The Pesticide Registration Branch

Desk Manual Chapter 3

2013

California Department of Pesticide Regulation

Chapter

3

Data Requirements

I. Introduction

This section contains data requirements for obtaining product registrations and label amendments. All studies required, with the exception of certain product chemistry studies, must be submitted in full. In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product.

Federal data requirements are found in 40 CFR, Part 158. Guidelines for conducting the tests are found in OPPTS Series 810 through 885 and U.S. EPA's Pesticide Assessment Guidelines. DPR data requirements are found in Food and Agricultural Code sections 13121-13152, and Title 3 of the California Code of Regulations, sections 6159, and 6170 through 6200.

II. Study Report Acceptability

Study reports must be written and include all necessary information. The form used in scientific report writing (i.e., introduction, procedures and methods, results, conclusion, and discussion) is the style most preferred. The information must be presented in a clear and concise manner. For a report to be acceptable, it must be dated and signed by the person responsible for the study, and should include information on when, where, how the study was conducted, and the results of the study.

A brief report or testimonial letter only, stating that a study was conducted with favorable results, is usually not acceptable.

III. Good Laboratory Practice (GLP)

U.S. EPA requires GLP for studies submitted to support federal registration. GLP refers to the specific methods used to document a study and how the study was conducted. GLP is encouraged, but not required by DPR. Applicants should be advised to conduct the study using GLP if they intend to submit the study to U.S. EPA.

IV. Basic Data Requirements

Data requirements for FIFRA, section 18 emergency exemptions and FIFRA, section 24(c) Special Local Needs can be found in Chapter 4 of this manual.

The conditional registration may not be renewed unless this report is submitted with the renewal application.

To process additional data received to meet specified conditions, follow procedures in Chapter 8 under "Changing a Conditional Registration to a Full Registration."

A. New Active Ingredients

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data requirements found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH

- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for new active ingredients have been listed below. This should be used as a quick-guide only. If data requirements for a particular product are not identified, or if an applicant is unsure which data to develop or how to develop it, they should provide a copy of the draft label and the product formulation sheet (or CSF) to their Regulatory Scientist (RS) who will obtain a determination of the data requirements. The RS will informally route the documents to the predetermined point person at each appropriate evaluation station and the evaluation stations will provide a written summary of what is required to the RS. Informal summaries will be provided to the applicant within 60 days. For companies that have no RS assigned, the request will be routed to the Registration Branch Ombudsman.

Manufacturing Use Only Products

Conventional & Home/Garden Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-355

Antimicrobials (40 CFR, Part 161)

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340 FAC section 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190

Biochemicals (40 CFR, Part 158)

Acute Toxicology	Subpart U: Human Health Assm.158.2050
Chronic Toxicology	Subpart U: Human Health Assm.158.2050 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030

Microbials (40 CFR, Part 158)

Acute Toxicology	Subpart V: Toxicology 158.2140
Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC section 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120

Conventional Products for Commercial End-Use (e.g., agricultural) (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510,
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510, FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-355
Environmental fate (AB 2021) (First agricultural use only)	Subpart N: Environmental Fate 158.1300 FAC section 13141-13152
Product Performance*	Subpart E: Product Performance 158.400, 3 CCR section 6186
Ecological Effects	
Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms, 3 CCR section 6187, 3 CCR 6192
Human Exposure (if applicable)	Subpart K: Human Exposure 158.1000-1070, 3 CCR section 6176, 6177, 6183
Spray Drift (if applicable)	Subpart L: Spray Drift 158.1100, 3 CCR section 6192

TGA data (liquid agricultural products)	3 CCR section 6191

Antimicrobial End-Use Products (40 CFR, Part 161)

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 158 Part W for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

It should also be noted that antimicrobial products that are classified as biochemicals should follow the data requirements listed under the biochemicals section listed below.

