Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

California Notice 2017-05
Supersedes California Notice 2013-11

TO: Pesticide Product Registrants and Data Submitters

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

All scientific data submitted to the Department of Pesticide Regulation (DPR) Pesticide Registration Branch (PRB) must be formatted as described below. If PRB receives an incorrectly formatted data submission, DPR will stop all further processing of the submission, including review for additional deficiencies. DPR will send a letter to the applicant informing them that their submission is unacceptable due to formatting deficiencies.

If the applicant submits properly formatted data within six months from the date of DPR's letter, PRB will continue processing the submission. If the applicant fails to submit correctly formatted data to support an application for registration or application to amend a currently registered pesticide product within the six-month timeframe, the applicant will be required to submit a new application form, all relevant documents (including properly formatted data), and applicable application fee.

ACCEPTABLE DATA SUBMISSIONS:

- Pressboard report covers with prong fasteners (e.g., ACCO, Smead, or equivalent; not plastic, vinyl, or 3-ring) with holes punched on the left 11-inch side of the pages. Folder prongs must open to the front of the volume. Do not place tape on prongs, or bend them back double.

- If a study exceeds 400 pages, divide it into an appropriate number of pressboard folders with at least one-half inch on each pressboard 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 submission contains fewer than 15 pages, "Duo Tang" style cardstock folders, with three prongs may be used. 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.

UNACCEPTABLE DATA SUBMISSIONS (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, strip ("velo"), or spiral bindings.

DATA SUBMISSION LABELING:

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, etc.).

ORDER OF DATA SUBMISSION CONTENTS:

Front Cover
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
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.

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. Pages may be printed back to back.
- Ensure all pages are present, numbered, and in order.
- Do not include oversized computer printout or foldout pages.
- Bind a copy of the cover letter in the front of each volume of the submission.
- Do not bind applications for registration, labels, proof of federal registration, or Confidential Statements of Formula/Product Formulation Information 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 (EPA) guideline reference number and Master Record Identification Number (MRID). Place the MRID in a conspicuous place (e.g., adjacent to the study title on the title page or on the Table of Contents).
- For any studies conducted on chemicals other than the pesticide active ingredients or product formulations (e.g., inert ingredients, precursors, impurities, degradation products, etc.), 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) must be clearly identified.
- If the submission is in response to a data call-in, reevaluation, risk assessment, or is an adverse effects disclosure, prominently label the submission and identify 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.

ELECTRONIC DATA SUBMISSION (OPTIONAL):

DPR is developing an infrastructure for the electronic submission of applications for registration, including supporting scientific data. Until that time, 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 CD/DVD as the transport medium. Original electronic files must be 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.

Please submit three (3) copies of all CDs/DVDs containing scientific studies submitted to support the registration of products containing new active ingredients. This will facilitate concurrent review of the CD/DVD by multiple DPR evaluators. Upon receipt, each CD/DVD will be scanned for viruses, coded into the PRB Data Index, and circulated in the same manner as hard copy data.

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 a document would use all the characters in a font set. Embedding the unused characters increases the file size.
- **Format Compatibility:** Use Adobe Acrobat 5.0 (PDF version 1.4) or higher to ensure compatibility.
- **File security:** Do not apply PDF security of any type to the document.
- **Attached files:** Do not attach files to the PDF.
- **File standards:** Choose PDF/A.

CD/DVD LABELING:

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 questions regarding guidelines for hard copy submissions, please contact Mr. Eldred Green at <Eldred.Green@cdpr.ca.gov> or by telephone at 916-445-4382. For questions regarding electronic submissions, please contact Ms. Denise Alder at <Denise.Alder@cdpr.ca.gov> or by telephone at 916-324-3522.

Original signed by Ann Prichard — *February 24, 2017*

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

Date

cc: Mr. Eldred Green, DPR Staff Services Analyst
Ms. Denise Alder, DPR Senior Environmental Scientist (Specialist)