US Environmental Protection Agency
Office of Pesticide Programs

Pesticide Registration (PR) Notice 2011-3
Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)

November 30, 2011

Pesticide Registration (PR) Notice 2011-3

Notice To: Manufacturers, Producers, Formulators, Distributors and Registrants

Attention: Persons Responsible for Federal Registration of Pesticides Products

Subject: Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)

I. PURPOSE AND APPLICABILITY

This PR Notice updates and replaces Pesticide Registration Notice 86-5 and discusses both the recommended and the required procedures for submitting FIFRA and FFDCA data. All required procedures contained within this document, generally indicated by use of the word "must," were previously made mandatory by statute or regulation; this document creates no new legally binding requirements. Where indicated by the use of non-mandatory language such as "may," "should" and "can," this document provides recommendations or guidance.

The PR Notice applies to all data that are submitted to EPA to support any application, petition, or submission intended to persuade EPA to grant, modify or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following: an application for registration or amended registration of a pesticide product under FIFRA section 3 or 24; a submission of data required in conjunction with reregistration of a currently registered product under FIFRA section 4 (or its registration review under FIFRA section 3); an application for an experimental use permit under FIFRA section 5; a submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B); a petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA section 408 as well as studies submitted under FIFRA section 6(a)(2). (See generally, 40 CFR parts 150 – 189; specifically, 40 CFR parts 158, 160, 161 and 174.)

II. EFFECTIVE DATE

Effective immediately.

III. BACKGROUND

PR Notice 86-5 has served as the Office of Pesticide Programs' (OPP's) data formatting guidance since its publication on July 29, 1986. At the time PR Notice 86-5 was originally issued, the only acceptable medium for data submission was paper. Today, advances in information technology, statutory and regulatory changes, and new policy initiatives make this an opportune time to update the guidance. This new guidance gives registrants the option of submitting electronic submissions and provides a flexible but still acceptable format for data submission, regardless of the medium in which the data are submitted. Attachment 5 contains a listing of glossary terms used in this guidance.

IV. OVERVIEW OF CHANGES

The following list is a summary of the changes recommended by this guidance. A more detailed description of the changes to the guidance is described in sections IV and V.

- Electronic submission on CD or DVD is now an option for some types of data submissions. OPP plans to make this option available to more types of submissions. Check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm) for the latest information.

- Since the inception of PR Notice 86-5, Master Record Identifiers (MRIDs) have been assigned only to data documents that comply with its formatting instructions. One major process change being planned by OPP is that MRIDs will no longer be assigned after these documents have been screened. MRIDs are already being pre-assigned, in the case of electronic submissions. Similarly, MRIDs will be assigned to all of the data documents in a paper submission prior to our format screening process. Submitters will continue to be notified if a document does not meet the mandatory formatting elements.

- Currently, three identical copies of all applicable data are required. This applies to submissions that are entirely paper. Please note that as OPP phases in its up-front imaging of paper submissions, we expect to reduce this requirement to a single copy. For the latest information on the status of the up-front imaging effort and number of copies required please continue to check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm).

- Previous language discouraging double-sided printing and color printing has been eliminated.

- Section G of PRN 86-5, Special Requirements for Submitting Data to the Docket, is obsolete and has been eliminated.

- Information on asserting claims of data confidentiality has been updated in accordance with the latest edition of 40 CFR sections158, 161 and 174.

- The information on flagging of studies for potential adverse effects has been updated in accordance with the latest edition of 40 CFR sections 158 and 161.

- OECD dossier format is an option that did not exist when PRN 86-5 was written.

- References to the data requirements for antimicrobial pesticides, which have been redesignated in new 40 CFR 161, have been inserted as appropriate.

V. RELATIONSHIP OF THIS NOTICE TO OTHER OPP POLICY AND GUIDANCE FOR SUBMITTING DATA

A. Test reports and study profile templates

This notice contains guidance for organizing and formatting submissions of supporting data but does not address the substance of test reports themselves. Consult the OPP website at http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm for information on study profile templates and at http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm for information on harmonized test guidelines.

B. Adverse effects reporting

Detailed guidance on adverse effects reporting under FIFRA section 6(a)(2) is available at http://www.epa.gov/pesticides/fifra6a2/.

