Instructions for the Product-Specific Data Call-In
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Chapter 1: Product Reregistration Process and Summary of Instructions

Product Reregistration Process: Once a reregistration Eligibility Decision (RED) for a generic active ingredient is issued, reregistration of products containing the active ingredient begins. The table below helps explain the product reregistration process.

STEP	ACTION
1	EPA issues RED and product-specific Data Call-In (DCI).
2	Registrant responds to DCI by submitting the 90-Day Response.
3	EPA reviews 90-Day Response and answers requests from registrant.
4	Registrant submits application for reregistration, and any needed studies (the Eight Month Response).
5	EPA reviews the Eight Month Response.
6	EPA notifies registrant of results of review. Are product-specific data and the labels acceptable? …….Yes – the product is reregistered * ……. No – EPA may: …… – require the registrant to submit additional or amended information, or …….– proceed with suspension action.

* A product is reregistered only after each active ingredient within the product has become eligible for reregistration.

Responding: The 90-Day Response: Once the RED is issued, product reregistration begins with EPA issuing a product-specific Data Call-In notice (DCI). To satisfy the requirements of this Data Call-in, registrants must respond within 90 days of receipt of this notice. This response is called the 90 Day Response. The following table lists the steps for responding to the DCI.

STEP	ACTION
1	Locate the DCI forms sent with this DCI issuance. ……. Data Call-In Response Form ……. Requirement Status and Registrant's Response Form
2	Read the accompanying instructions.
3	Decide how you will respond.
4	Complete the forms.
5	Requests for time extensions for actual product specific data submissions (normally due at the 8 month response) and/or data waivers must be accompanied by a full justification and submitted as part of this 90-Day Response.
6	Submit forms and time extension requests/data waivers to your Chemical Review Manager (see contact name in DCI Notice Attachment #1).

Note: If your product is a 100% repack of another product registered with EPA, complete and submit only the Data Call-In Response Form as your 90-Day Response to the Agency.

How to Comment on the RED: When the RED is issued, EPA solicits comments on the information and conclusions in the RED. Below is a table that explains the process for commenting on the RED.

STAGE	DESCRIPTION
1	EPA issues the RED.
2	EPA announces RED availability in the *Federal Register* (FR).
3	Interested parties have 60 days to submit comments on the RED document once the FR Notice is published. Comments can be submitted to the Public Docket.
4	EPA Considers the responses and may amend the RED.
5	EPA announces in the FR that the RED is final and describes how comments were addressed.

Responding: The 8 Month Response: The following table lists the steps needed for submitting the 8 Month Response.

STEP	ACTION
1	Locate the Confidential Statement of Formula (CSF) Form 8570-4, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms
2	Complete this form according to the accompanying instructions in Chapter 5 within this document.
3	Your 8 Month Response must contain: • Two copies of the Confidential Statement of Formula form for each basic and alternate formulation. • Application for Reregistration, EPA Form 8570-1, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms • Five copies of the draft labeling revised according to requirements listed in the Fact Sheet. • Certification with Respect to Citations of Data, EPA Form 8570-34, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms • Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data, EPA Form 8570-32, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms • Product-specific Data if required by this Data Call-In Notice.
4	Submit this response within 8 months of receiving this notice.

Note: If your product is a 100% repack of another product registered with EPA, you must submit a Formulator's Exemption Statement, EPA Form 8570-27, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms and the first three items bulleted above under step 3 when you submit your 8 month response to the Agency.

Chapter 2: Instructions For Completing the "Data Call-In Response Form" for the Product-Specific Data Call-In for the 90-Day Response

Task 1. How to Complete Items 1 through 5 of the Data Call-In Response Form

Description: Items 1-5 cover basic information about your products covered by this Data Call- In.

Diagram: This is a diagram of the Product Specific Data Call-In Response for your reference.

<table>
<tr><td colspan="6">United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE</td><td>OMB Approval XXXX-XXXX</td></tr>
<tr><td colspan="7">Instructions: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.</td></tr>
<tr><td colspan="2">1. Company Name and Address
Sample Company
Street Address
City, State, zip code</td><td colspan="2">2. Case # and Name
XXXX Sample Name</td><td colspan="3">3. Date and Type of DCI and Number
02-Mar-2007
Product Specific
ID# PDCI-XXXXXX-XXXXX</td></tr>
<tr><td rowspan="2">4. EPA Product Registration</td><td rowspan="2">5. I wish to cancel the product registration voluntarily</td><td colspan="2">6. Generic Data</td><td colspan="3">7. Product Specific Data</td></tr>
<tr><td>6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below</td><td>6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."</td><td>7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."</td><td>7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."</td></tr>
<tr><td>XXXXXX-XXXX</td><td></td><td>N.A.</td><td>N.A.</td><td></td><td rowspan="2">9. Date</td></tr>
<tr><td colspan="5">8. Certification. I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.
Signature and Title of Company's Authorized Representative</td></tr>
<tr><td colspan="5">10. Name of Company</td><td>11. Phone Number</td></tr>
</table>

Check Information in Items 1-5: Follow these steps for completing items 1-5.

