Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

Fifteenth Annual Report

Process Improvements in the Pesticide Program

Pesticide Reevaluation Programs

Registration Review

Office-Wide Improvements

EPA's Office of Pesticide Programs (OPP) continues to find opportunities to be more efficient in the registration review process and has implemented several changes during FY'18. Some examples included streamlining Draft Risk Assessments and Proposed Interim Decisions into one deliverable, combining multiple chemical risk assessments into one assessment by class, and continuously improving program coordination and implementation.

OPP continued to improve the Pesticide Submission Portal (PSP) during FY'18. In FY'18, features were added to allow registrants to 1) submit Registration Review label amendments through PSP, 2) submit data on behalf of a consortium composed of multiple registrants, and 3) establish a passphrase hint. In addition, various bug fixes and user experience improvements were released in FY'18. These features will save a significant amount of registrant time and paper by eliminating the need to print and mail the submissions, as well as reducing the response burden on registrants that belong to a consortium.

Furthermore, in 2018, to improve transparency and communication of risk assessment results and registration review decisions, OPP completed the technical development of a pesticide registration review decision capture database. OPP's Chemical Review Managers are currently being trained on how to use the database to track mitigation measures required through registration review. OPP expects that this database will improve consistency of risk mitigation decisions across the program.

Pesticide Reevaluation Division Improvements

In November 2014, OPP management convened a "Lean Team" comprised of 10 staff from across OPP to participate in a 5-day Kaizen Event to improve the pesticide registration review process. The overarching goal of the Event was to optimize chemical team interactions in a manner that creates more consistent, defensible, protective, and enforceable pesticide risk management decisions that are timely and efficient. The Lean Team identified pesticide registration review as one topic and finalized the *Registration Review Process Map* and *Leaning Registration Review for Conventional Pesticides*. The report outlines potential registration review process improvements intended to guide a more efficient and effective registration review process.

Between 2015 and 2017, the Pesticide Re-evaluation Division (PRD) has been implementing the improvements identified in the report. Examples of major outcomes in 2015 from the Lean process included the development of aggregate pesticide use information tables to streamline incorporation of such information in the risk assessment process. In 2016, the program added more time between risk assessment and Preliminary Interim Decision (PID) publication to provide for the development and consideration of the benefit and impact of risk mitigation decisions. Additionally, PRD also developed a standard operating procedure (SOP) that defines the milestones and needed team engagement for risk mitigation decision development. The objective was to improve communication across the impacted divisions and ultimately improve the decisions documents that

PRD develops. In 2017, the program continued to implement the risk mitigation SOP as the registration review shifts into the risk-management phase.

In 2018, PRD made significant strides in continuously identifying potential hurdles and finding solutions in meeting the 2022 registration review deadline. In March 2018, the PRD management team, along with the Division's senior staff, held an all-day retreat. The Division revisited the 2014 Lean report action items and identified two additional areas for better coordination and planning. One area is for PRD's Chemical Review Managers to work more explicitly with their team members to clearly identify the risk management goals, especially for cases with ecological and worker risks, early on. Another area of impediments is the delay in receiving necessary data for the Agency to conduct risk assessments. To address the risk management goal and the data delay challenges, PRD is actively developing a weight of evidence approach for defining risk management goals and a framework to address data delays. In 2019, PRD will coordinate with the science divisions and the Biological and Economic Analysis Division to finalize a path forward on both issues for the Program. In terms of additional areas for efficiency, in 2018, PRD piloted "streamlined Interim Decision" for several cases where no significant comments or major changes were made on the Proposed Interim Decisions.

PRD continued to work with registrants to receive and review amended labels per registration review interim decisions. PRD completed review of nearly 300 labels in 2018 and will continue to provide updates on the number of product labels that have been approved with the required mitigation in future reports.

Antimicrobials Division Improvements
In FY'18, the Antimicrobials Division (AD) launched a series of weekly meetings with AD regulatory and science leadership to strategize options for meeting the 2022 registration review deadline. This improved the process for developing the annual registration review deliverable goals leading up to 2022.

Also, in FY'18, AD improved efforts to receive outstanding data that are necessary to complete registration review cases. AD implemented an Access Database to facilitate the tracking of Data Call-in (DCI) responses. This improved the process for identifying which registrants AD should contact regarding overdue data. Additionally, AD finalized a Product Suspension SOP to streamline the process for following up with delinquent registrants.

Finally, in FY'18, AD started receiving amended labels per registration review interim decisions. AD will provide updates on the number of product labels that have been approved with the required mitigation in future reports.