C. Electronic submissions

At this writing, electronic submission on CD or DVD is an option for some, but not all, types of data submissions. Electronic submission guidance is available on OPP's website at http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm. However, OPP continues to accept all types of data submissions in paper form.

D. OECD dossier format

There is an alternative to the overall submission format presented in this Notice for submitters who are planning a multi-national electronic submission on CD or DVD. Information on the OECD dossier format can be found at http://www.oecd.org. Submitters who use this format should arrange individual documents as described in this Notice, with the exception of the placement of any information claimed as confidential. Instead of preparing a confidential attachment for an individual document, all confidential information should be compiled in Document J of the dossier.

E. Technical amendments for antimicrobial pesticides, 40 CFR part 161

EPA has redesignated certain pesticide data requirements formerly located in 40 CFR 158 into a new part 161. The data requirements that have been transferred apply to antimicrobial pesticides. EPA has made conforming changes and cross-reference revisions to the re-designated material, including re-designation of 40 CFR part 158.32, 158.33, and 158.34 as 161.32, 161.33 and 161.34, respectively. These technical amendments, published in the Federal Register on October 24, 2007, (72 FR 60251) preserve the original data requirements for use with antimicrobial pesticides until such time as a final rule for antimicrobial pesticides can be promulgated and made effective.

F. Clarification of plant-incorporated protectants data submissions

The characteristics of plant-incorporated protectants (PIPs), such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment, distinguish them from traditional chemical pesticides. Therefore, PIPs are subject to different regulatory requirements and procedures than traditional chemical pesticides. 40 CFR 174 sets forth regulatory requirements, criteria, and procedures applicable to PIPs under FIFRA and FFDCA. When applied to PIPs, the definitions and regulations in 40 CFR 174 supersede the regulations found in 40 CFR parts 150 through 180 to the extent that the regulations conflict.

VI. FORMAT

A submission consists of all the documents sent to OPP at the same time in support of a single regulatory action or a group of related actions, such as a product amendment and a related tolerance petition. The documents should be accompanied by a transmittal document and related administrative material (e.g., EPA Forms 8570-1, 8570-4, etc.) as appropriate. For actions subject to a registration service fee (see FIFRA section 33), failure to comply with this guidance may result in rejection of the action during the 21-day completeness screening. This transmittal document and administrative material should be grouped together in the first physical volume if the submission is on paper. Consult the e-submission XML guidance document at http://www.epa.gov/pesticides/regulating/registering/submissions/XMLsubmissions/e-submission_xml_guidance_document_v1.pdf for specific information on the format of these documents as files on a CD/DVD.

A detailed discussion of format elements appears below and samples of some of the elements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality that can not be altered (see 40 CFR 158.33), these samples are illustrative. As long as the required information is included and clearly identifiable, then the form of the samples may be altered to reflect the submitter's preference.

A. Organization of the data submission package

The following physical format guidance applies to the transmittal document and data documents in a **paper** data submission. Consistency of electronic data submissions with the data submission requirements cited in this notice will be verified electronically.

- 8.5 x 11-inch white paper
- High contrast and good resolution
- Easily removable bindings*
- Pages in good condition
- No fold-out or oversize pages
- All pages present, consecutively paginated and in the correct order
- Double-sided printing acceptable, color printing acceptable

*Two examples of adequate binding are: 1) a staple in the upper-left corner of a small document or 2) plastic covers held together by two metal prongs. Transparent covers are preferred. Three-ring binders are discouraged.

B. Transmittal Document (Sample provided in Attachment 1)

The transmittal document is the first item in each submission. This document discusses basic information-- i.e., who is submitting the information, what regulatory actions are involved, the date of transmittal, a list of documents in the package and the contact information. Specifically, this document identifies:

- the submitting company's name and address, its EPA-assigned company number(s) if one has been previously assigned, and contact information, preferably including fax number and email address in addition to name and phone number and the regulatory or other action(s) identified by EPA-assigned number (such as the EPA registration number, case number or decision number) in support of which the package is being submitted. If no number has been assigned by EPA, describe the type of request: data call-in notice of MM/DD/YY, experimental use permit, etc.;

- the transmittal date; and

- a list of all documents included in the package in the order of their appearance. They should be grouped by discipline (e.g., product chemistry, toxicology, environmental fate) and arranged in ascending order by guideline number within each discipline.