STEP	ACTION
A	Check the accuracy of the preprinted information in item 1 (Company name, number, and address) and item 2 (Case number, case name, EPA chemical number and chemical name).
B	Is the information in items 1 and 2 correct? • If yes, move to step C.

	• If no, pencil in corrections on the form and move to step C. *Note: If your address is not correct, you must also formally change your address by sending a request separate from this action by U.S. mail to the following address:* U.S. Environmental Protection Agency Document Processing Desk (COADR) Office of Pesticide Programs (7504P) 1200 Pennsylvania Avenue, N.W. Washington, DC 20460
C	Look at item 3. Note that this form is entitled "Product Specific". *Note: Product-specific data are from studies conducted on a pesticide product itself (i.e., on the pesticide product after it is formulated).*
D	Check item 4. This item identifies the EPA product registrations affected by the Data Call-In. *Note: Registrants are responsible for informing the Agency about any product that they believe may be covered by this Data call-In but that is not listed by the Agency in Item 4. They must notify the Agency of such omissions within 90 days of receipt of this form.*
E	Use the following instructions for a 100% repack: • If your product is a 100% REPACK of another valid registered product, then write "REPACK OF PRODUCT (enter EPA registration number here)" prominently in block 7 on the form. Skip to Task 3 (Blocks 8, 9, 10, and 11).
F	Do you intend to voluntarily cancel any of your products? • If yes, mark an "X" or "YES" in item box 5 across from the product you intend to cancel. Note: This will initiate voluntary cancellation of this product. EPA will send you a letter notifying you of the cancellation. • If no, move to Task 2, which explains item 7a and 7b.

Skip Items 6a and 6b: Items 6a and 6b do not apply to the product-specific data requirements in this notice. They deal with possible exemption from the generic data requirements. EPA uses the same form for both generic and product-specific data, however, items 6a and 6b apply ONLY to generic data.

Task 2. How to Complete Items 7a and 7b of the Data Call-In Response Form.

Description: Items 7a and 7b only apply to product-specific data. Use the following table to determine your responses to items 7a and 7b.

If you have a …	and ….	then…
Manufacturing-use product (MUP)	You wish to maintain the registration	Mark "yes" in box 7a
End-use product (EUP)	You wish to maintain the registration	Mark "yes" in box 7b

Note: Even if you wish to request a data waiver, answer "yes" to the appropriate item (7a or 7b). Also on the Requirements Status and Registrant's Response form discussed in Chapter 3 under item 9, respond with option 7 (Waiver Request) for each study for which a waiver is requested (see Task 3, Option 7 starting on page).

Task 3. How to Complete Items 8 through 11 on the Data Call-In Response Form.

Authorized Signature and Contact Person: Use the following table to complete items 8-11.

STEP	ACTION
A	For item 8, an authorized representative of each company must sign the certification statement. Include the representative's title. Additional pages used in the response must be initialed and dated in the lower left corner by this representative.
B	For item 9, enter the date of signature.
C	For item 10, enter the name of the person EPA should contact with questions regarding the response.
D	For item 11, enter the phone number of the company contact.

Note: Please provide additional information that does not fit on this form in a signed letter that accompanies the response. For example, you may wish to report that a product has been transferred to another company or that it has been voluntarily canceled. For these cases, please supply all relevant details.

Chapter 3: Instructions For Completing the "Requirements Status and Registrant's Response" Form for Product-Specific Data for the 90-Day Response

Task 1. Check Items 1 through 3 on the "Requirements Status and Registrant's Response" Form.

Description: Items 1-3 describe basic information about your products covered by the Data Call- In, the requirements of which are listed on the "Requirements Status and Registrant's Response" form. Below is a sample form.

<table>
<tr><td colspan="7">United States Environmental Protection
Agency Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE</td><td>OMB Approval XXXX-XXXX</td></tr>
<tr><td colspan="8">Instructions: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.</td></tr>
<tr><td colspan="2">1. Company Name and Address
Sample Company
Street Address
City, State, zip code</td><td colspan="3">2. Case # and Name
XXXX Sample Name</td><td colspan="3">3. Date and Type of DCI and Number
02-Mar-2007
Product Specific
ID# PDCI-XXXXXX-XXXXX</td></tr>
<tr><td>4. Guideline Requirement Number</td><td>5. Study Title</td><td>Prot</td><td>Progress Reports
1</td><td>2</td><td>3</td><td>6. Use Pattern</td><td>7. Test Substance</td><td>8. Time Frame (Months)</td><td>9. Registrant Response</td></tr>
<tr><td>830.1550
830.1600
830.1620

830.1650</td><td>Product identity
Description materials
Description of production process
Description of formulation process</td><td></td><td></td><td></td><td></td><td>A,B,C,D,E,F,G
A,B,C,D,E,F,G
A,B,C,D,E,F,G

A,B,C,D,E,F,G</td><td>MP or EP
MP or EP
MP or EP

MP or EP</td><td>8 mos.
8 mos.
8 mos.

