UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

[DATE GENERATED UPON DCI ISSUANCE]

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachments 2 and 3 of this Notice to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing the active ingredient(s). Within 90 days after you receive this Notice, you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or,

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, *Requirements Status and Registrant's Response* Form, (see section III-B); or,

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions,* as well as a list of all registrants who were sent this Notice (Attachment 5).

You may respond to this Data Call-In Notice either electronically through the Central Data Exchange (CDX) or by mail as described in Attachment 1. When submission of responses is discussed throughout this Notice, either method can be used.

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, and/or section 408(f)(l)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Collection of this information is in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) as approved by the Office of Management and Budget (OMB) under Control Number 2070-0174.

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

The Attachments to this Notice are:

Section I. Why You Are Receiving This Notice

The Agency has reviewed existing data for the active ingredient(s) identified in Attachments 2 and 3 of this Notice, and reevaluated the data needed to support continued registration of products containing the subject active ingredient(s) and the continuation of any existing tolerances or exemptions for such active ingredient. This reevaluation identified additional data necessary to assess the health and safety of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

Section II. Data Required by This Notice

II-A. Data Required

The data required by this Notice are specified in the Attachment 3, *Requirements Status and Registrant's Response* Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. Schedule for Submission of Data

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, *Requirements Status and Registrant's Response* Form, within the time frames provided.

II-C. Testing Protocol

All studies required under this Notice must be conducted in accordance with protocols which meet the purpose of the test standards outlined in the OCSPP Harmonized Test Guidelines

for those studies for which guidelines have been established and which provide data of suitable quality and completeness as typified by the protocols cited in the guidelines.

These EPA Guidelines are available to the public on the EPA's Chemical Safety and Pollution Prevention website (http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR Part 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable ·standards. The OECD protocols are available electronically on the OECD website (http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices (40 CFR Part 160).

II-D Registrants Receiving Previous Section 3(C)(2)(B) or (4) Data Call-In Notices Issued by the Agency

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

Section III. Compliance with Requirements of This Notice

III-A. Schedule for Responding to the Agency

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the Data Call-In forms (Attachments 2 and 3).

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. Options for Responding to the Agency

1. Generic Data Requirements

The options for responding to this Notice are: a) voluntary cancellation, b) delete use(s), c) claim generic data exemption, d) agree to satisfy the data requirements imposed by this Notice, or e) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A

discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form and the Attachment 3, *Requirements Status and Registrant(s) Response* Form. The Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form must be submitted as part of every response to this Notice. Note that the company's authorized representative is required to sign the first page of the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form and the Attachment 3, *Requirements Status and Registrant(s) Response* Form and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, write or email EPA as indicated in Attachment 1.

a. Voluntary Cancellation – You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form, indicating your election of this option. Voluntary cancellation is item number 5 on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form. If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Use Deletion – You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Attachment 3, *Requirements Status and Registrant(s) Response* Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Attachment 3, *Requirements Status and Registrant(s) Response* Form. You must also complete an Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form by signing the certification, item number 8. For additional instructions on how to delete a use, please refer to the EPA webpage for "Voluntary Cancellation of a Pesticide Product or Use" at https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90-day response, must bear an amended label.

c. Generic Data Exemption – Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i) The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you;

(ii) Every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii) You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption, you must submit a completed Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form and all supporting documentation. The Generic Data Exemption is item number 6a on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form. If you claim a generic data exemption, you are not required to complete the Attachment 3, *Requirements Status and Registrant(s) Response* Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Data Requirements of this Notice – There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Attachment 3, *Requirements Status and Registrant(s) Response* Form and option 6b and 7 on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

e. Request for Data Waivers – Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Attachment 3, *Requirements Status and Registrant(s) Response* Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice, or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form, and the Attachment 3, *Requirements Status and Registrant(s) Response* Form, for the product specific data. The Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form must be submitted as part of every response to this Notice. In addition,

one copy of the Attachment 3, *Requirements Status and Registrant(s) Response* Form, must also be submitted for each product listed on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form, unless the voluntary cancellation option is selected. Note that the company's authorized representative is required to sign the first page of the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form, and the Attachment 3, *Requirements Status and Registrant(s) Response* Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation – You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Attachment Generic and Product Specific Data Call-In Response Form.

III-C. Satisfying the Data Requirements of This Notice

If you acknowledge on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form related to data production for each data requirement. Your option selection is to be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Attachment 3, *Requirements Status and Registrant(s) Response* Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1. Developing Data

If you choose to develop the required data, then it must be in conformance with the Agency's deadlines and other requirements that are referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in accordance with the requirements of Pesticide Registration Notice (PRN) 2011-3 entitled "Standard Format for Data

Submitted Under FIFRA and Certain Provisions of FFDCA" (http://www.epa.gov/pesticide-registration/pesticide-registration-notices-year), and, as applicable, comply with 40 CFR Part 26, "Protection of Human Subjects." In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Attachment 3, *Requirements Status and Registrant(s) Response* Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol, you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the *Requirements Status and Registrant(s) Response* Form (Attachment 3) are those allowed by the Agency for the submission of completed study reports or protocols. The noted deadlines begin from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s) and the affected tolerances or exemptions are subject to revocation.

