. S. EPA will often issue a new registration number to the product and classify it as a new product, or significant label changes may be required (new labels and data would be required). If the change is determined to be substantive, the RS should:

- Prepare a letter for the applicant explaining why the formulation revision cannot be process as a non-substantive change

- Print 2 white copies and 1 yellow surname copy. Write "Return File" in the upper right-hand corner of one white copy and your last name in the upper right-hand corner of the yellow copy. The surname copy will be returned to the RS once the process is complete.

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½" x 11" or 6"x 9" envelope.

- Sign the applicant letter and surname the yellow copy

- Place the letter designated "Return File" *in* the colored folder, on top of all the submitted documents

- Clip the applicant's return letter, envelope, and yellow surname copy to the front cover of the colored folder.

- Submit the package to his/her supervisor

IV. How to Process a Notification

Certain label changes or a change in source of active ingredient may be submitted using the DPR Notification Process. The criteria for allowed changes are found in California Notice 2002-1. The RS assigned to the company will process these types of changes. These types of changes do not require data or scientific evaluation and should be processed along with all other submissions received by the RS (i.e.,

first in- first out).

When a registrant makes minor changes to their label or formulation that comply with California Notice 2002-1, and they submit their notification of minor changes application to DPR with three revised labels, they do not need to wait for approval from DPR before distributing or selling the product. However, the following items should be noted:

- Notifications must be received by DPR before the registrant can distribute or sell product with the changed label or formulation and must comply with the items described in California Notice 2002-1

- The applicant will receive a DPR response only if the submission does not meet the criteria for notification
- A product distributed or sold with a changed label or formula before DPR receives the notification submission is considered unregistered and subject to enforcement action

- A product distributed or sold with a changed label or formula that was submitted through the DPR Notification process, but does not comply with the criteria, is considered unregistered and subject to enforcement action. This is also the case for non-notification criteria.

A. General Guidance

1. Quick Reference - Items that must be submitted by the Applicant to Support a Notification

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

- Notification of Minor Changes form

- For label revisions, three copies printer's proof or final printed labels

- For formula revisions, one copy of the Application for Registration form (in addition to the Notification of Minor Changes form)

- A copy of the U.S. EPA notification form and any other

documents submitted to U.S. EPA in support of the notification (if required by U.S. EPA)

2. General Intake Process

Intake

Once the Intake Technician receives the notification submission in the mail, he/she should proceed as follows:

- Generate a status sheet that will include information about the notification and currently registered product such as the reason for submission, active ingredient, chemical(s) and DPR chemical code, applicant, and type of registration request. See sample copy in Appendix F.
- Assign a sequential tracking ID# with a "NO" prefix to identify the type of submission
- 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 there is an attention flag (computer assigned) on the status sheet, give the entire sheet to the designated supervisor who will forward the package to the Indexing Technician or the Regulatory Scientist

Memo:
10-25-94

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

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.

3. Items that should be Included with the Product Submission

a) Status Sheet

A status sheet should accompany all notifications. 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! 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

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. This is especially important for notifications because it can provide the RS with a detailed description of the changes being made.

c) Complete Notification of Minor Changes **form (**39-031**)**

The form must be filled out and signed. The firm name and address shown on the form must be consistent with federal documentation (unless the product is an adjuvant). The application form must be signed and dated by an authorized representative.

3 CCR 6170.1, 6170.5, and 6157

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 97-6 and 99-4

CA Notice 2009-5

Memo: 8-31-98

The RS must revise the status sheet and any other pertinent documentation before the product is posted 30-to Register.

The brand name on the form must be the same as the name shown on the label and consistent with federal documentation.

d) Application Fee

A $25 application feel must accompany all label amendments.

e) A copy of the U.S. EPA Application for Pesticide Registration/Amendment (Notification form) (8570-1) **or related documents (if applicable)**

If required by U.S. EPA, the applicant must submit a copy of the U.S. EPA Application for Pesticide Registration/Amendment (notification) form with their submission to DPR. As previously noted, the RS should be familiar with those items that can and cannot be submitted by notification to U.S. EPA by reviewing PR-Notice 98-10.