8 mos.</td><td></td></tr>
<tr><td colspan="7">10. Certification. I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.
Signature and Title of Company's Authorized Representative</td><td>11. Date</td></tr>
<tr><td colspan="7">12. Name of Company</td><td>13. Phone Number</td></tr>
</table>

Check Information in Items 1-3: Follow these steps for checking items 1 through 3.

STEP	ACTION
A	Check the accuracy of the preprinted information in item 1 (Company name and address) and item 2 (Case number, case name, EPA registration number for that chemical).

B	Is the information in items 1 and 2 correct? • If yes, move to step C. • If no, pencil in corrections on the form and move to step C. *Note: If your address is not correct, you must also formally change your address by sending a request separate from this action by U.S. mail to the following address:* U.S. Environmental Protection Agency Document Processing Desk (COADR) Office of Pesticide Programs (7504P) 1200 Pennsylvania Avenue, N.W. Washington, DC 20460
C	Look at item 3. This block is entitled "Product Specific" and has a unique identifier assigned by EPA (ID#). • Product-specific data are from studies conducted using a pesticide product AFTER it is formulated with other ingredients (e.g., inert ingredients such as perfumes, solvents, or other pesticide active ingredients) into a manufacturing-use or end-use pesticide product. • The unique ID# assigned by EPA must be used in any document transmitting any data submitted in response to this Product Specific DCI.

Task 2. Read the Description of Items 4 through 8.

Description: Items 4 through 8 cover the information the Agency is requiring to be conducted on your specific product(s).

- Item 4 – Guideline Requirement Number – Identifies guideline requirement numbers for each study necessary to support the product's continued registration.
- Item 5 – Study Title – Identifies the study title associated with the guideline requirement number.
- Item 6 – Use Pattern – Includes all possible use patterns of the pesticide.
- Item 7 – Test Substance – Identifies the form of the pesticide that must be tested.
- Item 8 – Timeframe – Identifies the amount of time given to conduct and submit the required study to the Agency starting from receipt of this Data Call-In Notice.

Task 3. How to Complete Items 9 through 13.

Item 9, Registrant Response: In order to show how you intend to comply with the data requirements listed in the "Requirements Status and Registrant's Response" form, you must choose **one** response code (option) for each data requirement. You may select from the following options when indicating how you wish to respond to each data requirement in item 9.

Option Number	Description	Definition	Details on Page
1	Developing Data	You will generate and submit the data within the specified time frame.	

2	Cost Sharing	You will enter into an agreement with one or more registrants to develop data jointly, and share the cost.	
3	Offer to Cost Share	You have made unsuccessful offers to other data submitters to cost share.	
4	Submitting an Existing Study	You are submitting an existing study that has not been submitted previously to the Agency by anyone.	
5	Upgrading an Existing Study	You are submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable.	
6	Citing an Existing Study	You are citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.	
7	Waiver Request	You are requesting the Agency to waive a required study because you believe it is inappropriate for your product. You must attach a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines, or policies.	
8	Not Applicable	Your product meets the criteria for "not applicable" as expressed in the footnote for that specific Guideline requirement.	

Example #1

If you want to …	**then select response code ….**	**and place response code in item 9 column next to that specific study …**
Develop the data	1	e.g., Guideline 830.1550
Submit an existing study	4	e.g., Guideline 830.1600

The diagram below of the "Requirements Status and Registrant's Response" form illustrates Example #1.

United States Environmental Protection Agency Washington, D.C. 20460 **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**								OMB Approval XXXX-XXXX
Instructions: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.								
1. Company Name and Address Sample Company Street Address City, State, zip code		2. Case # and Name XXXX Sample Name				3. Date and Type of DCI and Number 02-Mar-2007 Product Specific ID# PDCI-XXXXXX-XXXXX		
4. Guideline Requirement Number	5. Study Title	Prot	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.1550 830.1600 830.1620 830.1650	Product identity Description materials Description of production process Description of formulation process					A,B,C,D,E,F,G A,B,C,D,E,F,G A,B,C,D,E,F,G A,B,C,D,E,F,G	MP or EP MP or EP MP or EP MP or EP	8 mos. 8 mos. 8 mos. 8 mos.	1 4
10. Certification. I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative								11. Date4	
12. Name of Company								13. Phone Number	

Items 10 through 13: Use this table to complete items 10-13.

STEP	ACTION
A	For item 10, an authorized representative of each company must sign the certification statement. Include the representative's title. Additional pages used in the response must be initialed and dated in the lower left corner by this representative.
B	For item 11, enter the date of signature.
C	For item 12, enter the name of the person EPA should contact with questions regarding your response.
D	For item 13, enter the phone number of your company contact.

For 100% Repacks: If your product is a 100% repack of another product registered with EPA, then you will not be conducting product-specific data and you do not need to submit this form.