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, then the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. 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 lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. FIFRA section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding

arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has (or have) refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data (see Attachment 6). In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form (Attachment 2) and a *Requirements Status And Registrant(s) Response* Form (Attachment 3) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to 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 for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

(i) You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) "raw data means any laboratory worksheets, records, memoranda, notes, or

exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments:" The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

(ii) Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post- May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

(iii) You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

(iv) If any existing study involves testing subject to 40 CFR Part 26, you must comply with all applicable requirements in EPA's regulations at 40 CFR Part 26 entitled "Protection of Human Subjects."

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PRN 2011-3.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is

satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, write or email as indicated in Attachment 1. If you submit data to upgrade an existing study, you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PRN 2011-3.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PRN 2011-3) EPA Form 8570-34.

III-D. Requests for Data Waivers

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

a. Low Volume/Minor Use Waiver – (Option 8 on the Attachment 3, *Requirements Status And Registrant(s) Response* Form). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be

approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i) Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

(viii) A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

a. Documentation of the usefulness of the active ingredient(s) in Integrated Pest

Management,

b. Description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives,
c. Information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and
d. Description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver. Low volume minor use waivers may not be available for data required for continuation of tolerances or exemptions.

b. Request for Waiver of Data – (Option 9 on the Attachment 3, *Requirements Status and Registrant(s) Response* Form). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered and no tolerance or tolerance exemption exists or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to FIFRA section 3(c)(2)(B) or section 4(f)(l)(A). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Attachment 3, *Requirements Status and Registrant(s) Response* Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PRN 2011-3). This will be the 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. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific *Requirements Status and Registrant(s) Response* Form (Attachment 3). Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

Section IV. Consequences of Failure to Comply with This Notice

IV-A. Notice of Intent to Suspend Registration/Order Revoking or Modifying Tolerance or Exemption

The Agency may issue a Notice of Intent to Suspend products subject to this Notice or an order

revoking or modifying associated tolerances or tolerance exemptions due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B) or FFDCA section 408(f). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

    a. Inform EPA of intent to develop and submit the data required by this Notice on an Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form and an Attachment 3, *Requirements Status And Registrant(s) Response* Form.

    b. Fulfill the commitment to develop and submit the data as required by this Notice; or,

    c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. Basis for Determination That Submitted Study Is Unacceptable

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend or an order revoking or modifying a tolerance or tolerance exemption. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting

Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PRN 2011-3. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

4. Requirements, as applicable, set forth in 40 CFR Part 26 entitled "Protection of Human Subjects."

IV-C. Existing Stocks of Suspended or Canceled Products

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of FIFRA.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a FIFRA section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting the registrants permission to sell, distribute; or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90-day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received <u>after</u> the 90-day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90-day response was due <u>unless</u> you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and

good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

Section V. Registrant(s) Obligation to Report Possible Unreasonable Adverse Effects

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on human health or the environment. This requirement continues as long as the products are registered by the Agency.

Section VI. Inquiries and Responses to This Notice

If you have any questions regarding the requirements and procedures established by this Notice, contact EPA as listed in Attachment 1, the *Data Call-In Chemical Status Sheet.*

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* form and a completed Attachment 3, *Requirements Status And Registrant(s) Response* Form and any other documents required by this Notice, and must be submitted either electronically through CDX or by mail as identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Attachment 2, *Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions* Form need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely,

Anita Pease
Acting Director
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

Attachment 1
Data Call-In Chemical Status Sheet

DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

Submit all responses to the Product Specific and/or Generic Data Call-In (PDCI and GDCI) using the information below. To expedite processing, include the DCI identification number(s) (e.g., GDCI-555555-5555 & PDCI-555555-5555) in the subject line of all DCI-related correspondence.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions or need assistance responding to the DCI(s), contact the Antimicrobials Division Reevaluation team at **OPP_AD_Reevaluation_DCI_Team@epa.gov**.

All responses to this notice for the DCI data requirements are to be submitted electronically through the Central Data Exchange (CDX) or by mail as described below.

If You Choose to Respond through the Central Data Exchange (CDX):

The DCI receipt acknowledgement, 90-day response, and data can be submitted through CDX via the DCI application of the Pesticide Submission Portal (PSP). If you have a CDX account with access to the PSP, you may follow the link below to sign in, acknowledge receipt, and access your DCI(s): https://cdx.epa.gov/.