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340 FAC section 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190
Product Performance	Subpart D: Product Performance 161.640 3 CCR section 6186
Human Exposure (if applicable)	Subpart D: Reentry Protection 161.390 3 CCR section 6176, 6177, 6183

Home and Garden End-Use Products (40 CFR, Part 158)

Note: this section does not include antimicrobial products for home use. See section above for home-use antimicrobial product data requirements.

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355
Environmental fate (Residential Outdoor – very limited)	Subpart N: Environmental Fate 158.1300
Product Performance*****	Subpart E: Product Performance 158.400 3 CCR section 6186
Ecological Effects Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms, 3 CCR section 6187, 3 CCR section 6192
Human Exposure (if applicable)	Subpart K: Human Exposure 158.1000-1070, 3 CCR sections 6176, 6177, 6183

Biochemical End-Use Products (40 CFR, Part 158)

Note: this section includes all products that are classified as biochemical end-use products (home use, conventional, antimicrobial) but does not include biochemical products registered under an experimental use permit (EUP). EUP biochemical product data requirements are listed below.

Acute Toxicology	Subpart U: Human Health Assm 158.2050
Chronic Toxicology	Subpart U: Human Health Assm 158.2050 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030
Product Performance*	Subpart U: Product Performance 158.2070 3 CCR section 6186

Non-Target Organisms and Environmental Fate	
Phytotoxicity (if applicable)	Subpart U: Non-Target Plant Protection 158.2060, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart U: Non-target Organisms 158.2060, 3 CCR section 6187, 3 CCR section 6192
Environmental Fate (AB 2021))	Subpart U: Environmental Fate 158.2060 FAC section 13143
Human Exposure (if applicable)	Subpart U: Human Health Assm.158.2050 3 CCR section 6176, 6177, 6183

Note: If the product contains a lepidopteron pheromone, only chemistry and product performance must be submitted.

Note: It should be noted that the data requirements for biochemical and microbial products are often determined at "pre-registration" between the company and U.S. EPA. Applicants are encouraged to discuss data requirements with DPR prior to submitting their applications for registration.

Microbial End-Use Products (40 CFR, Part 158)

Note: this section includes all products that are classified as microbial end-use products (home use and conventional) but does not include microbial products registered under an experimental use permit (EUP). EUP microbial product data requirements are listed below.

Acute Toxicology	Subpart V: Toxicology 158.2140
Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC section 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120
Product Performance*	Subpart V: Product Performance 158.2160 3 CCR section 6186
Non-Target Organisms and Environmental Fate	
Phytotoxicity (if applicable)	Subpart V: Non-Target Plant Protection 158.2160, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart V: Non-target Organisms 158.2150 3 CCR section 6187, 3 section CCR 6192

Environmental Fate (if applicable)	Subpart V: Environmental Fate 158.2150 FAC section 13143

Note: It should be noted that the data requirements for biochemical and microbial products are often determined at "pre-registration" between the company and U.S. EPA. Applicants are encouraged to discuss data requirements with DPR prior to submitting their applications for registration.

Experimental Use Products (40 CFR, Part 158)

EUP Conventional Products for Commercial Use

Acute Toxicology	Subpart C: Toxicology 158.230
Chronic Toxicology	Subpart C: Toxicology 158.230, FAC section 13121-13135
Product Chemistry	Subpart C: Chemistry 158.210
Environmental fate (AB 2021) (Agricultural use only)	Subpart C: Environmental Fate 158.260 FAC section 13143
Ecological Effects Fish and Wildlife (if applicable)	Subpart C: Non-target Organisms 158.240 and 158.243, 3 CCR section 6187, 3 CCR section 6192
Product Performance (very limited)	Subpart C: Product Performance 158.220 3 CCR section 6186

EUP Biochemical Products

Acute Toxicology	Subpart U: Human Health 158.2083
Chronic Toxicology	Subpart U: Human Health 158.2083 FAC 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2081-2082
Non-Target Organisms and Environmental Fate Fish and Wildlife	Subpart U: Non-target Organisms 158.2084 3 CCR section 6187, 3 CCR section 6192

Note: If the product contains a lepidopteron pheromone, only chemistry and efficacy are required.