Option 1: Develop Data

Introduction: Select Option 1 if you are going to develop data to satisfy this data requirement. By selecting this option, you certify that you will comply with all the requirements for submitting this study as outlined in the Data Call-In Notice.

Rules:

- If you choose to develop the required data, it must conform with deadlines and requirements referenced in this notice.
- All data generated and submitted must comply with the Good Laboratory Practice rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.
- The Agency does not grant time extensions for the 90-Day Response.

How to Use Option 1: Complete the following steps if you choose Option 1.

STEP	ACTION
1	Enter "1" next to the guideline requirement, under column 9, on the "Requirements Status and Registrant's Response" form for which you will develop data.

Data submission deadline: The time frames stated in column 8 in the "Requirements Status and Registrant's Response" form are those the Agency is allowing for submission of completed studies. These deadlines are calculated from the date of receipt of the DCI Notice by the registrant. If the data are not submitted by the deadline, the registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

Requesting Time Extension for Studies: If you intend to seek additional time to meet the data requirement(s), use the following procedure to request a time extension.

STEP	ACTION
1	Prepare a request which includes: • A detailed description of the expected technical or laboratory difficulty; and • A proposed date for meeting the requirement.
2	Provide documentation from the laboratory performing the testing.
3	Submit request to your Chemical Review Manager (see contact name in DCI Notice Attachment #1).

Conditions for Approval: Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant.

Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the subject deadline.

EPA Response: EPA will review your request and respond in writing. While the Agency is considering your request, the original deadline remains. The possible outcomes are as follows:

If …	then ….
the Agency approves your request,	a new due date will be assigned.
the Agency denies your request,	the due date specified in your original due date from the DCI will not normally be changed and the Agency may proceed with enforcement action against the affected product registration.

Option 2: Agreement to Share in the Cost to Develop Data

Introduction: Select Option 2 for each specific guideline for which you have an agreement to share in the cost of developing data.

Note: Do not select this option if you have offered to cost share and have been rejected by the other registrant(s) (see Option 3).

Rules: This option is only available:

- For acute toxicity data and certain efficacy data, and
- When EPA has indicated that at least two products are similar and can depend on the same data (see page 1 8).

How to Use Option 2: Complete the following steps if you choose Option 2.

STEP	ACTION
1	Enter "2" next to the guideline requirement, under column 9, on the "Requirements Status and Registrant's Response" form for which you have a cost share agreement, once you have determined that your product is eligible (based on the criteria set forth in the Rules above).
2	Submit to the Agency a completed EPA Form 8570-32, Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data, which is available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms. Provide the Registration Number of the product for which the data will be submitted. If you are not producing the data yourself, you must also provide the name of the registrant who will be producing the data under your agreement to cost share.
3	Submit with the 90-Day Response evidence that an agreement exists. Evidence may include, for example: • A letter offering to join in an agreement along with an acceptance letter from the other registrant; or • A written statement by the parties that an agreement exists.

4	Notes: • The other registrant must fulfill its commitment to develop and submit the data. • If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration will also be subject to the initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension.

Note: The agreement to produce the data need not specify all the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(C)(2)(B) of FIFRA provides that if parties cannot resolve the terms of the agreement, they may resolve them through binding arbitration.

Option 3: Offer to Share in the Cost of Developing Data

Introduction: Select Option 3 for each specific guideline for which you have made an offer to pay, or enter into or amend an existing agreement, to share in the cost of developing data, and you have been rejected by the other registrant(s).

As a general policy, the Agency will not suspend the registration of a product in situations where the registrant has in good faith sought and continues to seek to enter into a joint data development program and where the other registrant(s) developing data has refused to accept the offer.

By choosing this option, you are requesting the Agency to exercise its discretion not to suspend your registration(s), even though you did not comply with the data submission requirement.

Rules: This option is only available:

- for acute toxicity data and certain efficacy data, and
- if EPA has indicated that at least two products are similar and can depend on the same data (see page 18).

How to Use Option 3: Complete the following steps if you choose Option 3.

STEP	ACTION
1	Enter “3" next to the guideline requirement for which you have offered to share in the cost of developing data, once you have determined that you qualify for this option. To qualify for Option 3, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit the data) to share in the burden of developing data.

2	Submit to the Agency a completed Form 8570-32, Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data, which is available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms. Note: Your offer to cost share will be subject to binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not include any conditions that qualify this offer.
3	Provide proof that the registrant to whom you made the offer to cost share has not accepted your offer. Example: A copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt).
4	The other registrant must also inform the Agency that it intends to develop and submit the data by indicating this on the "Data Call-In Response" form, and "Requirements Status and Registrant's Response" form. Notes: • The other registrant must fulfill its commitment to develop and submit the data. • If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration will also be subject to the initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension. In order for you to avoid suspension under Option 3, you may not withdraw your offer to cost share.