Submitters commonly provide this information in a cover letter. This is adequate so long as all of the elements above are included.

C. Individual documents

A data document is most commonly the report of a single scientific investigation including all supporting analyses required for logical completeness. It may also be a compilation of product chemistry data, a summary document that relates to two or more other documents in the submission, a rationale for a data waiver request, or any other document that addresses a data requirement. If a study is a commentary on or supplement to another previously submitted document, or if it responds to EPA questions raised with respect to an earlier document, then submitters should include on the title page the EPA MRID of the earlier document, if known. Previously submitted documents should not be resubmitted unless specifically requested by OPP.

Each document should be consecutively paginated beginning with the title page and continuing throughout the document, including any appendices. If it is extremely long, binding in multiple volumes may be necessary. In this case, the pagination should continue consecutively through all of the physical volumes. Each physical volume should be plainly identified by its title and its position in the multi-volume sequence (e.g., volume 1 of N, 2 of N, etc.). An English translation must be provided for any information in another language, as specified in 40 CFR 158.32(c)(4).

Currently, three identical copies of all applicable data are required. This applies to submissions that are entirely paper. Please note that as OPP phases in its up-front imaging of paper submissions, we expect to reduce this requirement to a single copy. For the latest information on

the status of the up-front imaging effort and number of copies required, please continue to check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm).

1. Document Title Page (Sample provided in Attachment 2)

Contains the following information for unpublished documents*:

- Document title. This should be as descriptive as possible and include the substance(s) or product tested.
- Test guideline(s) http://www.epa.gov/oppts/pubs/frs/home/guidelin.htm
- Author(s). Submitters should cite only individuals with primary intellectual responsibility for the content of the document.
- Study completion date, if applicable; otherwise submitters should use the date on which the document was created.
- Performing laboratory(ies). If the document reports work done by one or more labs, submitters should include on the title page the name and address of the performing lab(s) and the lab's internal project number(s) for the work
- Laboratory project identifier. Submitters should clearly distinguish between the lab's project identifier and any other reference numbers provided by the sponsor or submitter.
- Total page count for the document (Page 1 of xx).

*Published documents should be identified by the relevant facts of publication, such as journal title, volume, issue, page range and publication date.

2. Statement of Confidentiality Claim

The regulations that address data confidentiality requirements are specific to the three categories below. The first category represents the majority of documents submitted to the Office of Pesticide Programs.

- All pesticides other than antimicrobial pesticides and plant-incorporated protectants,
- Antimicrobial pesticides, and
- Plant-incorporated protectants (PIPs).

A. Documents supporting all pesticides other than antimicrobial pesticides and plant-incorporated protectants (See 40 CFR 158.33):

One of the two statements below must appear on the second page of each data document. The wording of these statements is prescribed by 40 CFR 158.33. Neither deviations from the text of these two statements nor claims or markings on the document or its attachments other than the statement provided on page 2 of the document will be recognized as asserting a claim of confidentiality. The statement must be signed and dated by an authorized representative of the submitter.

1) NO CLAIM OF CONFIDENTIALITY

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

2) CLAIM OF CONFIDENTIALITY

Information claimed as confidential has been removed to a confidential attachment.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Use of the statement above requires that all information claimed as confidential be submitted in a separate confidential attachment to the document and cross referenced to the specific location from which it was removed. The confidential attachment must have its own title page and be paginated separately from the non-confidential document.

In the confidential attachment, information claimed confidential under FIFRA 10(d)(1)(A), (B) and (C) must be individually identified.

- FIFRA 10(d)(1)(A): Information that consists of (or whose disclosure would in turn disclose) manufacturing or quality control processes.

- FIFRA 10(d)(1)(B): Information that consists of (or whose disclosure would in turn disclose) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide.

- FIFRA 10(d)(1)(C): Information that consists of (or whose disclosure would in turn disclose) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

Sample cross references between the non-confidential document and its confidential attachment are provided in Attachment 3.