EUP Microbial Products

Acute Toxicology 158.2173	Subpart V: Toxicology
Chronic Toxicology 158.2173	Subpart V: Toxicology FAC section 13121-13135
Product Chemistry 158.2171 &	Subpart V: Product Analysis 158.2172
Non-Target Organisms and Environmental Fate	
Phytotoxicity (if applicable) Testing	Subpart V: Non-Target Plant 158.2174, 3 CCR section 6192
Fish and Wildlife Organisms 158.2174	Subpart V: Non-target 3 CCR section 6187, 3 CCR section 6192

Note: If the product contains a lepidopteron pheromone, only chemistry and efficacy are required.

* U.S. EPA has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration.

Test Guidelines

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It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158 or Part 161. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

Environmental Chemistry guidelines (formerly Subdivision N) are not available on U.S. EPA's website but can be found by choosing the following link: Environmental Chemistry

Certain antimicrobial data guidelines (formerly Subdivision G) are also not available on- line, but can be accessed by selecting the following link: Antimicrobials.

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by

U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics

- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for conventional products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355

End-Use Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355
Environmental fate (AB 2021) (First agricultural use only)	Subpart N: Environmental Fate 158.1300 FAC section 13141-13152

Product Performance* Performance 158.400	Subpart E: Product 3 CCR section 6186
Ecological Effects Phytotoxicity Protection	Subpart G: Nontarget Plant 158.660, 3 CCR section 6192
Fish and Wildlife Terrestrial and Aquatic	Subpart G: 158.630 Nontarget Organisms, 3 CCR section 6187, 3 CCR section 6192
Human Exposure (if applicable)	Subpart K: Human Exposure 158.1000-1070, 3 CCR section 6176, 6177, 6183
Spray Drift (if applicable) 158.1100,	Subpart L: Spray Drift 3 CCR section 6192
TGA data (liquid agricultural products)	3 CCR section6191

***** U.S. EPA has waived the requirement to submit product performance data (efficacy) unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration.

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Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by

reviewing the data requirements described in 40 CFR, Part 158. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

Environmental fate guidelines (formerly Subdivision N) are not available on U.S. EPA's website but can be found by choosing the following link: Environmental fate

B. Home and Garden Products

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

Note: This section does not include data requirements for biopesticides or antimicrobial products. All biopesticide products are covered in section D and antimicrobial products are covered in section E of this chapter.

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by

U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage

- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for home and garden products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355

End-Use Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355
Environmental fate (Residential Outdoor – very limited)	Subpart N: Environmental Fate 158.1300
Product Performance*	Subpart E: Product Performance 158.400 3 CCR section 6186

Ecological Effects	
Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms 3 CCR section 6187, 3, CCR section 6192

Note: The Pesticide Registration Branch normally waives Terrestrial and Aquatic Nontarget Organisms (Fish and Wildlife) data with the exception of rodenticide and avicide products.

Note: The Pesticide Registration Branch normally waives Terrestrial and Aquatic Nontarget Organisms (Fish and Wildlife) data with the exception of rodenticide and avicide products.

* U.S. EPA has waived the requirement to submit product performance data (efficacy) unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration.

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

C. Biopesticide Products

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics

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- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part161 (antimicrobials).

For guidance, general data requirements for biopesticide products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Products (40 CFR, Part 158) Biochemicals

Acute Toxicology	Subpart U: Human Health Assm.158.2050
Chronic Toxicology	Subpart U: Human Health Assm.158.2050 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030

Microbials

Acute Toxicology	Subpart V: Toxicology 158.2140
Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC section 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120

End-Use Products (40 CFR, Part 158) Biochemical End-Use Products

Acute Toxicology	Subpart U: Human Health Assm.158.2050

Chronic Toxicology	Subpart U: Human Health Assm.158.2050 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030
Product Performance*	Subpart U: Product Performance 158.2070 3 CCR section 6186

Non-Target Organisms and Environmental Fate

Phytotoxicity (if applicable)	Subpart U: Non-Target Plant Protection 158.2060, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart U: Non-target Organisms 158.2060 3 CCR section 6187, 3 CCR section 6192
Environmental Fate (AB 2021)	Subpart U: Environmental Fate 158.2060 FAC section 13141-13152
Human Exposure	Subpart U: Human Health Assm.158.2050 3 CCR section 6176, 6177, 6183

Note: If the product contains a lepidopteron pheromone, only chemistry and efficacy must be submitted.

