Department of Pesticide Regulation

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California Notice 2023-15

TO: Pesticide Registrants and Other Stakeholders

SUBJECT: Policy For Addressing Missing/Incomplete Data During the Scientific Evaluation Process

The Department of Pesticide Regulation (DPR) Pesticide Registration Branch (PRB) is responsible for the pesticide registration process, including coordinating the evaluation of scientific data by other DPR branches and state agencies to support product registration and amendments. Applicants who apply for registration of a new pesticide product or amendment of a currently registered pesticide are required to submit an accurate and complete application with supporting documents, data, and fee to support the registration of their product. Pursuant to Title 3 of the California Code of Regulations (3 CCR) section 6170(a), if the application, supporting documents, data, and fee are incomplete, missing, or inaccurate, DPR cannot continue the scientific evaluation process for the submission. This policy, effective January 15, 2024, describes PRB's timeframe for applicants to respond to required supporting documents and/or data deficiencies while the submission is undergoing the scientific evaluation process.

For information regarding DPR's return policy for pesticide product registrations and amendments before the scientific evaluation process, please see California Notice 2022-12.

15-BUSINESS DAY TIMEFRAME TO RESPOND TO DATA DEFICIENCIES

Pursuant to the California Code of Regulations, 3 CCR sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192, and 6200, submissions to register a new pesticide product or amend a currently registered pesticide product in California must include or reference all applicable scientific data. In addition, DPR may rely upon data previously submitted to support the registration of a substantially similar product, regardless of the data ownership.

After initial review by the Regulatory Scientist (RS), the submission may require scientific evaluation by specific DPR evaluation programs. If during the scientific evaluation, an evaluation program determines the supporting documents and/or data submitted are incomplete, the RS will e-mail the applicant's authorized representative or agent listed on the application to inform them of the deficiencies. The RS will contact the applicant's authorized representative or agent by e-mail and provide them with a 15-business day timeframe for PRB to receive the deficient supporting documents, data, and/or reference to any DPR previously evaluated data.

The following are examples of deficiencies that could be identified during the scientific evaluation and addressed by the applicant to within the 15-business day timeframe:

- *Missing or incomplete required data/studies*

- *Missing a reference to data on file previously approved by DPR to support registration or amendment of a currently registered product (3 CCR section 6170) to support the labeling claims/changes*
- *Undisclosed content of proprietary blends in product formulation (3 CCR sections 6170, 6170.5, California Notice 2020-13)*

The 15-business day timeframe starts on the date of the e-mail from the RS. If the deficiencies are addressed within the 15-business day timeframe, the evaluator will continue their evaluation. If the applicant's authorized representative agent is unresponsive or unable to provide complete information correcting the deficiency within the 15- business day timeframe, the evaluator will conclude data do not support registration or amendment of the product for their specific evaluation program. The RS will add a "PREDECISIONAL" watermark to the draft "Do Not Register" recommendation evaluation. This draft will be sent to the company's authorized representative and the product will proceed to review by the next evaluation unit (if any) until all required scientific reviews are complete. If complete and accurate supporting documents and/or data addressing the deficiencies is received by PRB while the product is still under scientific evaluation by any program, then the product can be routed back to the evaluation program where the deficiency was recorded. Once all evaluation programs have completed their review, a final recommendation can be made to register or deny the submission.

DENIAL PROCESS

When one or more evaluation programs determine there is insufficient data to support the registration or amendment of a pesticide product, the submission will receive a "Do Not Register" determination from that program. If other required reviews are needed, the submission will proceed to the next evaluation program. If the "Do Not Register" recommendation impacts another program's review, the product will not be routed to the reliant evaluation program. The submission will continue until it has completed its full evaluation(s). When this process is completed, PRB will then propose to deny the submission. The proposed denial will be posted for public comment on the next weekly Notice of Proposed and Final Decisions and Public Reports (NOD) for 30 days. PRB sends a formal "Proposed Denial" letter to the applicant's authorized representative and agent. If an applicant submits information in response to the Proposed Denial letter, the applicant must provide all the incomplete or missing supporting documents and/or data to support their application before the RS can submit the new information to the evaluation program for reconsideration. The applicant's cover letter should include the product brand name, EPA registration number, and DPR tracking identification number (ID#) listed in the upper right corner of the Proposed to Denial letter. If complete and accurate supporting documents and/or data addressing the deficiencies is not received by PRB within 30 days of the date of the original Proposed Denial letter, the final decision to deny the product will be posted on the subsequent NOD.

An applicant may withdraw their application at any time during the registration process, including during scientific evaluation or the public comment period. To do so, the applicant must submit their request to withdraw an application in writing (i.e., by letter or e-mail). The application fee will not be refunded, and the application package will be shredded. If the

applicant requests to withdraw their application, the final decision to deny the product will be posted on the subsequent NOD. However, the NOD will state the product was withdrawn at the request of the applicant.

To assist with understanding the registration process and data requirements, PRB provides stakeholders with several reference documents, such as guides and checklists for product registration, amendment, and notification. These references are available on DPR's Web site at <cdpr.ca.gov/docs/registration/references.htm>. PRB highly encourages applicants to review these resources before submitting a pesticide registration or amendment application.

If you have questions regarding the denial process, please contact the RS assigned to the submission or the Pesticide Registration Branch Ombudsman, Mr. Aron Lindgren at <Registration.Ombudsman@cdpr.ca.gov> or by telephone at 916-324-3563.

Original signed by *12/08/2023*

Tulio Macedo, Chief
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916-324-3527

Date

cc: Mr. Aron Lindgren, Senior Environmental Scientist (Specialist), DPR