Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report

March 1, 2013

Process Improvements in the Pesticide Program

Pesticide Reevaluation Programs

Product Reregistration

The EPA continued to place a significant emphasis on improving the timeliness and overall productivity of the product reregistration program. As a result of these efforts, the agency is making good progress toward meeting its goal of completing product reregistration for all conventional pesticides in FY 2014. It is important that the EPA complete product reregistration within the next few years so that mitigation measures required by pesticide Reregistration Eligibility Decision (RED) documents will be included on pesticide product labels, and so that the agency can divert vital resources to the registration review program and ensure that we complete the first 15-year cycle of registration review by October 1, 2022.

In FY 2012, the Office of Pesticide Programs (OPP) conducted a pilot of a Center of Excellence (CoE) for acute toxicity reviews. The objective of the pilot was to achieve a more efficient way of performing product science reviews within OPP and achieve a more consistent review product, reduced review time, and a more nimble organization to respond to workflow across the program. The impetus of this process improvement was to find ways for OPP to meet its production goals during a time of decreased resources. During the pilot, acute toxicity reviews for reregistration and registration were distributed across the program for review in the Registration Division, Antimicrobials Division and Pesticide Reevaluation Division. The goal was to reduce the resources expended through a redistribution of workload to maximize productivity while maintaining environmental and health protection.

We conducted training prior to the pilot on the standardized review format and processes. The pilot included a QA/QC review of completed data evaluation records to ensure work product quality.

As a result of the two-month pilot, we determined that distributing workload across the program could improve efficiencies. The biggest roadblock to establishing the acute toxicity CoE is having a system for distributing work-load and tracking deliverable dates. Concerns include the additional manual tracking of packages between divisions and maintaining the level of productivity, as well as the need for an OPP standard repository for storing electronic files of completed toxicity reviews. At this time we are reviewing the CoE to determine whether it can be adopted across the program, and we are assessing information technology tools.

Registration Review

As part of the agency's ongoing efforts to implement our responsibilities under the Endangered Species Act (ESA), the EPA with the U.S. Departments of Commerce and Interior (the Services) and the Department of Agriculture has continued to explore process and scientific issues that, once resolved, will enhance our ability to meet our obligations in a sound and timely manner while providing increased transparency and opportunities for collaboration.

Proposal for Enhancing Stakeholder Input. On August 17, 2012, the EPA published a Federal Register Notice announcing and requesting comment on a "Proposal for Enhancing

Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically Feasible Reasonable and Prudent Alternatives." Prepared jointly by USDA, the National Marine Fisheries and Fish and Wildlife Services, and the EPA, the paper recognizes the vital role of stakeholders in shaping pesticide regulatory assessments and decisions. Based on significant dialogue among the agencies and stakeholders during the previous year, the document describes changes that the EPA plans to make in its pesticide registration review process, as well as modifications the Services can make to increase transparency and opportunities for stakeholder involvement in the ESA consultation process for pesticide regulatory actions.

Most significantly, as a result of ongoing feedback and discussion, the EPA proposes to:

- Hold Focus Meetings for pesticides beginning registration review to clarify current uses and label directions and consider the potential for early risk reduction; and
- Initiate any needed formal ESA consultations later in the process, allowing time to engage stakeholders in the development of more refined ecological risk assessments and more focused consultation packages including mitigation for listed species.

As part of the proposal, the EPA will summarize and organize comments received on Reasonable and Prudent Alternatives (RPAs) and provide those comments to the Services. The Services will prepare a document to include in the administrative record for the consultation explaining how comments were considered and, if appropriate, how the final biological opinion was modified to address the comments received. The proposal also expands the role of the USDA and the pesticide user community in providing current pesticide use information to inform and refine the EPA's ecological risk assessments.

The EPA, USDA and the Services proposed these process changes because many stakeholders have expressed concerns regarding the apparent lack of transparency surrounding ESA consultations conducted during registration review. The intent of the proposed process changes is to provide more opportunity for affected stakeholders to submit information relevant to ESA consultations during registration review. Of particular interest to stakeholders is the opportunity to consider, review and comment on the economic and technological feasibility of any RPAs resulting from a pesticide ESA consultation.