Option 4: Submitting an Existing Study

Introduction: Select Option 4 for each specific guideline for which you would like to submit an existing study that satisfies the requirements of this Data Call-In Notice. **Do not use this option if you are submitting data to upgrade a study.**

What is an existing study: An existing study is one that:

- Predates the DCI Notice; and
- Has not been previously submitted to the Agency (or cited by anyone).

Criteria for Existing Study: To submit an existing study, the following three criteria must be met.

Criteria	DESCRIPTION
1	Raw data and specimens from the study are available for audit and review. • you must certify that these are available. • you must also identify where they are available.

2	The study contains all quality assurance and quality control information required by Good Laboratory Practice Standards (see 40 CFR Part 160).
3	The study fulfills the purpose of the acceptance criteria for the study, and the study has been conducted in accordance with the Pesticide Assessment Guidelines (PAG) (see page on how to obtain a copy of the acceptance criteria and the PAG). Or, a study not conducted according to the PAG may be submitted to the Agency if the registrant certifies that the study meets the purpose of the PAG. Refer to 40 CFR 158.70 for the Agency's policy regarding acceptable protocols.

Suspension for Inadequate Study: If the existing study does not meet the Agency's standards, then the Agency may suspend registration of the pesticide products supported by these data.

Reporting Unreasonable Adverse Effects: You must notify the Agency if you know of a study containing factual information regarding unreasonable adverse effects pertaining to any requirement in this Notice, even if the study does not meet the criteria above.

How to Use Option 4: Complete the following steps if you choose Option 4.

STEP	ACTION
1	Enter "4" next to the guideline requirement for which you have decided to submit an existing study.

Option 5: Upgrading a Study

Introduction: Select Option 5 for each specific guideline for which you have a previously rejected, but upgradable, study that can be amended to satisfy a data requirement in the DCI Notice.

What is Upgradable: The term "upgradable" is a term used by the Agency in its reviews to describe the quality of a study. If the Agency determines that a study is upgradable, then the study may be made acceptable if certain critical information is supplied.

Example: Purity of Test Material: Providing the purity of the test material is an example of information that could be used to upgrade a study.

Counter-example: No NOAEL Established: For example, if a No Observed Adverse Effect Level (NOAEL) is not established during a toxicity study, then a study cannot be upgraded. The Agency's review would state this. The study would need to be repeated to obtain the necessary information.

How to Use Option 5: Complete the following steps if you choose Option 5.

STEP	ACTION
1	Look at the Agency's review of the study. Has the study been reviewed by EPA and found to be "upgradeable"? • If no, select another option. Do not submit additional data to upgrade a study if the Agency has determined that it cannot be upgraded. • If yes, go to step 2.

2	Mark “5" on the “Requirements Status and Registrant’s Response” form.
3	Submit the additional data to correct all deficiencies identified by EPA as you would any other submission of data (see page for further explanation on how to request a copy of PR notice 86-5 which explains this procedure). Make sure to reference the MRID number of the study you are upgrading.

If the Upgrade is Rejected: If the agency decides the requirement is not satisfied by the additional data that you submit, you may still be required to submit new data usually without a time extension. Also, once you exceed the due-date for the submission of your study, your product registration is subject to enforcement action (suspension)**.**

Already Submitted Information to Upgrade: Select this option if you have already submitted information to upgrade the study and the Agency has not yet reviewed it. With your 8-month response, submit a separate page with MRID numbers of both the original submission and that of the new data upgrading the original submission.

Option 6: Citing an Existing Study

Introduction: Select Option 6 for each specific guideline for which you have an existing study that the Agency has classified as acceptable, or that has been submitted but not reviewed by the Agency.

Citing Another Registrant’s Data: Rules:

- This option is available only for acute toxicity or certain efficacy data.
- The cited study must have been conducted on your product, an identical product, or a product which EPA has “grouped/batched” with your product, or which EPA agrees provides an appropriate bridge.
- If you decide to cite another registrant’s data, you must also submit a completed “Certification with Respect to Citations of Data,” EPA form 8570-34, available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms.

How to Use Option 6: Whether you are citing your own data or another registrant’s study, you must complete the following steps if you choose Option 6.

STEP	ACTION
1	Enter “6" next to the guideline requirement for which the Agency has an existing study previously classified as acceptable* or an existing study that has been submitted but not reviewed by the Agency on the Requirements Status and Registrant’s Response Form under column 9, the Registrant Response column.
2	By the specified due date, you must provide the MRID or Accession number(s) for the cited data with your 8-month response.

Criteria for Citing an Existing Study: To cite an existing study, the following criteria must be met:

Criteria	DESCRIPTION

1	The study contains all quality assurance and quality control information required by Good Laboratory Practice Standards (see 40 CFR Part 160).
2	The study fulfills the purpose of the acceptance criteria for the study, and the study has been conducted in accordance with the Pesticide Assessment Guidelines (PAG) (see page on how to obtain a copy of the acceptance criteria and the PAG).

Suspension for Inadequate Study: If the cited existing study does not meet the Agency's standards, then the Agency may suspend registration of the pesticide products supported by these data.

