

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report



March 1, 2016

Process Improvements in the Pesticide Program

Pesticide Reevaluation Programs

Registration Review

Audrey III Model Development. OPP analyzes aspects of a pesticide's risk by modeling various scenarios of its real world applications. Model development and use have routinely been conducted exclusively by the science divisions within OPP. Risk managers within OPP receive the model outputs and interpret the results and apply them to risk mitigation strategies. This stove pipe approach of risk managers and risk assessors not working together during the model development and initial model use has led to some confusion about the model outputs and their applicability to risk mitigation.

In FY'15, the Environmental Fate and Effects Division (EFED) began development of a new tier II plant exposure estimation tool, Audrey III, to replace and upgrade the existing TerrPlant model. As a process improvement, risk assessors included risk managers during the model development process to discuss the conceptual model and the implications of the model outputs. Involvement by a more diverse OPP team in the initial phases of the model development will allow greater acceptance and more efficient use of the model and its outputs.

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

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 are often ill-structured, inconsistent, sometimes ill-timed, and too often fraught with lack of understanding or 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 is needed earlier in the process,

particularly to identify risk management goals and align plans for the risk assessments with those goals. The Team recognized that some chemical teams are utilizing short-cuts in the process, but that the short-cuts are not formalized in any way and are not considered or used consistently across chemical teams. 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 does not exist in the current process, and there is not enough time allocated for mitigation discussions amongst the team and with stakeholders in advance of decision timeframes. The team also identified a need for greater engagement of registrants 9 to 12 months before docket opening to identify active ingredients or registrations that will not be supported, preliminarily clarify use patterns, as well as obtain bibliographies of studies (and individual studies) that have not been submitted to EPA but could inform the chemical case. Furthermore, the team determined that label clarifications and subsequent label changes earlier in the registration review process have the potential to substantially reduce uncertainty in and rework of risk assessments.

Finally, the Lean Team acknowledged and adopted existing efforts to improve registration review. In the short to medium term, completed, high-quality Use Summary Tables are a powerful tool to facilitate consistency in the way different divisions assess risks, and their use is highly supported by the Team either as registrant submission or a derivation of the Label Use Information System (LUIS) Report. In the long term, a fully-populated SmartLabel database with full-functionality for EPA staff is expected to subsume the role of a Use Summary Table.

The Lean Team is updating the Standard Operating Procedures (SOPs) for Conventional Chemical Registration Review in FY 16 to incorporate the process improvements above. For a typical registration review case, the updated SOPs are expected to result in a 20% reduction in the time required to complete a typical conventional registration review case, an 80% reduction in the time required to complete a simplified case. To track progress, the Team is conducting internal registration review customer satisfaction surveys at annual intervals, tracking re-work of deliverables, the number of cases where short-cuts are used, the time duration between Last Study Due Dates and Proposed Interim Decisions, and whether registration review decision goals are met each 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 triflusulfuron-methyl. The toxicity of sulfonylureas to terrestrial plants is well established and drives the Agency's ecological risk conclusions. This new streamlined assessment approach increased EFED's efficiency by a total of 10 FTEs and will provide a level playing field for developing risk mitigation for individual SU chemicals. OPP's SU strategy is also anticipated to provide a model for future streamlined assessments for the pyrethroids and other chemical groups. The sulfonylurea Registration Review human health risk assessments were written for individual sulfonylurea chemicals rather than as a single streamlined assessment because there are different human health endpoints for the individual chemicals, based on the most sensitive endpoint across all body systems.

Reduced Timeline for Plant-Incorporated Protectants (PIPs), genetically engineered plants that are considered pesticides. The Agency may accelerate the registration review process for PIPs. In FY'15, the registration review docket for two PIPs, Bt corn engineered to resist lepidopteran pests and BT corn engineered to resist coleopteran pests, was opened for public comment on a combined Work Plan and Proposed Interim Registration Review Decision. In both of these cases, because no additional data or risk assessment work was needed, and because the Agency continually reevaluates these PIPs through expiring registrations and terms of the registration, the Agency was able to advance the registration review to the regulatory decision phase. The program intends to use similar advancements with other appropriate Plant-Incorporated Protectant cases.