The EPA, USDA and the Services began meeting in January 2013 to discuss the more than 30 comments received during the public comment period on the proposal that closed October 16, 2012, and to identify next steps. Further information is available in docket EPA-HQ-OPP-2012-0442 at www.regulations.gov.

Focus Meetings. To help ensure that the agency has the best available data and information for making pesticide registration review decisions, the EPA has begun holding Focus Meetings for most pesticides early in the process. Announced in early December 2012, Focus Meetings are an important new process improvement that brings greater quality and efficiency to the registration review and ESA consultation process.

Usually initiated by the EPA and involving affected registrants and possibly other stakeholders, these meetings focus on the information needs identified by the EPA's chemical review team and

management for consideration during a pesticide's registration review. Focus Meetings provide an opportunity to address areas of uncertainty such as unclear pesticide labels or missing studies that could affect the agency's pesticide risk assessment and risk management decisions. By obtaining better information early in the process, we can narrow the scope of pesticide reevaluations to areas that pose real risk concerns based on current data and use patterns. We may be able to reduce data requirements, and avoid the use of overly conservative assumptions in our risk assessments that can lead to rework later in the process. We may be able to identify use patterns likely to result in ESA "may affect" determinations and work with registrants and stakeholders to obtain early adoption of risk reduction measures prior to the preliminary risk assessment and before initiating consultation with the Services.

To ensure transparency, the EPA places Focus Meeting minutes and related material in the docket shortly after the meeting. Visit the pesticide-specific registration review docket (EPA-HQ-OPP-2012-0778) at www.regulations.gov. For further information, see http://www.epa.gov/oppsrrd1/registration_review/focus-meetings.html.

Initiating Formal ESA Consultations Later in the Process. The EPA also is making adjustments in the registration review process to change the point in the process where any necessary consultations will be initiated with the Services. As discussed in the Proposal for Enhancing Stakeholder Input, rather than initiate formal consultation during the preliminary risk assessment stage, we plan instead to increase use of the informal consultation process at that stage. Working with the Services, we could gather information on species habitat, range, and behavior to include in a more refined biological evaluation before initiating any needed formal consultation. If formal consultation is necessary, the EPA would initiate it at a later point in the process, probably at the proposed decision phase. We plan to develop this process change during FY 2013.

NAS Report. In March 2011, EPA Administrator Jackson, on behalf of the EPA, the Services, and the USDA, asked the National Research Council (NRC) of the National Academy of Sciences to convene a committee of scientific experts to review the key scientific and technical issues that have arisen in carrying out our joint responsibilities under ESA and FIFRA and provide independent advice. The topics on which we seek advice include identifying best available scientific data and information; considering sub-lethal, indirect and cumulative effects; assessing the effects of mixtures and inert ingredients; the use of models to assist in analyzing the effects of pesticide use; incorporating uncertainties into the evaluations effectively; and the use of geospatial information and datasets in these assessments. The committee of independent experts selected by the NRC began its review in November 2011 and is expected to complete its report in spring 2013, as described in this report's section on science review improvements. When the EPA, USDA and the Services receive the NAS report, we will carefully consider its recommendations in updating our scientific tools and approaches for developing ecological risk assessments for listed species.

Stakeholder Meetings. As described in the previous sections, in an effort to provide a transparent and collaborative endangered species consultation process, the EPA continues to work with the Services and the USDA on activities to increase opportunities for stakeholder and public involvement. In response to public interest in attaining a greater role in ESA Section 7 consultations, the EPA, the Services and the USDA continue to be engaged in discussions with

stakeholders that focus on broadening opportunities to provide information relevant to the agency's risk assessments and consultations for listed species.

The EPA has continued to work this year with the Pesticide Program Dialogue Committee (PPDC) to provide background information on the status of ESA/FIFRA consultations and obtain input from members regarding their concerns related to the consultation process. Further, the EPA continues to work with the PRIA Process Improvement Workgroup, a PPDC workgroup, to discuss opportunities for public participation in ESA-related work during registration review. Through these and other meetings and discussions, the Agency is making good progress toward attaining a more transparent and collaborative process. These ideas and developing process improvements will be pursued further during 2013.