Microbial End-Use Products

Acute Toxicology	Subpart V: Toxicology 158.2140
Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC section 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120
Product Performance*	Subpart V: Product Performance 158.2160 3 CCR section 6186

Non-Target Organisms and Environmental Fate

Phytotoxicity (if applicable)	Subpart V: Non-Target Plant Protection 158.2160, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart V: Non-target Organisms 158.2150 3 CCR 6187, 3 CCR 6192
Environmental Fate (if applicable)	Subpart V: Environmental Fate 158.2150

FAC section 13143

Note: It should be noted that the data requirements for biochemical and microbial products are often determined at "pre-registration" between the company and U.S. EPA. Applicants are encouraged to discuss data requirements with DPR prior to submitting their applications for registration.

* U.S. EPA has waived the requirement to submit product performance data (efficacy) unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration.

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158 or through pre-registration meetings. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

D. Antimicrobial Products

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

Note: Antimicrobial products that are classified as biochemicals are not included in this section. Registrants should follow the data requirements listed under the biochemicals section (Part D).

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 158 Part W for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
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- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial

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products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for antimicrobial products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340 FAC section 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190

End-Use Products

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340 FAC section 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190
Product Performance	Subpart D: Product Performance 161.640 3 CCR section 6186
Human Exposure (if applicable)	Subpart D: Reentry Protection 161.390 3 CCR section 6176, 6177, 6183

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 161. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

Certain antimicrobial data guidelines (formerly Subdivision G) are not available on-line but can be accessed through the following link: Antimicrobials.

E. Adjuvant Products

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 and 40 CFR, Part 161) substantially meet California data requirements, with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements." **However, adjuvants do not require federal registration and are only subject to the data requirements identified in 3 CCR, which are more limited.**

If an applicant is unsure which data to develop or how to develop it, they should provide a copy of the draft label and the product formulation sheet (or CSF) to their Regulatory Scientist (RS) so the data requirements can be determined. The RS will informally route the documents to the predetermined point person at each appropriate evaluation station and the evaluation stations will provide a written summary of what is required to the RS. Informal summaries will be provided to the applicant within 60 days. For companies that have no RS assigned, the request will be routed to the Pesticide Registration Branch Ombudsman.

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color

- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product.

For guidance, general data requirements for adjuvant products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products

Acute Toxicology	3 CCR section 6179
Product Chemistry	3 CCR section 6192

End-Use Products

Acute Toxicology	3 CCR section 6179
Product Chemistry	3 CCR section 6192
Product Performance (efficacy)	3 CCR section 6186

pH control buffers: Data must show how much product is required to buffer 100 gallons of water having hardness equivalent to 175 ppm as calcium carbonate to the pH recommended on the label, except for swimming pool products. If no pH is recommended on the label, then pH may be used as the criteria, except for swimming pools. Buffering capacity for other pHs may be requested in some cases.

Drift Control: Data showing control achieved and giving conditions of the test must be submitted. For this requirement, data must show how many feet less the spray drifts when used at minimum label recommended rate, compared to without it. The trials with and without the drift control formulation must use the same equipment and conditions and preferably run on the same day. Alternative methods of demonstrating drift control that are acceptable to DPR may be used.