3) VOLUNTARY RELEASE OF INFORMATION TO STATES AND FOREIGN GOVERNMENTS (40 CFR 158.33(c)(4))

In addition to the required use of one of the two confidentiality statements above, submitters are encouraged to include an additional statement to allow EPA to share information with state and foreign governments to facilitate coordination of pesticide reviews. EPA will not consider such a statement to be a waiver of confidentiality or proprietary claims for the information. The statement is as follows:

> **I authorize the Environmental Protection Agency to release any information contained in this document to State and foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.**
>
> Submitter: _____*signature*_____ Date: _____
> Typed Name of Signer: _____
> Typed Name of Company: _____

Information designated as releasable to state or foreign governments in accordance with the above statement may be released to those governments without further notice to the submitter. EPA will inform the state or foreign government of any confidentiality claims associated with the information.

B. Documents supporting antimicrobial pesticides (See 40 CFR 161.33):

40 CFR 161.33 is the regulation that currently governs the procedures for claims of confidentiality of data in antimicrobial pesticide documents. One of the two statements below must appear on the second page of each data document. The statement must be signed and dated by an authorized representative of the submitter.

1) NO CLAIM OF CONFIDENTIALITY

If no claim of confidentiality is being made for information described by FIFRA section 10(d)(1)(A), (B), (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement. This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature:

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

Submitter: _____*signature*_____ Date: _____

Typed Name of Signer: _____
Typed Name of Company: _____

2) CLAIM OF CONFIDENTIALITY

Any information claimed to be confidential under FIFRA 10(d)(1)(A) through (C) must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a claim of confidentiality for such information under FIFRA section 10(d)(1)(A), (B) or (C). The attachment must have a cover page that is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA section 10(d)(1)(A), (B) or (C). Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA section 10(d)(1)(A), (B) or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (*i.e.*, identified by number). Each item in the attachment must be referenced in the body of the study by its number in the attachment.

The following statement must appear on the Statement of Data Confidentiality Claims and must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature:

Information claimed as confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Sample cross references between the non-confidential document and its confidential attachment are provided in Attachment 3.

Any information not described by FIFRA section 10(d)(1)(A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

- The information must be clearly marked in the body of the study as being claimed confidential.

- A separate Supplemental Statement of Data Confidentiality Claims must be submitted, identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

- The Supplemental Statement of Data Confidentiality Claims must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

C. Documents supporting plant-incorporated protectants (PIPS) (See 40 CFR 174.9):

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. To assert such a claim, the submitter must comply with all of the following procedures:

- Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

- Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the following points in substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation and will suspend any applicable review of such submissions until the required substantiation is provided.

    1. The portions of the information that are alleged to be entitled to confidential treatment;
    2. The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event or permanently);
    3. The purpose for which the information was furnished to EPA and the approximate date of submission, if known;
    4. Whether a business confidentiality claim accompanied the information when it was received by EPA;
    5. Measures taken by the business to guard against undesired disclosure of the information to others;
    6. The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;
    7. Pertinent confidentiality determinations, if any, by EPA or other federal agencies, and a copy of any such determination, or reference to it, if available;
    8. Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business's competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial and an explanation of the causal relationship between disclosure and such harmful effects; and
    9. Whether the business asserts that the information is voluntarily submitted information as defined in §2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

3. Statement of compliance or non-compliance with good laboratory practice (GLP) standards (40 CFR 160)

Sample compliance statements are provided in Attachment 4. This statement is required only if a document meets the following definition of a study:

> S*tudy* means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term "study" does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility. [Excerpt from 40 CFR 160.3]

4. Flagging of studies for potential adverse effects (See CFR 158.34 and 161.34)

Any study of a type listed in tables 1 and 2 below must include the appropriate one of the two statements below, together with the signature of the authorized representative of the submitter and the date of signature on its fourth page.

1) If the study does not meet or exceed criteria listed in the table:

I have applied the criteria of 40 CFR 158.34/40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

2) If the study meets or exceeds criteria listed in the table:

I have applied the criteria of 40 CFR 158.34/40 CFR161.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Table 1 - Flagging Criteria for All Pesticides other than Antimicrobials
(See 40 CFR 158.34)

Study Types	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined chronic feeding study	870.4200 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend $p \leq 0.05$); or	1
		A statistically significant (pairwise $p \leq 0.05$) increase of any type of neoplasm in any test group, males or females at any does level, compare to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90-day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

Table 2 - Flagging Criteria for Antimicrobial Pesticides
(See 40 CFR 161.34)