Option 7: Waiver Request

Introduction: Select Option 7 for each specific guideline for which you believe the data requirement is inappropriate for your product.

Example: A registrant requested and received a waiver for the acute inhalation toxicity study (Guideline 870.1300) because they believed their product did not pose an inhalation hazard because it was a paste that had no volatile components**.**

How to Request a Waiver: Follow these steps to request a waiver.

STEP	ACTION
1	Enter "7" next to the guideline requirement you would like to have waived on the Requirements Status and Registrant's Response Form under column 9, the Registrant Response column.
2	Attach a complete justification for this request, including technical reasons, data, and references to relevant EPA regulations, guidelines or policies. **Note #1:** Any supplemental data must be submitted in the format required by PR Notice 86-5. **Note #2:** This is your only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA.

What if the waiver Request is Denied: If the Agency denies your request you must:

- Within 30 days of your receipt of the Agency's written decision, submit a revised "Requirement Status and Registrant's Response" form with a new response option chosen (for the requirement study that was denied the waiver status).
- Meet the deadline for submission of data as specified by the original DCI Notice.

Option 8: "Not Applicable"

Introduction: Select Option 8 for each specific guideline only if your product meets the criteria for *not applicable*, as expressed in the footnote for that specific guideline. To determine if a relevant footnote exists, refer to the bottom of the "Requirements Status and Registrant's Response" form. These footnotes are reproduced from the 40 CFR, sections 158.190, (Physical and Chemical Characteristics) and 158.340, (Toxicology).

Example: If your product is a solid, the boiling point study would not be applicable, as expressed in footnote (7).

Contrast with Data Waivers: In data waiver situations, the justification for not performing the test involves issues not covered by a footnote.
Instructions: To claim a requirement as not applicable:

STEP	ACTION
1	Enter "8" next to the requirement you consider to be inapplicable under column 9 on the Requirements Status and Registrant's Response Form.
2	Prepare and attach a complete justification for this request, including technical reasons, based on the footnote.

EPA will then review your request. The possible outcomes are as follows:

If …	then ….
the Agency approves your request,	you will not be required to supply the data.
the Agency denies your request,	submit a revised "Requirements Status" form with a new response option within 30 days of your receipt of the Agency's written decision. You must choose a method of meeting the data requirements of this Notice by the due date stated in this Notice. The due date specified in your original DCI generally will not be changed.

Chapter 4: Sharing Testing Costs with Others Using Batching or Bridging

Introduction: To reduce the resources needed to fulfill the acute toxicity data requirements for reregistration, the Agency allows acute toxicity testing of one or more selected products to represent a group of products. This may be done using "batching" or "bridging".
Note: The Agency reserves the right to require, at any time, acute toxicity data for an individual product.

What is Batching: Batching is the Agency's process of grouping together products. The acute toxicity of a "batch" of similar products may be characterized by a set of tests on one product instead of for each product within the batch. The registrant may select any product in the batch as the test material. For example, products with identical formulations would be placed in the same batch for acute toxicity testing.

What is Bridging: Sometimes the Agency will batch together similar but not identical products. To characterize the range of toxicity within this type of batch, the Agency may choose certain products within the batch for testing. This is called bridging. The Agency may select the product(s) within a batch that will best characterize the range of potential toxicity of products within the batch. When the Agency selects the products to be tested it will state so in the batching tables. Registrants may also propose bridging strategies for approval by the Agency.

Criteria Used for Batching: The Agency uses the following criteria to group products into batches:

1) Type of formulation (e.g. emulsifiable concentrate, wettable powder, etc.).
2) Active and inert ingredients:
   - identity
   - percent composition
   - toxicological activity

Policy: Not Substantially Similar: Applications for new "me-too" products must be "substantially similar" to a currently registered product. Products in the same batch are considered "toxicologically similar" but may not be "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Others May Cite Studies: Choosing not to participate with other registrants in a batch does not preclude those other registrants from citing your studies and offering to "cost-share" for those studies.

How to Find Your Product's Batch and the Names of Other Registrants in Your Batch

Introduction: The Agency provides both a table listing products in your batch and a list of registrants sent the product-specific Data Call-In so that you may contact them to plan a testing strategy.

Who's in Your Batch: Use the following table to identify your product's batch and the other registrants with products in your batch:

STEP	ACTION
A	Refer to the enclosed batching tables. Look for your product's "registration number" in the "EPA Reg. No." column. Is your product listed? • If yes, note the batch in which your product has been placed. Now go on to Step B. • If no, contact your Chemical Review Manager (see contact name in DCI Notice Attachment #1).
B	Note the company numbers of the other products in your batch. The first set of numbers in the Registration Number identifies the company; the second, the product. For example, take this Registration Number "524-23": the Company Number is 524 and under that company number the Product Number is 23.
C	Now locate the enclosed "List of All Registrants Sent This Data Call-In Notice."
D	Look in the left column which lists these registrants' company numbers. Find the company numbers of other registrants in your batch. Look across the table to find their names and addresses (e.g., company number 524 identifies the Monsanto Company).
E	Contact other companies in your batch about sharing the cost of testing.