Test Guidelines

Although U.S. EPA does not consider adjuvants pesticides, registrants are encouraged to conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. They may also seek assistance from DPR staff; preferably at the same time they seek advice on which studies are required. U.S. EPA's test guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

F. Supplemental Distributor Products

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in40 CFR, Part 158 (conventional, biochemical, and microbial products) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for supplemental distributor products have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products

Conventional & Home/Garden Products (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-355

Antimicrobials (40 CFR, Part 161)

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340 FAC section 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190

Biochemicals (40 CFR, Part 158)

Acute Toxicology	Subpart U: Human Health Assm.158.2050
Chronic Toxicology	Subpart U: Human Health Assm.158.2050 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030

Microbials (40 CFR, Part 158)

Acute Toxicology	Subpart V: Toxicology 158.2140
Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120

Conventional Products for Commercial End-Use (40 CFR, Part 158)

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510,
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510, FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-355
Environmental fate (AB 2021/Ag only)	Subpart N: Environmental Fate 158.1300 FAC section 13143
Product Performance*	Subpart E: Product Performance 158.400, 3 CCR section 6186
Ecological Effects Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms, 3 CCR section 6187, 3 CCR section 6192
Human Exposure (if applicable)	Subpart K: Human Exposure 158.1000-1070, 3 CCR section 6176, 6177, 6183
Spray Drift (if applicable)	Subpart L: Spray Drift 158.1100, 3 CCR section 6192
TGA data (liquid agricultural products)	3 CCR, section section 6191

Antimicrobial End-Use Products (40 CFR, Part 161)

Title 3 of the California Code of Regulations (3 CCR) provides that data required by U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 158 Part W for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

It should also be noted that antimicrobial products that are classified as biochemicals should follow the data requirements listed under the biochemicals section listed below.

Acute Toxicology	Subpart D: Toxicology 161.340
Chronic Toxicology	Subpart D: Toxicology 161.340

	FAC 13121-13135
Product Chemistry	Subpart C: Product Chemistry 161.150-190
Product Performance	Subpart D: Product Performance 161.640 3 CCR 6186
Human Exposure (if applicable)	Subpart D: Reentry Protection 161.390 3 CCR 6176, 6177, 6183

Home and Garden End-Use Products (40 CFR, Part 158)

Note: this section does not include antimicrobial products for home use. See section above for home-use antimicrobial product data requirements.

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355
Environmental fate (Residential Outdoor – very limited)	Subpart N: Environmental Fate 158.1300
Product Performance*	Subpart E: Product Performance 158.400 3 CCR 6186
Ecological Effects	
Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms, 3 CCR 6187, 3 CCR 6192
Human Exposure (if applicable) 1070	Subpart K: Human Exposure 158.1000- 3 CCR 6176, 6177, 6183

Biochemical End-Use Products (40 CFR, Part 158)

Note: this section includes all products that are classified as biochemical end-use products (home use, conventional, antimicrobial) but does not include biochemical products registered under an experimental use permit (EUP). EUP biochemical product data requirements are listed below.

Acute Toxicology	Subpart U: Human Health Assm 158.2050
Chronic Toxicology	Subpart U: Human Health Assm 158.2050 FAC 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2030
Product Performance*	Subpart U: Product Performance 158.2070 3 CCR 6186

Non-Target Organisms and Environmental Fate

Phytotoxicity (if applicable)	Subpart U: Non-Target Plant Protection 158.2060, 3 CCR 6192
Fish and Wildlife (if applicable)	Subpart U: Non-target Organisms 158.2060 3 CCR 6187, 3 CCR 6192
Environmental Fate (if applicable)	Subpart U: Environmental Fate 158.2060 FAC 13143
Human Exposure (if applicable)	Subpart U: Human Health Assm.158.2050 3 CCR 6176, 6177, 6183

Note: If the product contains a lepidopteron pheromone, only chemistry and product performance must be submitted.

Note: It should be noted that the data requirements for biochemical and microbial products are often determined at “pre-registration” between the company and U.S. EPA. Applicants are encouraged to discuss data requirements with DPR prior to submitting their applications for registration.

Microbial End-Use Products (40 CFR, Part 158)

Note: this section includes all products that are classified as microbial end-use products (home use and conventional) but does not include microbial products registered under an experimental use permit (EUP). EUP microbial product data requirements are listed below.

