



March 18, 2025

SUBMITTED VIA EMAIL

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

SUBJECT: BPIA Comments on:

- 1. Pre-Regulatory Information on Proposed Definitions and Updates to DPR's Processes for Amendments, Notification, and Non-Notification**
- 2. Draft California Notice: Changes to New Active Ingredient and New Major Use Assignments**
- 3. Draft California Notice: Concurrent Submission of New and Amended Pesticide Products to The Department of Pesticide Regulation and The U.S. Environmental Protection Agency**
- 4. Draft California Notice: Adding and Revising Bilingual Translations on Pesticide Labeling**

Dear Mr. Macedo:

The Biological Products Industry Alliance (BPIA) appreciates the opportunity to provide comments to the California Department of Pesticide Regulation (DPR) regarding the draft policies listed above.

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 and biostimulant products used extensively by farmers in California.

1. PRE-REGULATORY INFORMATION ON PROPOSED DEFINITIONS AND UPDATES TO DPR'S PROCESSES FOR AMENDMENTS, NOTIFICATION, AND NON-NOTIFICATION

DPR has requested feedback and comments on the following three categories:

- Proposed definitions of New Active Ingredients and New Major Use
- Proposed definitions of Amendment, Notification, and Non-Notification
- Types of product changes/revisions that fall under each category of Amendment, Notification, and Non-Notification

BPIA has reviewed DPR's draft document and has the following comments.

PROPOSED DEFINITIONS OF NEW ACTIVE INGREDIENTS AND MAJOR NEW USE

NEW ACTIVE INGREDIENTS

DPR defines a “new active ingredient” as any ingredient (through an end-use product or master label) that has never been registered in California or any previously-registered ingredient with no currently registered products over the previous one (1) year from the date of new product application. While the “never been registered” classification is appropriate, the “not actively registered for more than one year” prohibition seems unduly harsh and unwarranted absent any findings that the ingredient no longer meets the requirements for registration. Products are often withdrawn from one or more states due to lack of market penetration or other financial reasons totally unrelated to the safety or efficacy of the product. So long as the active ingredient maintains federal registration with US EPA, new registrations submitted to California for end-use products containing that active ingredient should be treated as existing active ingredients and not new active ingredients.

NEW MAJOR USE

DPR defines a “new major use” as a new product or product amendment proposing to add for the first time in California a new use of the active ingredient for one of the following: (1) outdoor agricultural use; (2) direct application and use in aquatic habitats (*e.g.*, watercress, cranberries, lakes, ponds, streams); (3) use on rice (with certain exclusions, such as biopesticides and plant growth regulators). BPIA has no objections to these classifications.

We would recommend that the Department continue to refer to this category as being “major new use” (rather than “new major use”) in the Notice and also within the CalPest system for consistency and to clarify that this is not a newly created term.

PROPOSED DEFINITIONS OF AMENDMENT, NOTIFICATION, AND NON-NOTIFICATION

As noted in this proposed document, DPR’s definitions of these terms differ from US EPA’s definitions. To the extent practicable, BPIA urges DPR to harmonize its definitions with US EPA’s definitions. This will bring more consistency and less confusion to registrants and result in better compliance and adherence to the process.

In addition, we recommend that DPR include clarifying language that only the changed text submitted in the notification by the registrant be subject to review under the notification process, as all other language has previously been approved by the Department and will have undergone review already.

TYPES OF PRODUCT CHANGES/REVISIONS THAT FALL UNDER EACH CATEGORY OF AMENDMENT, NOTIFICATION, AND NON-NOTIFICATION

The examples of each category are clear and representative of appropriate changes under each. BPIA suggests that in the non-notification category, paragraph E, DPR explicitly include intellectual property markings, including trademark symbols (™ and ®), patent numbers or patent pending notations, and ownership attributions of same (*e.g.*, “Product” is a registered trademark of ABC Corporation; “Product” is patented under US Patent No. 123456). BPIA also would offer that changes in label color (*e.g.*, addition, removal, or substitution of background, font, or highlighting color) similarly be allowed by non-notification.

Additionally, BPIA has a suggestion concerning CA-specific restrictions and limitations that either are not required by US EPA or are in addition to existing US EPA requirements, such as buffer zones, boom height restrictions, and suppression vs control claims. In these instances where CDPR requires these additions and the label needs to be amended federally with US EPA prior to DPR approval, BPIA asks that DPR consider establishing a “fast-track” review and approval of the label to confirm that the requested changes have been made as no other changes from the previously reviewed label would have been made. This process improvement will benefit both DPR and the registrant by limiting the amount of time required to conduct the final review and approval of the label.

2. DRAFT CALIFORNIA NOTICE: CHANGES TO NEW ACTIVE INGREDIENT AND NEW MAJOR USE ASSIGNMENTS

DPR’s proposal to assign new active ingredient and/or new major use assignments to the “New AI” team workload at submission to be followed by assignment to a specific New AI team member is reasonable and BPIA has no objections. BPIA would ask that this new “New AI” team be posted on DPR’s website with the members listed such that BPIA member companies are informed which DPR staff are assigned to the “New AI” function.

3. DRAFT CALIFORNIA NOTICE: CONCURRENT SUBMISSION OF NEW AND AMENDED PESTICIDE PRODUCTS TO THE DEPARTMENT OF PESTICIDE REGULATION AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY

DPR’s proposal to add two (2) additional application types (*i.e.*, (1) major new use; and (2) amendments in response to US EPA Registration Review Interim/Final Decisions) to the list of those eligible for concurrent review while the product is also undergoing federal review with US EPA is a positive step towards streamlining registration and BPIA fully supports this effort.

4. DRAFT CALIFORNIA NOTICE: ADDING AND REVISING BILINGUAL TRANSLATIONS ON PESTICIDE LABELING

DPR’s proposal to allow bilingual labeling on product labels by non-notification rather than the current policy of requiring formal amendment to the label is a welcome change and one that BPIA fully supports.

Thank you for the opportunity to provide these comments on DPR’s proposed changes to product registration action definitions, product team assignments, concurrent review, and bilingual labeling. 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