F	If you decide to cooperate with others in a batch, then you may choose to participate with: • all other registrants, or • only some of the other registrants

Requesting Rebatching or How to Rely on Data From Another Batch

Introduction: You may believe that the acute toxicity of your product can be adequately characterized by data from another batch of products. In this case you may request that your product be rebatched.

Circumstances Requiring Rebatching: The following circumstances commonly require rebatching of products:

- You have recently changed your formula;
- Your product's Confidential Statement of Formula is out-of-date.

How to Request Rebatching: Use the following instructions to request "rebatching":
Write a letter explaining why your product should be in another batch and send it to your Product Reregistration Manager (see cover letter for their name and address). Provide a detailed rational which supports your claim. Submit a new Confidential Statement of Formula with your letter.

Requesting Initial Batching: Occasionally, a product may be registered or reinstated during the time lag between batching and mailing the Product Specific Data Call-in Package. In this case request initial batching. Follow the same instructions as for "rebatching" described above.

Batching and Your 90-Day Response

Introduction: If you choose to participate in a batch to satisfy your acute toxicity testing requirements, indicate that in your 90-day response.

List of Response Options: You may select from the following options when completing your 90-day Response. Please refer to the instructions for the "Requirements Status and Registrant's Response" form in Chapter 3 for a detailed discussion of these options.

Option Number	Description
1	Developing Data
2	Cost Sharing
3	Offer to Cost Share
4	Submitting an Existing Study
5	Upgrading an Existing Study
6	Citing an Existing Study
7	Waiver Request
8	Not Applicable

Choosing Response Options: Use the following table to determine the universe of acceptable response options for the "Requirements Status and Registrant's Response" form.

If you are …	**Then select option ….**
Supplying data to support a batch of products.	1, 4, 5, or 6
Depending on another's data.	2, 3, or 6
Not participating in a batch (supplying data for only your product).	1, 4, 5, or 6
Requesting a waiver.	7 For guidance on requesting a waiver, please see the footnotes following the "Requirements Status and Registrant's Response" form. Note: Common justifications for requesting waivers include: • test cannot be performed (for example acute inhalation testing is not required if test material cannot be formulated into respirable particles) • test is not needed (for example, primary dermal irritation is not needed if the material is known to be highly acutely toxic by the dermal route).
Claiming the study is inapplicable.	8 For guidance on claiming the study inapplicable, please see the footnotes following the "Requirements Status and Registrant's Response" form. For example: • the requirement for boiling point would be inapplicable if the product was formulated as a solid.

Choices for Participation: Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. Use the following table to decide whether to generate a new study or cite an existing study.

If a registrant …	**Then the registrant ….**
chooses to generate data for a batch	must use one of the products within the batch as the test material

chooses to rely upon previously submitted data	may do so provided that the: • the data are complete (see Chapter Six, List of Available Documents, for information on how to obtain acceptance criteria), • the formulation tested is considered by EPA to be similar for acute toxicity, and • the formulation has not been significantly altered since submission and acceptance of the acute toxicity data.

Note: When submitting studies for Agency review, clearly identify the test material by EPA Registration Number. If more than one Confidential Statement of Formula (CSF) exists for a product, identify the corresponding CSF.

Batching Tables (example)

Batch 1: Example

Registration Number	Percent Active Ingredient: ethafluralin	Formulation:
62719-184	10%	Granular
65242-135	10%	Granular
ND90000200	10%	Granular
ND91000200	10%	Granular

Acute data on any product in batch 1 (listed above) may be used to support any other batch 1 product.

Batch 2: Example

Registration Number	Percent Active Ingredient: ethafluralin	Formulation:
34704-610	36.1%	Liquid
51036-190	36.1%	Liquid
And so on …		

Again, acute data on any product in batch 2 (listed above) may be used to support any other batch 2 product.

Chapter 5: How to Complete the Confidential Statement of Formula Form for the 8 Month Response

Introduction: Two signed copies of the CSF (EPA Form 8570-4, which is available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms) are required for each basic and each alternate formulation of a product undergoing reregistration. This form is part of the "8 Month Response."

Rules: The following rules apply to all CSFs submitted to the Agency:

- The CSF must comply with PR Notice 91-2 by declaring the active ingredient as a nominal concentration.
- All blocks in the form must by filled out completely. If any block is not applicable, mark it N/A.
- The CSF must be signed and dated, with the telephone number and name of the responsible party provided.
- All applicable information which is on the product specific data submission must also be reported on the CSF.
- When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Procedure for Completing the CSF Form: The following steps will assist you in completing the CSF form:

Note: Please refer to the back of the original form for further information.