Acute Toxicology	Subpart V: Toxicology 158.2140

Chronic Toxicology	Subpart V: Toxicology 158.2140 FAC 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2120
Product Performance*	Subpart V: Product Performance 158.2160 3 CCR 6186
Non-Target Organisms and Environmental Fate:	
Phytotoxicity (if applicable)	Subpart V: Non-Target Plant Protection 158.2160, 3 CCR 6192
Fish and Wildlife (if applicable) 158.2150	Subpart V: Non-target Organisms 3 CCR 6187, 3 CCR 6192
Environmental Fate (if applicable)	Subpart V: Environmental Fate 158.2150 FAC 13143

Note: It should be noted that the data requirements for biochemical and microbial products are often determined at "pre-registration" between the company and U.S. EPA. Applicants are encouraged to discuss data requirements with DPR prior to submitting their applications for registration.

***** U.S. EPA has waived the requirement to submit product performance data (efficacy) unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration.

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

Environmental fate guidelines (formerly Subdivision N) are not available on U.S. EPA's website but can be found by choosing the following link: Environmental fate

G. Interim Registrations

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by

U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

Since interim registrations are issued for conventional agricultural products, the data requirements are identical to those identified for conventional products for commercial use with the following exception: three of the efficacy or environmental fate studies specified below may be deferred to a later date.

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability

- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for interim registrations have been listed below. This should be used as a quick-guide only.

Manufacturing Use Only Products (Never be granted as an interim registration)
End-Use Products

Acute Toxicology	Subpart F: Toxicology 158.500 & 158.510
Chronic Toxicology	Subpart F: Toxicology 158.500 & 158.510 FAC section 13121-13135
Product Chemistry	Subpart D: Product Chemistry 158.300-158.355
Product Performance*	Subpart E: Product Performance 158.400 3 CCR section 6186 (unless deferred)
Environmental fate (AB 2021)	Subpart N: Environmental Fate 158.1300 FAC section 13143 (3 studies may be deferred)
Ecological Effects	

Phytotoxicity (if applicable)	Subpart G: Nontarget Plant Protection 158.660, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart G: 158.630 Terrestrial and Aquatic Nontarget Organisms, 3 CCR section 6187, 3 CCR section 6192
Human Exposure (if applicable) 1070	Subpart K: Human Exposure 158.1000- 3 CCR 6176, 6177, 6183
Spray Drift (if applicable)	Subpart L: Spray Drift 158.1100, 3 CCR section 6192
TGA data (liquid agricultural products)	3 CCR section 6191

***** U.S. EPA has waived the requirement to submit product performance data (efficacy) unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Therefore, all efficacy data requirements other than those listed above have been removed from 40 CFR, Part 158.

Note: this does not excuse the applicant from submitting product performance data in California. Product performance data is required for all products submitted to DPR for registration, unless deferred under an interim registration.

Note: The Director may defer up to three of the following studies:

- Efficacy studies pursuant to FAC section 12824
- KOW (octanol water partition coefficient) pursuant to paragraph (3) of subdivision (a) of FAC section 13143
- Soil photolysis pursuant to paragraph (6) of subdivision (a) of FAC section 13143
- A field dissipation study pursuant to paragraph (6) of subdivision (a) of FAC section 13143
- A study pursuant to subdivision (a) of FAC 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

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

Environmental fate guidelines (formerly Subdivision N) are not available on U.S. EPA's website but can be found by choosing the following link: Environmental fate

H. Emergency Registrations

Data Requirements

Emergency registrations may be issued for any type of pesticide product (i.e., agricultural, antimicrobial, etc.). Therefore, the data requirements will vary. The applicant must determine which category the product falls under and determine the applicable data requirements listed in this chapter.

I. Structural Devices

Data Requirements

All structural devices must be supported by safety and efficacy data. They must also submit structural integrity data including a wood damage study generated using their device.

