



May 9, 2022

Mr. Keith J. Jones  
Biological Products Industry Alliance  
8000 Towers Crescent Drive, Suite 1398  
Vienna, Virginia 22182

Dear Mr. Jones:

Thank you for taking the time to review and provide comments to the Department of Pesticide Regulation (DPR) on the proposed *Application Return Policy for Pesticide Product Registrations and Amendments* and *Reprioritization of Submission* policies. The purpose of these notices is to provide guidance to California registration applicants and to departmental staff, while also increasing transparency into the departments processes. DPR encourages feedback from stakeholders on process improvements and appreciates your comments. DPR received several letters from stakeholders regarding the proposed policies. While you had specific questions, comments and feedback from all stakeholders have been summarized and addressed below.

## APPLICATION RETURN POLICY FOR PESTICIDE PRODUCT REGISTRATIONS AND AMENDMENTS

### *What is DPR's intent with the return policy?*

The intended purpose of the return policy is to provide transparency, consistency, and guidance to both the regulated community and departmental staff by creating a formal written policy for these registration actions. The department's goal is to create a more transparent policy where all registrants understand the requirements to satisfy deficiencies during the registration process within an appropriate timeframe. As a result, this policy could also help in reducing submission processing timeframes. Additionally, departmental staff will be held to the same standard and can reference the return policy when deficiencies are present.

### *Is the return policy driven by delays in mailing times, reduced staff, and overall delays in processing times of applications during the pandemic?*

As mentioned above, the policy is striving for transparency and consistency with the regulated community and departmental staff by establishing set standards and deficiency timeframes. Though the pandemic has impacted most organizations, including DPR, these changes are not a result of the pandemic.

Mr. Keith J. Jones

May 9, 2022

Page 2

*Why is this policy being proposed during the pandemic when registrants have limited access to their offices?*

DPR is implementing this policy in an effort to provide consistency and clear standards for registrants and departmental staff. Previously, DPR had an informal 5-business day return policy that was not applied uniformly because it lacked a more specific framework. After a comprehensive review of past submissions, the new policy timeframe is increased to 15-business days and sets clear standards.

*Will concurrent and expedite product submissions be impacted by the return policy?*

All submissions to the department will be held to the same standards and guidelines, including submissions that have been either expedited or granted concurrent review with the U.S. Environmental Protection Agency (U.S. EPA). DPR recognizes that concurrent submissions will not include U.S. EPA documentation at the time of submittal to the department.

*When will the 15-business day timeframe begin?*

The Regulatory Scientist (RS) will contact the registrant's authorized representative or agent by e-mail and provide them with a 15-business day timeframe for the Pesticide Registration Branch (PRB) to receive all corrected items. The 15-business day timeframe starts on the date of the e-mail from the RS.

*What if the registrant cannot address deficiencies in a 15-day timeframe? Can a registrant request an extension?*

The RS will return the submission if the registrant's authorized representative or agent is unable to provide application materials correcting the deficiency within the 15-business day timeframe. DPR will not grant an extension to the 15-business day timeframe. With a return, registrants are provided the opportunity to resubmit any corrected application materials within six months (180 calendar days) of the date of the original return letter without payment of a new fee.

*Why does the California Notice use broad language in the statements "The following are examples of deficiencies that may qualify for the 15-business day timeframe" and "The following are examples of the types of deficiencies that will result in an immediate return"?*

DPR encounters various types of deficiencies and cannot account for all situations. The examples listed in the notice are the most common deficiencies received. DPR will consider revisiting language in the notice before implementing the policy.

*In the event that a registrant is out of the office, does the 15-business day timeframe still begin when the e-mail is sent from the assigned RS?*

The 15-business day timeframe starts on the day the RS sends the deficiency e-mail. DPR recognizes that situations could occur when authorized representatives or agents are out of the office for an extended period of time. DPR is unable to plan for these occurrences and encourages authorized representatives or agents to have backup representatives to address any concerns that come up while out. DPR must have a current letter of authorization for all representative agents to work on the submission.

Mr. Keith J. Jones

May 9, 2022

Page 3

*DPR should consider a "hold" or "pause" status on submissions if a registrant cannot correct deficiencies within the given timeframe, so it does not impact the schedule of the registration process.*

DPR's current processes and databases are not capable of implementing a hold or pause on submission processing timeframes. DPR expects applicants to have compiled all the necessary information for registration prior to submitting to DPR. Regarding any deficiencies DPR does find, if the needed information cannot be provided within the 15 business days, the submission will be returned. Upon a return, the deficiency can be corrected and the application resubmitted within an additional 6 months to resubmit without paying a new fee. This will continue to be the case in the California Pesticide Electronic Submission Tracking (CalPEST) system.