STEP	ACTION
1	In boxes 1-6, enter the appropriate information.
2	In box 7, enter all weights as pounds per gallon for liquids and pounds per cubic feet for solids.
3	In box 8, indicate the pH of the product.
4	In box 9, the flashpoint must be in degrees fahrenheit and flame extension in inches.
5	In boxes 10-12, list the components in the formulation, the supplier and the Registration number of the currently registered source products. Notes: • The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported. • For active ingredients, the percent purity of the source product must be reported under column 10 and must be exactly the same as on the source product's label.
6	In box 13, all weights must be in pounds, kilograms or grams. Notes: • In no case will volumes be accepted. • Do not mix English and metric system units (i.e. pounds and kilograms). • All items under 13.b. must total 100.00 percent.
7	In box 14, all items under 14.a. and 14.b. for the active ingredients must represent pure active form. Notes: • The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. • An explanation must be provided if the proposed limits are different than standard certified limits and they must be supported by the analysis of 5 batches that are submitted along with the certification statement.
8	In boxes 15-21, enter the appropriate information, including the date of the application to which this form applies.

Chapter 6. List of Available Documents

Introduction: The Agency provides reference materials concerning this RED document, including additional copies, and general information on the pesticide reregistration program.

If you want …	Then contact ….	And request . . .
1. PR Notice 2011-3 updates and replaces PR Notice 86-5: Standard Format for Data Submitted Under FIFRA and Certain provisions of FFDCA	https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year **OR** National Technical Information Service (NTIS) 5301 Shawnee Road Alexandria, VA 22312 Tel: 1-800-553-6847 or 703-605-6000 Email: info@ntis.gov http://www.ntis.gov/	EPA Number 540/PR-99-007
2. PR Notice 91-2: Accuracy of Stated Percentages for Ingredients Statement	https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year **OR** See NTIS information above.	EPA Number 540/PR-99-008
3. The Agency's Acceptance Criteria (within the FIFRA Accelerated Re-registration Phase Three Technical Guidance Package)	See NTIS information above.	PB-90-161530
4. Application for Pesticide Registration	Find at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms **OR** Office of Pesticide Programs (OPP) (7504P) U.S. Environmental Protection Agency 1200 Pennsylvania Ave., NW Washington, DC 20460 Tel: 703-308-8893 for conventional pesticide products Tel: 703-308-6427 for antimicrobial pesticide products Tel: 703-308-0152 for biological/biochemical pesticide products	Form 8570-1
5. The Confidential Statement of Formula (CSF) form	See OPP information above.	Form 8570-4
6. Formulator's Exemption Statement form	See OPP information above.	Form 8570-27

7. A complete copy of this or any other RED document.	Find the specific docket for a particular RED at: https://www.regulations.gov/ **OR** EPA's "National Service Center for Environmental Publications" (EPA/NSCEP) U.S. EPA/ NSCEP P.O. Box 42419 Cincinnati, OH 45242-0419 Tel: 1-800-490-9198, Fax: 301-604-3408 Email: nscep@bps-lmit.com https://www.epa.gov/nscep **OR** **See NTIS information above.**	EPA Publication Number
8.Electronic copies of this or any other RED and fact sheet, and PR Notices.	Using World Wide Web, Find RED at: https://archive.epa.gov/pesticides/reregistration/web/html/status.html **OR** http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1 Find Notices at: http://www.epa.gov/pesticide-registration/pesticide-registration-notices-year	
9. More information about EPA's pesticide reregistration program, the RED, or reregistration of individual pesticide products.	See: https://www.epa.gov/pesticide-reevaluation https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-regulatory-divisions-ad-bppd-prd-rd Pesticide Re-evaluation Division (7508P) Office of Pesticide Programs (OPP) US EPA 1200 Pennsylvania Ave., N.W. Washington, DC 20460 Tel: 703-308-8000 for conventional pesticides Antimicrobials Division (7510P) Office of Pesticide Programs (OPP) US EPA 1200 Pennsylvania Ave., N.W. Washington, DC 20460 Tel: 703-308-6411 for antimicrobials Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs (OPP) US EPA 1200 Pennsylvania Ave., N.W. Washington, DC 20460 Fax: 703-308-7026 for biologically-based pesticides	

10. Information about the health effects of pesticides, or assistance in recognizing and managing pesticide poisoning symptoms.	National Pesticides Information Center (NPIC) Oregon State University 310 Weniger Hall Corvallis, OR 97331-6502 Tel: 1-800-858-7378 Email: npic@ace.orst.edu http://npic.orst.edu/	

ATTENTION DCI RESPONDENTS:

The supporting statement for the Information Collection Request (ICR) covering this DCI request is entitled "Pesticides Data Call-In Program" (OMB No. 2070-0174; EPA No. 2288).

For more information about the Agency's burden estimates, please go to the following RegInfo.gov website produced by the office of Management and Budget (OMB): https://www.reginfo.gov/public/do/PRAMain.

From this site location, under the "Information Collection Review" heading, submit a search by the agency name, or, in the blue bar area at top right of the page, select "ICR" and in the search window nearby type the OMB control number (2070-0174), then click on the "Go" button at the right of the search window.

Specifically, the ICR associated with the DCI request is located at: https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0174