Toxicity studies	Pesticide assessment guideline No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study]	83-2	Treated animals show any of the following:	
		An incidence of neoplasms in males or females which increases with dose;	1
		or	
or		A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any does level), compared to concurrent control animals of the same sex;	2
Subchronic feeding study	82-1	or	
		An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals;	3
		or	
		A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	4
Teratogenicity	83-3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels.	5
Neurotoxicity	81-7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/oncogenicity study	83-1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI.	7
		or	
		General (systemic) toxicity NOEL less than 100 times the current existing ADI.	8
Reproduction study	83-4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82-1	Cholinesterase inhibition NOEL less than 100 times the current ADI.	10
		or	
		General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	11

VII. PAPERWORK REDUCTION ACT NOTICE

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. The corresponding Information Collection Request (ICR) documents for the pesticide application process have been assigned under the following ICRs: Application for New and Amended Pesticide Registration EPA ICR number 0277.15 approved OMB control number 2070-0060; Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2), EPA ICR number 1204.11 approved OMB control number 2070-0039; Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients, EPA ICR number 0597.10 approved OMB control number 2070-0024; Experimental Use Permits (EUPs) for Pesticides, EPA ICR number 0276.14 approved OMB control number 2070-0040; Notice of Pesticide Registration by States to Meet a Special Local Need (SLN) under FIFRA Section 24(c), EPA ICR number 0595.10, approved OMB control number 2070-0055; and the Pesticide Data Call-in Program, EPA ICR number 2288.01, approved OMB number 2070-0174.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

Under the PRA, 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 numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable.

VIII. SUBMISSION OF INFORMATION

See http://www.epa.gov/PR_Notices/pr2006-1.pdf for instructions on transmitting information to the Office of Pesticide Programs.

IX. FOR FURTHER INFORMATION

If you have questions or need further information about this notice, you may contact Teresa Downs, Information Technology and Resources Management Division, at downs.teresa@epa.gov or (703)305-5363.

Dated: November 30, 2011

Steven Bradbury, Ph.D., Director
Office of Pesticide Programs, OCSPP
U.S. Environmental Protection Agency

ATTACHMENT 1
SAMPLE TRANSMITTAL DOCUMENT

Submitter:

Smith Chemical Corp.
1234 West Smith Street
Cincinnati, OH 98765

Company Contact: _____*(signature)*_____
Typed Name of Signer: _____

Phone: _____
Fax: _____optional_____
Email address: _____ optional_____

Regulatory Action in Support of Which this Package is Submitted:

EPA registration number: 98765-1, My Flea Product
Amendment to add ticks to the label.

Submission date:

MM/DD/YY

List of Submitted Documents:

Volume 1 Administrative materials (This list is for illustration purposes and does not attempt to list all of the necessary forms to support a specific regulatory action.)

- Amendment form
- Data Matrix
- Proposed label text
- Confidential Statement of Formula

Volume 2 Title of first data document (Guideline No.)

Volume 3 Title of second data document (Guideline No.)

ATTACHMENT 2
SAMPLE TITLE PAGE

TITLE

Product ABCXYZ
Acute Oral Toxicity in Rats

TEST GUIDELINE

OPPTS 870.1100

AUTHOR

John C. Davis

STUDY COMPLETION DATE

01/22/2008

PERFORMING LABORATORY

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, DE 33445

LABORATORY PROJECT ID

ABC 08-34

PAGE COUNT

1 of 35

ATTACHMENT 3
SAMPLE CROSS REFERENCES TO A CONFIDENTIAL ATTACHMENT

Reference on page 12 of the non-confidential text:

> *Information claimed confidential has been removed to the confidential attachment. See Cross Reference 1.*

Reference on page 18 of the non-confidential text:

> *Information claimed confidential has been removed to the confidential attachment. See Cross Reference 2.*

Complementary reference in the confidential attachment:

> Cross Reference 1, page 12
> FIFRA reference: 10(d)(1)(A)
>
> *Reproduce the deleted text here.*

Complementary reference in the confidential attachment:

> Cross Reference 3, page 18
> FIFRA reference: 10(d)(1)(B)
>
> *Reproduce the deleted text here.*

ATTACHMENT 4
SAMPLE GOOD LABORATORY PRACTICE COMPLIANCE STATEMENTS

Example 1:

This study was conducted in accordance with 40 CFR 160.

