

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

Thirteenth Annual Report



March 1, 2017

Process Improvements in the Pesticide Program

Pesticide Reevaluation Programs

Registration Review

Risk-Management Decision Process Improvement. OPP has moved into the risk-management phase of registration review. To help leverage previous decisions, improve consistency across cases with similar risk concerns and encourage timeliness of decisions, the Pesticide Reevaluation Division (PRD) developed and began piloting a risk management process improvement. The process improvement is designed for identifying key steps and timeframes for the chemical case manager (the chemical review manager or CRM) to follow as they move from the risk assessment to risk-management decisions. This process articulates the expectation that early in the process, the CRM will be in regular and substantive contact with the chemical team, 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 process is to help the CRM and the team to fully understand the outcome and uncertainties of the assessments and move toward meaningful mitigation.

During the last half of FY' 16, PRD began piloting the process. Through the pilot, PRD was able, in cooperation with the science divisions (EFED, HED and BEAD), to refine the process into a final living guidance document that was completed and ready for implementation in early FY' 17.

Optimizing Chemical Team Interactions in Registration Review – Lean Team Update.

[Lean refers to a collection of principles and methods that focus on the identification and elimination of non-value added activity (waste) in any process.] Risk manager and risk assessor interactions are critical to develop pesticide registration decisions. OPP management recognized that there are opportunities to improve risk manager and risk assessor interactions, which have often been ill-structured, inconsistent, sometimes ill-timed, and too often fraught with misunderstanding. To address this problem, 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 chemical team interactions. The overarching goal of the 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 timelier and less resource intensive.

The Lean Team focused on chemical team interactions in conventional chemical registration review under FIFRA. During the Kaizen Event, the team mapped out the current review process for conventional chemicals, identified steps that added value to (or subtracted value from) the process, created a new registration review process, and developed a plan to implement the new process.

The Lean Team identified multiple opportunities for improvement in the conventional chemical registration review process. With regard to chemical team interactions specifically, the Team determined that more teamwork, thought, and discussion were needed earlier in the process, particularly to identify risk management goals and align plans for the risk assessments with those

goals. The Team also identified a need for consistency in decision-making through cross-team discussion on potential mitigation measures and the development of a decision-capture database that allows staff to compare risk management decisions across chemicals, uses, and types of risk.

The Lean Team also identified improvements less specific to chemical team interaction. For example, structured time for benefits, impact, and alternatives assessments did not exist in the registration review process, and there was not enough time allocated for mitigation discussions amongst the team and with stakeholders in advance of decision timeframes.

Since the 2014 Kaizen Event, the Lean Team has finalized the *Registration Review Process Map* and *Leaning Registration Review for Conventional Pesticides*, a 25-page justification of necessary registration review process improvements intended to guide registration review SOP development. The Team spurred BEAD and ITRMD development of aggregate use information tables to streamline incorporation of use information in the risk assessment process. Based on the Team's findings, OPP added an additional quarter between risk assessment publication and Preliminary Interim Decision (PID) publication to provide more time for decision development, required team meetings to discuss draft risk assessments and facilitate better communication between the risk assessment and risk management divisions, and required internal mitigation discussions as soon as risk assessments are published to allow more time for decision-making on risk conclusions that are not likely to change as a result of the public comment process.

PRD has worked to develop and has started using a decision capture database with the Lean Team's input on its structure and function that will facilitate identification of mitigation options across similar chemicals. PRD has implemented several elements of the Team's improved process to improve consistency in decision-making. The team is developing risk assessment communication tools to promote discussion of refinements, risk characterization, and mitigation options consistent with the Team's process improvement objectives. The Lean Team is currently improving templates for meetings and deliverables in the registration review process, and intends to integrate the remaining process improvements in further revisions of registration review SOPs in the coming year.

Combined Sulfonylurea Risk Assessment. EPA developed a sulfonylurea (SU) Registration Review risk assessment strategy to assess 22 sulfonylurea pesticides as a chemical class with regard to ecological risks in a single, streamlined assessment, rather than conducting assessments by individual chemical. The 22 SU chemicals included in this assessment are bensulfuron-methyl, chlorimuron-ethyl, chlorsulfuron, flazasulfuron, foramsulfuron, halosulfuron-methyl, imazosulfuron, iodosulfuron-methyl-sodium, mesosulfuron-methyl, metsulfuron, nicosulfuron, orthosulfamuron, primisulfuron-methyl, prosulfuron, rimsulfuron, sulfometuron-methyl, sulfosulfuron, triasulfuron, tribenuron-methyl, thifensulfuron-methyl, trifloxysulfuron-sodium, and triflurosulfuron-methyl. EPA's streamlined ecological risk assessment and chemical-specific human health risk assessments for the SUs were followed by the publication of a streamlined SU Proposed Interim Decision (PID). The SU PID, entitled the "Proposed Interim Registration Review Decision for 22 Sulfonylurea (SU) Herbicides," is a single document covering 22 sulfonylurea chemicals. The SU PID was signed on June 30, 2016 and published in the July 14, 2016 Federal Register. The original public comment period for the SU PID ended on September 12, 2016 but due to requests from registrants, was followed by an extended public comment

period that closed on November 14, 2016. Since the close of the PID comment period, EPA has begun negotiation discussions with SU technical registrants. We expect to publish an Interim Decision for the SUs in June 2017.

Streamlined Pyrethroid Ecological Risk Assessment. 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 toxicity of pyrethroids to aquatic organisms is well established, and drives the Agency's ecological risk conclusions. The 22 pyrethroid chemicals included in this assessment effort are bifenthrin, cyfluthrin (and beta-cyfluthrin), cypermethrin (and alpha & zeta cypermethrin), cyphenothrin, d-phenothrin, deltamethrin, esfenvalerate, etofenprox, fenpropathrin, flumethrin, cyhalothrins (gamma and lambda), imiprothrin, momfluorothrin, permethrin, prallethrin, pyrethrins, tau-fluvalinate, tefluthrin, and tetramethrin.

The new, updated registration review ecological risk assessment specifically included bifenthrin, cypermethrin, cyfluthrins, deltamethrin, esfenvalerate, fenpropathrin, cyhalothrins, permethrin, and the pyrethrins. EPA's approach is to use this new assessment to serve as the basis for making risk management, mitigation, and regulatory decisions for these chemicals and all of the other pyrethroids currently undergoing registration review, including cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, tefluthrin, and tetramethrin. This approach is described further in EPA's risk management rationale for the pyrethroids registration review. The streamlined assessment approach will create a level playing field for developing risk mitigation for the pyrethroids. The registration review pyrethroid human health risk assessments were not combined, but were conducted for the individual pyrethroids, because there are different human health endpoints for the individual chemicals based on the most sensitive endpoint among all body systems.