*Will DPR accept corrected application materials if sent during the 15-business day timeframe but is expected to arrive late?*

Yes, please provide the package tracking information to your assigned RS as a means to verify that the corrected application materials were sent during the 15-business day timeframe. Under the return policy, the deficiencies will only be satisfied when the department receives all the corrected application materials. Deficiencies will not be met by contacting DPR with a status update on the corrected materials.

*DPR should consider a "sunset" date on the return policy once CalPEST is functional.*

DPR is currently not considering a "sunset" date for this policy. CalPEST will help in minimizing the number of errors on submitted applications. However, the CalPEST will still rely on stakeholders submitting accurate information that the system will not be able to verify (e.g., cross referencing an application and a proposed label to confirm that the application information is accurate). The majority of deficiencies outlined in the notice will be applicable even after CalPEST is fully implemented. Additionally, DPR will continue to accept paper-based submissions after CalPEST is implemented.

*DPR should consider removing "product revisions that require U.S. EPA approval" from the immediate return section as registrants are in a better position than the RS to determine the appropriate U.S. EPA action.*

DPR staff closely track and follow publications, the federal label review manual, and other resources U.S. EPA publishes. As a result, DPR staff are well-informed on changes that would require U.S. EPA approval before appearing on marketing labels in the State of California. If it is unclear whether a revision requires U.S. EPA's approval, the RS will confirm with U.S. EPA before returning the submission.

*DPR should consider implementing processes similar to U.S. EPA's Pesticide Registration Improvement Extension Act (PRIA).*

DPR continues to strive for ways to be transparent with stakeholders in the best way possible according to DPR's capabilities regarding submission timeframes and the registration process. However, DPR has not found it feasible to implement a PRIA-like process

Mr. Keith J. Jones

May 9, 2022

Page 4

*DPR should consider receiving corrected application materials from registrants via e-mail since the department will be issuing these notices by the same mechanism.*

DPR currently does not have the capabilities to store digital contents nor print large documents to facilitate satisfying a deficiency by e-mail. Printing of documents of a few standard sized pages, may be considered and should be discussed with the assigned RS.

*DPR should consider requiring the RS to respond to registrant emails within 2-3 business days.*

Currently, RSs are tasked to respond to all business inquiries within one-business day. If an RS is out of the office for an extended period, then an "out of office" automated response is set. DPR will revisit these requirements with all RSs before implementing the return policy.

*DPR should consider removing the bullet points related to missing data and undisclosed proprietary blends from 15-business day return timeframe.*

In accordance with Title 3 California Code of Regulations (3 CCR) section 6170, DPR requires registrants to submit a complete application before a product is registered in the State of California. Registrants must disclose a product's full composition to the department, including proprietary blends, before registration of the product can occur. Supplemental distributor registrants should coordinate with their basic registrant to ensure that the appropriate information is provided to the department. DPR also requires all applicable data to support product registration, or reference to data on file with the department, be provided at the time the registrant submits their application. If registrants do not satisfy the requirement of providing a complete application to the department, including proprietary blends and applicable data, the registrant will be given 15-business days to satisfy such requirements before the application is returned.

*Will an RS continue reviewing the submission upon receipt of the corrected application materials or will the submission go to the end of the queue?*

If the submission was not returned, the RS will continue reviewing the submission once corrected application materials are received by the department. The submission will not be placed at the end of the RS queue. If the submission is returned, it will enter the RSs queue and be processed in the order it was received.

*Please provide additional clarification to the statement "when the registrant addresses deficiencies and makes substantive changes to the product/label that go beyond addressing the deficiencies (e.g., additional use sites, additional pests)."*

Under the new return policy, DPR would immediately return submissions if registrants add substantive changes to the product label while also addressing deficiencies during the 15-business day timeframe. Substantive changes include, but are not limited to, addition of new use sites, pests, efficacy claims, and less restrictive changes to precautionary statements and environmental hazards. Non-substantive changes are outlined in California Notice 2002-01, titled California Notification Process. Consult with your assigned RS before additional changes are made to the product label outside of addressing deficiencies.

