August 9, 2023

SUBMITTED VIA EMAIL

Mr. Tulio Macedo, Chief
Pesticide Registration Branch
Department of Pesticide Regulation
California Environmental Protection Agency
1001 I Street
Sacramento CA 95814

Re: Comments regarding policy for addressing missing/incomplete data during the scientific evaluation process

Dear Mr. Macedo:

The Biological Products Industry Alliance (BPIA) appreciates the opportunity to provide comments to the Department of Pesticide Regulation (DPR) regarding policy for addressing missing/incomplete data during the scientific evaluation process.

BPIA is a not-for-profit organization that promotes the responsible development of safe and effective biological products including biopesticides, biofertilizers, and biostimulants. These beneficial tools are used for commercial agriculture, forestry, golf courses, home gardens, horticulture, ornamentals, and more. BPIA also supports public health through education, outreach, and advocacy activities at the state, federal, and international levels. BPIA's membership includes both large and small producers of biological pest control products or biopesticides used extensively by farmers in California.

Considering that DPR's current intake system is paper-based, and it can take at least three weeks for front end staff to process and catalogue any new data that is submitted to address deficiencies, we respectfully believe that a longer response time may be necessary in order to guarantee that all documentation that is submitted to the Department in response to scientific evaluation deficiencies will reach the assigned Research Scientist within the allotted time.

Our members also have the following questions.

- Does this apply to new active ingredient submissions?
- Is an e-submission sufficient to meet the deadline if you say you have also put hard copies in the mail?
- Is a response back to DPR which challenges their deficiency identification or is a question for clarification considered a response (and then there could be multiple fifteen-day response opportunities)? For example, they say your efficacy data is insufficient, you request a conditional registration on day three, they say no on day 10, and now you need to go back in and update your graphic label by day fifteen still?
- What is the policy for requesting an extension of the fifteen-day period if it is unrealistic to respond in that amount of time (is an extension request or a request for a meeting considered a response)? What if your response involves requesting a label or data review through public records which takes time?

Thank you for the opportunity to provide comments. We welcome the opportunity to further discuss with DPR. Should you have questions about or wish to have further discussion regarding these comments, please contact me.

Sincerely,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director