

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report



March 1, 2018

Process Improvements in the Pesticide Program

Pesticide Reevaluation Programs

Registration Review

In November 2014, Office of Pesticide Programs (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 more 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. 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 include the development of aggregate pesticide use information tables to streamline incorporation of such information in the risk assessment process. Another improvement identified by the Lean Team was the critical role that benefit and impact analyses play in risk management decisions and the amount of time needed to do an effective assessment. Based on the Team’s findings, 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. In 2016, PRD also developed a standard operating procedure (SOP) that defines the milestones and needed team engagement for risk mitigation decision development. The SOP articulates the expectation that early in the process, PRD’s chemical review managers will be in regular and substantive contact with the chemical team regarding potential risk mitigation, particularly the scientists and economists from the Health Effects Division (HED), the Ecological Fate and Effects Division (EFED) and the Biological and Economic Analysis Division (BEAD). The objective is 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. Additionally, OPP continued to find opportunities to be more efficient in the registration review process and implemented several changes. Some examples of these opportunities and improvements include:

Combining Draft Risk Assessments and Proposed Interim Decisions

The development of draft risk assessments (DRAs) and proposed interim decisions (PIDs) are two distinct type of deliverables in the pesticide registration review process. Both deliverables require public participation and a minimum 60-day public comment period for each. Typically, OPP completes the DRA for a particular pesticide and releases it for public comment. The PID then is completed and released for public comment about 9 months after the DRA. To streamline and find efficiency in the registration review process, PRD initiated a new effort of combining the two public comment periods into one for chemicals where the expected risks are minimal. The rationale is that these low-risk chemicals would result in minimal mitigation action, if any; therefore, both documents can be released for public comment simultaneously. In 2017, PRD

Implementing the Pesticide Registration Improvement Act – Fiscal Year 2017

completed seven combined DRAs and PIDs: aliphatic esters, bromuconazole, cloransulam, mepiquat chloride/mepiquat pentaborate, nitrapyrin, noviflumuron, and pendimethalin. For these chemicals, OPP was able to complete the DRAs and the PIDs at the same time. This was possible as the DRAs were relatively simple and presented limited risks. Performing both at the same time is a significant resource reduction for OPP but it can also reduce the resources that stakeholders need as only one comment period is needed instead of two. PRD will continue to look for opportunities similar to these in FY'18 and beyond.

Combining Individual Chemical Risk Assessments into one Assessment by Class

In 2015, OPP developed a sulfonylurea (SU) risk assessment strategy to assess 22 sulfonylurea pesticides as a chemical class, instead of individual chemicals, for ecological risk. OPP released a streamlined ecological risk assessment and chemical-specific human health risk assessments for the SUs. In 2016, PRD continued to use the streamlined approach and developed one Proposed Interim Decision (PID), entitled the “Proposed Interim Registration Review Decision for 22 Sulfonylurea (SU) Herbicides,” covering the entire class. In 2017, PRD finalized negotiation discussions with SU technical registrants on necessary risk mitigation and published one streamlined SU Interim Decision. Throughout the development of risk management decision for this class of chemicals, OPP received positive feedback from key stakeholders including the registrants and grower groups regarding the streamlined process.

Additionally, PRD continued to look for additional opportunities to utilize a similar process for other classes of chemicals for registration review. For example, in 2016, EPA developed a pyrethroid registration review risk assessment strategy to assess 22 pyrethroid pesticides as a chemical class with regard to ecological risks, rather than conducting assessments by individual chemical. The human health risk assessments were conducted for individual pyrethroids because there are different human health endpoints based on the most sensitive endpoint among all body systems. In 2017, PRD began to work on a coordinated and streamlined pyrethroid risk mitigation strategy that addresses both potential ecological and human health risks. This effort will allow PRD to address potential pyrethroid risks consistently across the class of chemicals as well as potentially save significant resources. EPA will continue to work on this pyrethroid mitigation strategy in FY'18 with plans to complete it towards the end of FY'18 or early FY'19.

Improving Program Coordination and Implementation

In 2017, in an effort to improve transparency and communication of risk assessment results and registration review decisions, OPP developed a pesticide registration review decision capture database. This database tracks mitigation measures required through registration review, along with their corresponding risks of concern to help the Program track and report on what mitigation measures have been required as a result of registration review. Furthermore, chemical review managers overseeing each case of pesticide registration review can use the database to effectively find mitigation actions previously used for similar chemicals and consider the information as a starting point for the current risk management decision making. Ongoing activities for FY'18 include populating the database with antimicrobial and biopesticide chemical case information and the development of reporting capability. OPP expects that this database will improve consistency of risk mitigation decisions across the program in FY'18 and beyond.

OPP has moved into the risk-management phase of registration review which concludes with label implementation. To help leverage current knowledge and resources, improve consistency across label implementation, and encourage timeliness of label implementation, in 2017, PRD launched a

Implementing the Pesticide Registration Improvement Act – Fiscal Year 2017

label implementation team and reallocated resources within the division to focus on the effort. This team concentrated on developing a process for tracking, reviewing and approving the product labels that require label mitigation. This team will become a dedicated branch in 2018 whose main focus is registration review label implementation. PRD will provide updates on the number of product labels that have been approved with the required mitigation in future reports.

Improving the Data Submission Process for Industry

OPP continued to improve the Pesticide Submission Portal (PSP) during FY' 17. Functionality of the PSP has been expanded to allow pesticide registrants to respond to registration review Data Call-ins (DCIs) since 2016. In FY' 17, features were added to allow registrants to 1) electronically revise their 90 day responses to the DCI and 2) voluntarily submit data electronically that they believe to be relevant to a registration review case, even though the data were not required by a DCI. Both of these features will save a significant amount of time and paper by eliminating the need to print and mail the submissions. Additionally, PSP has a new feature that allows registrants to track the progress of OPP's review of their DCI submissions.