*Please provide additional clarification to the statement "Submitted data not formatted appropriately according to California Notice 2017-05."*

Data submitted must be bound and formatted according to California Notice 2017-05. This notice specifies the formatting requirements for scientific data submitted to the department. This notice focuses solely on acceptable data formatting and not data requirements or study standards. Though hard copies of data volumes are required, the notice also provides guidance on the submission of electronic data, which is optional.

*DPR should consider removing "submitted data not formatted appropriately according to California Notice 2017-05" from the immediate returns and providing a 15-business day timeframe.*

California Notice 2017-05 states "If PRB receives an incorrectly formatted data submission, DPR will stop all further processing of the submission, including review for possible additional deficiencies. DPR will send a letter to the applicant informing them that their submission is unacceptable due to formatting deficiencies," and the submission will be returned. If the applicant submits properly formatted data within six-months from the date of DPR's return letter, PRB will continue processing the submission. If the applicant fails to submit correctly formatted data within the six-month timeframe, the submission will be shredded, and no further action will be taken. For DPR to consider registration of the product, the applicant must submit a new application form, all relevant documents (including properly formatted data), and applicable application fee.

*DPR should consider a front-end screen process that includes review timeframes for submitted applications before the submission moves in the queue of an RS.*

PRB will explore a front-end screening process.

*How did DPR arrive at 15-business day timeframe and is 30-business days more appropriate?*

At this time, DPR is not considering a 30-business day timeframe. Presently, DPR has an informal 5-business day return policy. DPR has proposed to increase the timeframe to 15-business days with a more definitive policy as a courtesy to stakeholders. The new policy will help achieve greater transparency in DPR's registration process and increase clear communication and expectations between stakeholders and departmental staff.

## REPRIORITIZATION OF SUBMISSIONS

*How does reprioritization lead to delays?*

Currently, reprioritization of submissions creates delays in the processing of other submissions. DPR's tracking system cannot be updated when a product is reprioritized, which increases the burden on the RS and therefore increases DPR's processing timeframes. The RSs must manually track reprioritized submissions. Manual tracking is challenging and subject to errors when submissions have been switched; all of which cause delays in processing other submissions.

Mr. Keith J. Jones

May 9, 2022

Page 6

*Will there still be a way for companies to reprioritize their products?*

DPR recognizes there may be times when a company may need to reprioritize their submissions due to marketing or other needs. Therefore, the proposed California Notice still allows for product reprioritization. This policy allows stakeholders to submit a reprioritization request to the Pesticide Registration Branch Chief. When a reprioritization request is made, the Branch Chief will review the justification, and a response will be generated for the requestor in a timely manner. This determination needs to be conducted by the Branch Chief due to the resulting extended timeframes for other submissions. Branch Chief review also allows for consistent determinations on reprioritization requests.

*Will there be a "sunset" date for this policy?*

At this time, DPR is not considering a "sunset" date for this policy. With more transparency regarding workload and registration timeframes, DPR has created a California Notice reflecting the previous year's product submission timeframes. This California Notice will be published yearly. DPR encourages stakeholders to use this notice as a tool to plan submissions accordingly. DPR recognizes priorities for stakeholders can change (e.g., marketplace need, shortages of active ingredients). When those priorities change, the stakeholders still have the opportunity to request reprioritization of their submission (see above).

*Can DPR create a built in "pause/hold" functionality in the review process which would alleviate concerns about reprioritization negatively impacting timelines?*

DPR current database tracking system is limited and lacks the capability of a "pause/hold" function. A hold feature is being evaluated for certain circumstances in the California Pesticide Electronic Submission Tracking (CalPEST) system, however it is uncertain whether it could be used to address reprioritization.

Mr. Keith J. Jones

May 9, 2022

Page 7

These policies will assist DPR with increasing efficiencies, consistency, and transparency in the registration process while providing guidance to stakeholders and departmental staff. DPR appreciates your willingness to comment on the proposed policies.

If you have questions regarding this notice, please contact the Pesticide Registration Branch Ombudsman, Mr. Aron Lindgren at <Registration.Ombudsman@cdpr.ca.gov> or by telephone at 916-324-3563.

Sincerely,

*Tulio Macedo*

Tulio Macedo (May 9, 2022 13:30 PDT)

Tulio Macedo, Chief  
Pesticide Registration Branch  
Department of Pesticide Regulation  
916-324-3527  
Tulio.Macedo@cdpr.ca.gov

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