Test Guidelines

There are currently no test guidelines for devices. However, the following should be noted:

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 promotional materials.

The registrant should contact our Plant Disease Prevention (PDP) scientists for guidance on developing efficacy data, and Harvard Fong or the current Industrial Hygienist in the Worker Health and Safety Branch for guidance on developing safety data.

J. Master Labels

Data Requirements

Master Labels may be submitted for multiple types of pesticide products (i.e., agricultural, antimicrobial, etc.). Therefore, the data requirements will vary. The applicant must determine which category the product falls under and determine the applicable data requirements listed in this chapter.

K. 25(b) Products that Require Registration in California

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by

U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled “Supplemental Data Requirements.”

However, certain products that are exempt from federal registration are not exempt from registration in California. Products that do not require federal registration are only subject to the data requirements identified in 3 CCR, which are more limited.

If an applicant is unsure which data to develop or how to develop it, they should provide a copy of the draft label and the product formulation sheet (or CSF) to their Regulatory Scientist (RS) so the data requirements can be determined. The RS will informally route the documents to the predetermined point person at each appropriate evaluation station and the evaluation stations will provide a written summary of what is required to the RS. Informal summaries will be provided to the applicant within 60 days. For companies that have no RS assigned, the request will be routed to the Pesticide Registration Branch Ombudsman.

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product.

For guidance, general data requirements for FIFRA, section 25(b) products have been listed below. This should be used as a quick-guide only. It is advised that the applicant seek advice from DPR regarding the required data for their product prior to submitting an application for registration.

End-Use Products

Acute Toxicology	3 CCR section 6192
Chronic Toxicology	FAC section 13121-13135
Product Chemistry	3 CCR section 6192
Product Performance (Efficacy)	3 CCR section 6186

Note: Environmental fate data is generally not required for FIFRA, section 25(b) products. However, chronic toxicology data (SB 950) is required, unless the data has been waived.

Test Guidelines

Although the above mentioned products do not require federal registration, registrants are encouraged to conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. They may also seek assistance from DPR staff; preferably at the same time they seek advice on which studies are required. U.S. EPA's test guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

L. Experimental Use Permits

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

Data Requirements

Title 3 of the California Code of Regulations (3 CCR) provides that data required by

U.S. EPA regulations (40 CFR, Part 158 for conventional, biochemical and microbial products and 40 CFR, Part 161 for antimicrobial products) substantially meet California data requirements, along with additional data found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7, titled "Supplemental Data Requirements."

All studies except certain product chemistry studies must be submitted in full. The following chemistry data can be submitted in list form or as a copy of U.S. EPA's Summary Form of the Physical/Chemical Properties (PR Notice 98-1):

- Color
- Physical State
- Odor
- Oxidation/Reduction: Chemical Incompatibility
- Flammability/Flame Extension
- Explodability
- Miscibility
- Corrosion Characteristics
- Dielectric Breakdown Voltage
- pH
- Viscosity
- Density/Relative Density/Bulk Density
- Product Storage Stability (except microbial products which require submission of the study). Registrants of microbial products who certify that the microbial product consists of killed organisms may submit a summary statement for storage stability.

In lieu of relying on data submitted with an application, the Department may rely upon the evaluations of previously submitted data, regardless of data ownership, to support the registration or amendment of a pesticide product. Federal data requirements are found in 40 CFR, Part 158 (conventional, biochemical, and microbial) and 40 CFR, Part 161 (antimicrobials).

For guidance, general data requirements for interim registrations have been listed below. This should be used as a quick-guide only.