Study Director: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Laboratory: _____

Sponsor: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Submitter: _____*signature*_____ Date: _____
Typed Name or Signer: _____
Typed Name of Company: _____

Example 2:

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

_____
_____

Study Director: _____*signature*_____ Date: _____
Typed Name: _____
Typed Name of Laboratory: _____

Sponsor: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Example 3:

The submitter of this study neither sponsored this study nor conducted it and does not know whether the study was conducted in accordance with 40 CFR 160.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

ATTACHMENT 5
GLOSSARY

Applicant:	Any person or entity who sends any application, petition, or other submission to OPP with the intention to persuade OPP to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. (See 40 CFR 158.3).
Author(s):	Individual(s) primarily responsible for the intellectual content of a document. In the case of a document that meets the definition of a "study' in 40 CFR 160.3, the study director should be identified as the author.
Authorized Agent:	A person residing in the United States who is designated by an applicant to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and U.S. mailing address of his agent. (See 40 CFR 152.50(b)(3).) If an authorized agent signs any of the statements described in this notice, then it should be made clear that he is doing so as the applicant's (submitter's) authorized agent.
Data:	Information submitted by an applicant to satisfy an Agency data requirement such as those published in 40 CFR parts 158 and 161, or any other information requested by EPA or presented by the applicant in support of a scientific or regulatory decision by OPP. Includes, but is not limited to, data to support registration review, adverse effects information submitted under FIFRA 6(a)(2), information supporting applications for new or amended registration, experimental use permits, tolerance petitions and tolerance exemption petitions. This information is contained in documents that are collectively referred to as data. Studies (see definition below) are a subset of data. Studies are subject to the requirements of 40 CFR 160, OPP's Good Laboratory Practice Standards (GLPs).

MRID:	**M**aster **R**ecord **Id**entifier. A unique 8-digit number assigned to each document submitted to OPP. These documents are permanent records; you do not need to resubmit any document that has already been assigned a MRID unless specifically requested to do so by OPP. Use the MRID to cite a previously submitted document that supports a new regulatory action. Never re-use an MRID; EPA assigns a new MRID to an amended document in order to preserve the integrity of the records in our database.
OECD Dossier:	The Organization for Economic Co-operation and Development (OECD) has developed a format for pesticide data submissions that is accepted by numerous countries including the United States. See http://www.oecd.org.
Performing Laboratory:	Facility/facilities where a study or part of a study is conducted.
Person:	Includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity. (See 40 CFR 160.3.)
Plant-incorporated protectant (PIP):	A pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof. (See 40 CFR 174.3)
Sponsor:	A person who initiates and supports, by the provision of financial or other resources, a study. (See 40 CFR 160.3.)
Study:	Any experiment at one or more test sites in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms or media. The term "study" does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility. (See 40 CFR 160.3.)
Study Completion Date:	Date the final report is signed by the study director. (See 40 CFR 160.3.)
Study Director:	Individual responsible for the overall conduct of a study. (See 40 CFR 160.3 and 160.33.)
Study Profile Template:	A study profile records basic study information such as materials, methods, results, and the applicant's conclusions in a standard format

	known as the template that mirrors the template used by EPA science reviewers in preparing their Data Evaluation Records (DERs).
Submission:	Consists of all the documents sent to OPP at the same time in support of a single regulatory action or a group of related actions, such as a product amendment and a related tolerance petition by an Applicant (see definition above). The documents should be accompanied by a transmittal document and related administrative material (e.g., EPA Forms 8570-1, 8570-4, etc.) as appropriate. This transmittal document and administrative material should be grouped together in the first physical volume if the submission is on paper. Consult the e-submission XML guidance document at http://www.epa.gov/pesticides/regulating/registering/submissions/XMLsubmissions/e-submission_xml_guidance_document_v1.pdf for specific information on the format of these documents as files on a CD/DVD.
Submitter:	Any person making a submission to OPP.
Test Guideline:	Number that identifies a published testing procedure. The OCSPP harmonized test guidelines are available at: http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm
Transmittal Document:	Provides the who, what, when and why of the data submission by identifying the submitter, submission date, regulatory action being supported, and a list of the documents included in the submission. See 40 CFR 158.32(b), 161.32(a).