A user guide is available for instructions on what to do if you do not have a CDX account (page 16 in the link below) or if you need to add PSP to your account (page 51 in the link below): https://cdx.epa.gov/content/documents/PSP/OPP_CDX_Pesticide_Submission_PortalRegistration_UserGuidev1.0p.pdf.

If You Choose to Respond by Mail:*

By U.S. mail:
US EPA, OPP/Antimicrobials Division
(7510P)
c/o Front End Processing
Attn: Reevaluation Team Leader, PM 36
1200 Pennsylvania Ave NW
Washington, DC 20460

By express or courier service:
US EPA, OPP/Antimicrobials Division
(7510P)
c/o Front End Processing
Room S-4910, One Potomac Yard (South)
Attn: Reevaluation Team Leader, PM 36
2777 South Crystal Drive
Arlington, VA 22202

*NOTE: If this DCI was sent to you via email, you may acknowledgement receipt via email.

Attachment 2
Combined Generic and Product Specific
Data Call-In Response Form Plus Instructions

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

These instructions apply to the form titled "Data Call-In Response" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The respondent burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This is a mandatory collection under 40 CFR 158. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 2070-0174. Please send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Director, Regulatory Support Division, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that

request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice. If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product. Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 6b. ON THE GENERIC DATA FORM: Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the "Requirements Status and Registrant's Response" form that indicates how you will satisfy those requirements.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Note: Item 6a and 6b are not applicable for Product Specific Data.

Item 7a. ON THE PRODUCT SPECIFIC DATA FORM: For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the "Requirements Status and Registrant's Response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: Item 7a and 7b are not applicable for Generic Data.

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 9. ON BOTH FORMS: Enter the date of signature.

Item 10. ON BOTH FORMS: Enter the name of the person EPA should contact with questions regarding your response.

Item 11. ON BOTH FORMS: Enter the phone number of your company contact.

Attachment 3
Requirements Status and Registrant's Response Form

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms. EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The respondent burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This is a mandatory collection under 40 CFR 158. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 2070-0174. Please send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Director, Regulatory Support Division, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the "Requirements Status and Registrant's Response" Form.

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A Terrestrial food crop
B Terrestrial feed crop
C Terrestrial non-food
D Aquatic food crop
E Aquatic non-food outdoor
F Aquatic non-food industrial
G Aquatic non-food residential
H Greenhouse food crop
I Greenhouse non-food crop
J Forestry
K Residential
L Indoor food
M Indoor non-food
N Indoor medical
0 Indoor residential
P Aquatic non-food crop
Q Residential outdoor
R Agricultural premises and equipment
S Food handling/storage establishments, premises, and equipment
T Commercial, institutional & industrial premises and equipment

U Residential and public access premises
V Medical premises and equipment
W Human drinking water systems
X Materials preservatives
Y Industrial processes and water systems -once through
Z Industrial processes and water systems -not once through
AA Antifouling coatings
BB Wood preservatives
CC Swimming pools
DD Aquatic areas
EE Indoor use
FF High exposure antimicrobial
GG Low exposure antimicrobial
HH Occupational use conventional chemical
II Residential use conventional chemical

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP %	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAIM	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON BOTH FORMS: The time frame begins from the date of your receipt of this Data Call-In notice. However, your response to the Data Call-In itself is due 90-days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "*Certification With Respect To Data Compensation Requirements*" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response" form for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the *"Requirements Status and Registrant's Response* form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (b) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30-days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In Notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

Attachment 4
EPA Batching of End-Use Products for Meeting Acute Toxicological Data Requirements of Reregistration

(Only for Acute Toxicity Data Associated with Product Specific Data Call-Ins)

Attachment 5
List of All Registrants Sent This Data Call-In Notice

Attachment 6
Cost Share and Data Compensation Form

Includes Links to:

1. *Confidential Statement Of Formula Instructions*

2. *Confidential Statement Of Formula Certification Of Attempt To Enter Into An Agreement With Registrants For Development Of Data*

3. *Certification With Respect To Citation Of Data*

And Statement:

Attention DCI Respondents

LINKS TO FORMS:

The pesticide registration forms that are listed below can be found at:
http://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them

Link to Confidential Statement of Formula and Instructions (Form # 8570-4):
http://www.epa.gov/sites/production/files/2013-07/documents/8570-4_0.pdf

Certification of Attempt to Enter Into an Agreement With Registrants for Development of Data (Form # 8570-32):
http://www.epa.gov/sites/production/files/2015-10/documents/8570-32.pdf

Certification With Respect to Citation of Data (Form # 8570-34):
http://www.epa.gov/sites/production/files/2013-08/documents/8570-34.pdf

Link to Appendix B and the Label Tables in the RED for the Chemical Case:
http://archive.epa.gov/pesticides/reregistration/web/html/status.html

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):
http://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:
http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0174.