Manufacturing Use Products

Acute Toxicology	Subpart C: Toxicology 158.230

Chronic Toxicology	Subpart C: Toxicology 158.230 FAC section 13121-13135
Product Chemistry (limited)	Subpart C: Chemistry 158.210

End-Use Products

Conventional Products for Commercial Use

Acute Toxicology	Subpart C: Toxicology 158.230
Chronic Toxicology	Subpart C: Toxicology 158.230 FAC section 13121-13135
Product Chemistry (limited)	Subpart C: Chemistry 158.210
Environmental fate (AB 2021) (Agricultural use)	Subpart C: Environmental Fate 158.260 FAC section 13143
Ecological Effects Fish and Wildlife (if applicable)	Subpart C: Non-target Organisms 158.240 and 158.243, 3 CCR section 6187, 3 CCR section 6192
Product Performance (very limited)	Subpart C: Product Performance 158.220 3 CCR section 6186

EUP Biochemical Products

Acute Toxicology	Subpart U: Human Health 158.2083
Chronic Toxicology	Subpart U: Human Health 158.2083 FAC section 13121-13135
Product Chemistry	Subpart U: Chemistry 158.2081-2082

Non-Target Organisms and Environmental Fate	
Fish and Wildlife	Subpart U: Non-target Organisms 158.2084 3 CCR section 6187, 3 CCR section 6192

Note: If the product contains a lepidopteron pheromone, only chemistry and efficacy are required.

EUP Microbial Products

Acute Toxicology	Subpart V: Toxicology 158.2173
Chronic Toxicology	Subpart V: Toxicology 158.2173 FAC 13121-13135
Product Chemistry	Subpart V: Product Analysis 158.2171 & 158.2172
Non-Target Organisms and Environmental Fate	
Phytotoxicity (if applicable)	Subpart V: Non-Target Plant Testing 158.2174, 3 CCR section 6192
Fish and Wildlife (if applicable)	Subpart V: Non-target Organisms 158.2174 3 CCR section 6187, 3 CCR section 6192

Test Guidelines

It is recommended that registrants conduct their product tests according to the guidelines developed by U.S. EPA to minimize variations in testing procedures. A registrant must first determine which studies are required by reviewing the data requirements described in 40 CFR, Part 158. Once they have determined which studies they must conduct, they should review the test guidelines on U.S. EPA's website. These guidelines can be found at http://www.epa.gov/opptsfrs/home/guidelin.htm.

V. Supplemental Data Requirements

DPR may require supplemental data to support the registration or amendment of a pesticide product. Supplemental data may include, but is not limited to, the following:

- Hazards to bees
- Safety related to exposure

- Indoor exposure

Supplemental data requirements can be found in 3 CCR, Chapter 2, Subchapter 1, Article 3, sections 6176-6199.7.

VI. Unique Data Requirements

A. Adverse Effects Disclosure with Application for Renewal

Each application for renewal must include a statement that the applicant has complied with adverse effects disclosure requirements.

If adverse effects disclosure information or data is received with the renewal application, the data or information is forwarded to the Mail Log Technician. The data is assigned a tracking ID#, cataloged into the database, and forwarded to the designated Regulatory Scientist for processing. For more information, please see Chapter 8.

B. Conditional Registration Data for Renewal

The registrant of any conditionally registered pesticide must submit the required data within the specified time frame. An annual report detailing the progress towards development of the data is required for annual renewal of the product registration.

C. Residue Data

As per Califonia Notice 2004-7, the following data is longer required for product registration:

Nature of the Residue in Plants and Livestock

Magnitude of Residue:

Crop Field Trials
Processed Food/Feed
Meat/Milk/Poultry/Eggs
Water, Fish, Irrigated Crops
Food Handling
Storage Stability (Freezer)

Accumulation Studies:

Confined Rotational Crops
Field Rotational Crops

DPR will continue to require the following types of residue data, when applicable to the registration action requested:

Chemical Identity
Direction for Use
Residue Analytical Method
Multiresidue Method
Analytical Reference Standards

In addition, DPR will continue to confirm the existence of a federal tolerance or exemption from the requirement of a tolerance for each food or feed crop listed on the pesticide product label.

Applicants for an Emergency Exemption from Registration (FIFRA section 18) must still provide DPR with sufficient residue data for U.S. EPA to establish a time-limited tolerance.

DPR retains its authority to require an applicant to submit residue data on a case-by-case basis at any time, either during evaluation of a pesticide product or after registration.