U.S. EPA PR-Notice 98-10

f) Label Revisions Only - Three Copies of Printer's Proof or Final Printed Labels

Registrants must submit 3 copies printer's proof, final printed labels, or copies thereof **if submitting a label revision** by notification. Submitted labels must be identical to the latest stamped-accepted DPR label with only those revisions identified on the notification form. 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) Formula Revisions Only - Application for Pesticide Product Registration (form 39-030)

For **formula revisions** allowed by notification, the applicant must also submit a copy of the general Application for Pesticide Product Registration form. In lieu of filling out items 20 through 29 only, the applicant may attach a copy of their federal Confidential Statement of Formula (CSF).

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 amendment is approved.

B. Processing a Notification

To process a label or formula revision through the notification process, the RS should:

- Review the U.S. EPA documentation to identify the revisions being made (if applicable)
- Compare the proposed label or CSF to the label or CSF currently on file and confirm there are no revisions other than those identified on the Notification of Minor Changes form
- Confirm that the revisions being made through the notification process comply with CA Notice 2002-1.

Label or Formulation Revision Acceptable Through Notification

If the labels are identical, other than the specified changes, and the changes are allowed through notification, the RS should:

- Stamp one label with the appropriate notification stamp and fill in the necessary information (do not stamp the CSF)
- Write “Product File” in the top right corner of both the label (or CSF)
- Write “Product File” and fill out the required information in the top right corner of the “Notification of Minor Changes” form
- Clip the “Notification of Minor Changes” form, label (or CSF), and U.S. EPA documentation (when applicable) together, and place the packet in the designated “Product File”

box. If the company sent a cover letter and it contains pertinent information not covered on the application, place it in the back of the package.

- Enter the tracking ID# in the "NON-SUB CHANGE & FAL" column on his/her action log

DO NOT write a letter to the company.

Label Resource Center staff will file the documents in the appropriate product file.

Label or Formulation Revision Not Acceptable Through Notification

If the revision(s) to the product label is/are not acceptable through notification, determine:

- Whether the revised label or CSF can be processed as a label amendment or non-substantive change "as is;"

- Whether the revised label or CSF can be processed as a label amendment or non-substantive change with a minor amount of additional information from the company; or

- Whether a major amount of additional information is needed from the company to process the label or formula revision, and therefore, the submission must be returned.

If the package as submitted **can be processed** as an amendment or non-substantive change "as is" or with a minor amount of additional information that can be obtained by a phone call or e-mail request to the registrant, the RS should:

- Cross off the "NO" prefix on the status sheet. Make a copy of the amended status sheet (sign and date the change) and place in the appropriate "Notification's" box (not the status sheet corrections box).
- Prepare a letter to the applicant using the appropriate form letter. Include a description as to why the change did not meet the notification criteria.

- Process the submission as an amendment or non-substantive change (follow directions in this Chapter)

If the submission requires a major amount of additional information (i.e., data, a fee, six copies of the label, or other information that would normally result in a return of a label or amendment submission) and **cannot be processed** as either a notification or an amendment, the RS should:

- Prepare a letter to the registrant using the appropriate form letter. Include a description as to why the change did not meet the notification criteria.

- Print 2 white copies and 1 yellow surname copy. Write “Return File” in the upper right-hand corner of one white copy and his/her last name in the upper right-hand corner of the yellow copy. The surname copy will be returned to the RS once the process is complete

- Print an envelope with the appropriate company information. If there are more than 7 pages to be sent out, use an 8½” x 11” or 6”x 9” envelope.

- Sign the applicant letter and surname the yellow copy

- Place the letter designated “Return File” *in* the colored folder, on top of all the submitted documents

- Clip the applicant’s return letter, envelope, and yellow surname copy to the front cover of the colored folder

- Submit the package to his/her supervisor

Note: A designated staff person, not the RS, takes the action on a return package. **The tracking ID# is not placed on the weekly action log by the RS.**

V. FIFRA Section 2ee Statements

Printed statements produced by a company in accordance with **FIFRA Section 2(ee)** are not required by DPR, nor are they a part of the label acceptance process or the notification process. If a registrant chooses to submit printed claims allowed by FIFRA Section 2(ee), shred the submission and inform the company that such information need not be submitted to DPR. Examples of 2(ee) acceptable statements are outlined in U.S. EPA's Label Review Manual.