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Pesticide Registration (PR) Notice 86-5: 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)

July 29, 1986

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- Pesticide Registration Notices

Notice To: Producers, Formulators, Distributors And Registrants

Attention: Persons Responsible for Federal Registration of Pesticides

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

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. APPLICABILITY

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits (EUPs), tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA section 10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must

continue to be, submitted differently under separate cover.

III. EFFECTIVE DATE

This Notice is effective on November 1, 1986. Data formatted according to this Notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. BACKGROUND

On September 26, 1984, EPA published proposed regulations in the FEDERAL REGISTER (49 FR 37956) which include Requirements for Data Submission (Section 158.32 of Title 40 of the Code of Federal Regulations [40 CFR 158.32]), and Procedures for Claims of Confidentiality of Data (40 CFR 158.33). These regulations specify the format for data submitted to EPA under FIFRA section 3 and FFDCA sections 408 and 409, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this Notice.

The Office of Pesticide Programs (OPP) is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

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

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA section 3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

(The original PR Notice 86-5 had a paragraph about submitting extra copies of studies for the public docket. This practice is no longer followed.)

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this Notice, which applies only to data submitted with an application.

VI. FORMAT REQUIREMENTS

A more detailed discussion of these format requirements follows the index below, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

INDEX Example

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g., the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that

are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, EUP, section 3(c)(2)(B) Data Call-In Notice, section 6(a)(2) submittal, or a Special Review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guidelines Reference Number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g., the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR Part 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into Sections A, B, C . . . of the petition or application, as defined in 40 CFR 180.7 and 158.125 (petitions), or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies in section F.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1. Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for

other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases, each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end-use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an EUP, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 157-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to

contain Confidential Business Information (CBI) as defined in FIFRA section 10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this Notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (See Attachment 7.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Attachment 2
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required.	Attachment 3
Certification of Good Laboratory Practice (GLP)	If study reports laboratory work subject to GLP requirements.	Attachment 6
Flagging Statements	For certain toxicology	

studies. (When flagging requirements are finalized.)

Body of Study Always - with an English language translation if required.

Study Appendices At submitter's option

Cover Sheet to Confi- If CBI is claimed under
dential Attachment FIFRA section 10(d)(1)(A),
(B), or (C)

CBI Attachment If CBI is claimed under Attachment 5
FIFRA section 10(d)(1)(A),
(B), or (C)

Supplemental Statement Only if confidentiality is Attachment 4
of Data Confidentiality claimed on a basis other
Claims than FIFRA section
10(d)(1)(A), (B), or (C)

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; DO NOT INCLUDE CBI ON THE TITLE PAGE. An example of an acceptable title page is on Attachment 2 of this Notice.

The following information must appear on the title page:

a. Study Title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data Requirement Addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession Number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page.)

g. Facts of Publication. If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA section 10(d)(1)

Each submitted study must be accompanied by one of the two alternative forms of the Statement of Data Confidentiality Claims specified in the proposed regulation in sections 158.33(b) and (c) (see Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA section 10(d)(1)(A), (B), or (C). Use

the appropriate alternative form of the statement either to assert a claim of section 10(d)(1) data confidentiality (section 158.33(b)) or waive such a claim (section 158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE at bottom of Attachment 3).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA section 10(d)(1)(A), (B), or (C) (as described in D.2. above), all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (see Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA section 10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims
(See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA section 10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as

subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR Part 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID Number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

o Do not include frayed or torn pages.

o Do not include carbon copies, or copies in other than black ink.

o Make sure that photocopies are clear, complete, and fully readable.

o Do not include oversize computer printouts or fold-out pages.

o Do not bind any documents with glue or binding tapes.

o Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket (NOW OBSOLETE)

Data submittal packages associated with a Registration Standard or Special Review were originally required in four copies in order to include a copy for the Docket. This practice has been discontinued. Only three copies of a study are now required.

V. FOR FURTHER INFORMATION

For further information, contact Kathryn S. Bouve, Chief, Information Services Branch, Program Management and Support Division, at (703) 305-5032. [Address Updated 1/8/97]

original signer: James W. Akerman
Acting Director

Registration Division

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and Address of Submitter (or All Joint Submitters**)

+Smith Chemical Corporation Jones Chemical Company
1234 West Smith Street -and- 5678 Wilson Boulevard
Cincinnati, OH 98765 Covington, KY 56789

+Smith Chemical Corporation will act as sole agent for all submitters.

2. Regulatory Action in Support of Which This Package is Submitted

Use the EPA identification Number (e.g., 359-EUP-67) if you know it. Otherwise describe the type of request (e.g., experimental use permit, data call-in notice - of xx-xx-xx date).

3. Transmittal Data

4. List of Submitted Studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)
.
.
.
Vol n. Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

** Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name:
_____

Company Contact: _____
_____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical Name) - Magnitude of Residue on Corn

Data Requirement

Guidelines Reference No. 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA section 10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

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

Company: _____

Company Agent: Typed Name Date:
---------- ----------
Title Signature
---------- ----------

2. Claim of confidentiality under FIFRA section 10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA section 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.

Company: _____

Company Agent: Typed Name Date:
---------- ----------
Title Signature
---------- ----------

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA section 10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

o Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.

o Cite the reasons why the cited passage qualifies for confidential treatment.

o Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.

o Identify the measures taken to guard against undesired disclosure of this information.

o Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.

o Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.

o If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.

o If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1 (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross-reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE LINE REASON FOR THE DELETION FIFRA REFERENCE

6 14 Identity of Inert Ingredient section 10(d)(1)(C)
28 25 " "
100 19 " "

Example 2 (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross-reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):
( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE LINE REASON FOR THE DELETION FIFRA REFERENCE

20 4-17 Description of the quality section 10(d)(1)(C)
control process

Example 3 (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross-reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE(S) REASON FOR THE DELETION FIFRA REFERENCE

33-41 Description of product section 10(d)(1)(A)
manufacturing processing

ATTACHMENT 6

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter: _____

Sponsor: _____

Study Director: _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter: _____

Sponsor: _____

Study Director: _____

Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

Submitter: _____

ATTACHMENT 7

FORMAT OF THE SUBMITTAL PACKAGE

A. Transmittal Document.

B. Related Administrative Materials
(e.g., Method of Support Statement, etc.).

C. Other materials about the submittal
(e.g., summaries of groups of studies to aid
in their review).

D. Studies, submitted as unique physical
entities, according to the format below.

FORMAT OF SUBMITTED STUDIES

A.* Study title page.

B.* Statement of Confidentiality Claims.

C.* GLP and flagging statements - as appropriate.

D.* Body of the study, with English language translation if required.

E.** Appendices to the study.

F.** Title Page of the Confidential Attachment.

G.** Confidential Attachment.

H.** Supplemental Statement of Confidentiality Claims.

LEGEND

* Documents which must be submitted as appropriate to meet established requirements.

** Documents submitted at submitter's option.

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http://www.epa.gov/PR_Notices/pr86-5.html
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Last updated on Tuesday, July 27, 2010