



California Notice 2013-11
Supersedes California Notice 2006-06

TO: PESTICIDE PRODUCT REGISTRANTS AND DATA SUBMITTERS

SUBJECT: FORMATTING REQUIREMENTS FOR SCIENTIFIC DATA SUBMITTED TO THE DEPARTMENT OF PESTICIDE REGULATION AND OPTIONAL ELECTRONIC DATA SUBMISSION (2013 Update)

All scientific data submitted to the Department of Pesticide Regulation (DPR), **must** be formatted as described below. In the past, Pesticide Registration Branch (PRB) staff have, at times, assisted registrants by reformatting incorrectly formatted data. However, given the quantity of incorrectly formatted data being submitted, PRB no longer has the staff time nor resources to fix incorrectly formatted data.

Upon receipt of an incorrectly formatted data submission, PRB will send a letter to the submitter stating that we are returning their application. PRB will maintain the submission for six months. If the applicant resubmits the data, properly bound, within six months, PRB will continue processing the submission. If the applicant fails to submit correctly formatted data to support an application for registration or amendment within six months, an additional application fee of \$750 is required.

ACCEPTABLE BINDERS:

- Use “ACCO-PRESS” or equivalent (e.g., SMEAD) **pressboard** folders (**not** plastic or vinyl) with holes punched in the left-hand 11-inch side of the pages. Folder prongs must open to the **front** of the volume. Do not put tape on prongs, or bend them back double.
- If a study exceeds 400 pages, divide it into an appropriate number of ACCO-PRESS or equivalent folders. Leave at least one-half inch of length on each ACCO-PRESS folder prong for the addition of internal DPR documents.
- If a single study needs several volumes, clearly identify each volume in order (i.e. part. 1 of 5, part. 2 of 5, etc.).
- If the data that you are submitting contains fewer than 15 pages, you may use “Duo-Tang” type folders, with three prongs. Folder prongs must open to the **front** of the volume.
- Multiple small studies of similar type (e.g., several efficacy studies, all acute toxicity studies) may be bound together in one volume, provided divider pages and tabs are placed between each study. Include a table of contents and bind to a maximum thickness of 400 pages.



DO NOT USE:

ACCO folders with plastic spines/bindings or covers.
Any plastic, vinyl, construction paper, or plain paper covers.
2-, 3-, 4-ring binders.
Folders with comb-type, “velo”-type, or spiral-type bindings.

FORMAT SPECIFICATIONS:

- Submit only **one** complete copy of each study.
- Only one **type** of study per binder (except as described above).
- Use **only** 8½ by 11-inch white paper, printed with black ink, high contrast and good resolution. Color graphics and images should be printed in color. You may print back to back.
- Ensure that **all** pages are present, numbered and in order.
- **Do not** include oversized computer printout or fold-out pages.
- **Bind** a copy of your cover letter in the front of **each** volume of the submission.
- **Do not** bind applications for registration, labels, or proof of federal registration in data volumes.
- If the original report is not in English, provide a complete English translation.
- Identify each study by the U.S. Environmental Protection Agency (U.S. EPA) guideline reference number and Master Record Identification Number (MRID).
- For any studies conducted on chemicals other than pesticide active ingredients or product formulations (e.g., inert ingredients, precursors, impurities, degradation products, etc.) you **must** clearly identify the type of study (e.g., acute oral LD50), the compound on which the study was conducted, and the reason for its inclusion in this submission (e.g., to support registration of product XYZ, EPA Reg. No. 123-456).
- If your submission is in response to a data call-in, reevaluation, risk assessment, or is an adverse effects disclosure, label it prominently, identifying the specific reason for the submission. **Do not** include any data in the submission that does not relate to the specific purpose of the submission.

ORDER OF STUDY VOLUME CONTENTS:

Front cover
Copy of cover letter to PRB
Title page
Abstract (no confidential information)
Introduction
Materials and Methods
Results and Discussion
Summary of Study
Data, tables, appendices
Analytical methods, etc.
Protocols
U.S. EPA Data Evaluation Report (DER), if available
Back cover

Please **do not** remove or move “confidential” information from where it occurs in a study.

STUDY VOLUME LABELING:

Please clearly label **each** volume with the following information:

- Name of data submitter.
- Product brand name.
- Type of data in the volume (e.g., chemistry, efficacy).
- Number of volumes in the entire submission (e.g., 1 of 27, 2 of 27, etc.).

If the submission is in response to a specific PRB request, be sure to include the reason for submission on the label (e.g., reevaluation data call-in).

OPTIONAL ELECTRONIC DATA SUBMISSION:

DPR encourages applicants for registration of new and amended pesticide products, particularly products containing new active ingredients, to submit an electronic copy of all required data, in addition to the required hard copy.

For electronic submissions, please use compact disks (CDs/DVDs) as the transport medium. Original electronic files **should be converted to** (saved as) “portable document format (PDF) normal” to ensure that they can be accessed and used by DPR evaluators. Do not submit them as Microsoft (MS) Word, TIFF, or other common formats. Supporting raw data files may be submitted as MS Excel files.

In order to facilitate multiple DPR evaluators ability to review the supplied CD/DVD concurrently, DPR is requesting three (3) copies of all CDs/DVDs containing scientific studies submitted to support the registration of products containing new active ingredients.

When submitting electronic studies, please consider the following:

- Fonts: Embed all fonts. Make sure that no fonts are set to “Never Embed.” Subset fonts when percent of characters used is below 100%. Subsetting the embedded fonts is desirable because it is rare that a document would use all the characters in a font set. Embedding the unused characters increases the file size.
- Compatibility: Choose compatibility with Acrobat 5.0 (PDF 1.4)
- File security: Do not apply PDF security of any type to the document.
- Attached files: Do not attach files to the PDF.
- File archival standards: Choose PDF/A

CD/DVD LABELING:

Please clearly label **each** CD/DVD with the following information:

- Name of data submitter.
- Product brand name.
- Number of CDs/DVDs for the entire submission and the number of copies provided (e.g., 1 of 3 – copy #1, 1 of 3 – copy #2, 1 of 3 – copy #3; 2 of 3 – copy #1, 2 of 3 – copy #2, etc.).

QUESTIONS:

If you have any questions regarding these guidelines for hard copy submissions, please e-mail Ms. Jacquelyn Rivers at <jrivers@cdpr.ca.gov>, or telephone her at 916-324-3571. If you have questions regarding electronic submissions, please e-mail Ms. Denise Alder at <dalder@cdpr.ca.gov>, or telephone her at 916-324-3522.

Original signed by

Ann M. Prichard, Chief
Pesticide Registration Branch
916-324-3931

October 30, 2013

Date

cc: Ms. Jacquelyn Rivers
Ms. Denise Alder