January 27, 2022

SUBMITTED VIA EMAIL

Tulio Macedo, Chief
Pesticide Registration Branch
Department of Pesticide Regulation
916-324-3527

Re: Comments regarding proposed policies for the Application Return Policy For Pesticide Product Registrations And Amendments and Reprioritization of Submissions

Dear Mr. Macedo:

The Biological Products Industry Alliance (BPIA) appreciates the opportunity to provide comments to the Department of Pesticide Regulation (DPR) regarding the policies being proposed for how the Pesticide Registration Branch will process returns for incomplete applications and registrant requests to reprioritize submissions.

BPIA is an 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.

<u>Application Return Policy For Pesticide Product Registrations And Amendments</u>

- On page two, the first paragraph states, "The RS will also return the submission if any new deficiencies are identified that were not associated with the original submission." After issuing a fifteen-day deficiency letter, can DPR identify new deficiencies or issues and reject the dossier for reasons not identified in the fifteen-day deficiency letter? We request that any new deficiency identified be provided a separate fifteen-day timeframe in order to allow the registrant an opportunity to address the newly identified deficiency.

- Regarding immediate returns, please clarify where it states, "When the registrant addresses deficiencies and makes substantive changes to the product/label that go beyond addressing the deficiencies (e.g., addition use sites, additional pests)." Does this mean any addition of use sites or pests to the label after the initial submission would be returned? For example, while a label is in the evaluation queue, a new EPA stamped "Accepted" label may be issued. In the past registrants have been able to "swap in" the newly approved EPA label with permission from the specialist, even if there have been some substantial changes. Will this still be allowed?

Reprioritization of Submissions

- In the notice, please provide examples of justifications for reprioritization.
- In the notice, please include an exemplary schedule or timeline for the decision by the Pesticide Registration Branch Chief regarding a reprioritization submission requests.

Should you have questions about or wish to have further discussion regarding these comments, please contact me. Thank you for your consideration of these comments and for the opportunity for stakeholder engagement on this important issue.

Respectfully submitted,

BIOLOGICAL PRODUCTS INDUSTRY ALLIANCE

Keith J. Jones
Executive Director