

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report



March 1, 2014

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. Product reregistration is important 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'13, the EPA updated the format of the acute toxicity data evaluation review memo used for products undergoing reregistration. The update provides more information in a consistent format that has enhanced internal tracking. The new format streamlines the secondary review process within the agency and provides clearer information to the registrants resulting in less follow-up from registrants and within the agency.

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 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 March 27, 2013, the EPA published a Federal Register Notice announcing the availability of the final paper describing enhanced opportunities for stakeholder input during its review of pesticide registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and associated consultations under the Endangered Species Act (ESA). The paper was jointly prepared by the EPA, the U.S. Department of Agriculture (USDA), and the National Marine Fisheries Service (NMFS) in the U.S. Department of Commerce, and the U.S. Fish and Wildlife Service (USFWS) in the Department of Interior (collectively, the Services). The paper describes significant changes to the EPA's registration review process intended to facilitate ESA pesticide consultations and coordination across these federal agencies, and calls for a greater role for USDA. The EPA accepted public comment on the proposed changes for 60 days, and then reviewed the comments. Subsequently, EPA, USDA, and the Services revised the paper to outline specific roles and responsibilities for each agency, and to provide clarifying information on focus meetings and the timing for public input.

The paper recognizes the vital role of stakeholders in shaping pesticide regulatory assessments and decisions. Based on 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 Reasonable and Prudent Measures (RPMs) and provide those comments to the Services. The Services will prepare a document for inclusion 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 and RPMs resulting from a pesticide ESA consultation.

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 began holding Focus Meetings. Focus Meetings are OPP initiated meetings to discuss areas of uncertainty identified by OPP registration review team early in the process. Topics discussed can involve clarification of use practices, unclear labeling, potential data gaps or any other area that would enable the program to conduct a more accurate risk assessment the first time. For many chemicals, no specific issues are identified and no Focus Meeting is held.

Through 2013, there have been 47 Focus Meetings. Of these, 32 were face-to-face meeting and the remaining ones were conducted electronically as combination of conference calls and/or emails. Over half (28) involved a discussion on label clarity and/or use practices. Seven focused on discussing the development of a master label and 6 resulted in a commitment to modify labeling to improve label clarity. Fourteen meetings focused on potential data gaps and many of those discussions resulted in a commitment to provide certain existing studies.

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/oppsrd1/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'14.

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 sought advice included 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 concluded its review in spring 2013.

On April 30, 2013, the NRC released its report entitled, “Assessing Risks to Endangered and Threatened Species from Pesticides”. The report contains recommendations for assessing risks to listed species from the use of pesticides. Working collaboratively, the EPA, the Services, and USDA (the four agencies) reviewed the report and developed an implementation plan providing a timeline for responding to the panel's recommendations and implementing the appropriate revisions to risk assessment procedures and approaches. During the week of August 5-9, 2013,

the four agencies held a workshop during which interim scientific policies and procedures were developed jointly to address the recommendations contained in the April 2013 NRC report. Going forward, it is the agencies' intention to apply the "Interim Approaches" developed at the August workshop to risk assessments for listed species under the registration review program. The "Interim Approaches" resulting from the August workshop were presented to the public on November 15, 2013 at a stakeholder workshop entitled, "Status of Efforts to Implement the Recommendations of the National Academy of Sciences' Report, 'Assessing Risks to Endangered and Threatened Species from Pesticides'" by the four federal agencies. The stakeholder workshop provided an opportunity for the public to provide feedback on the "Interim Approaches". A white paper describing the "Interim Approaches" can be found at <http://www.epa.gov/oppfead1/endor/2013/nas.html>

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. 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 2014.

De minimis Evaluations. In 2013, the De Minimis sub-group of the OPP's Risk Management Forum and Science Policy Council was formed to assist chemical review teams. The sub-group assists teams determine if the characteristics of particular chemicals or uses pose minimal risks without performing a formal risk assessment. These de minimis determinations for select chemical cases will free up vital resources to assess chemicals and uses that may pose risks that may need to be addressed. In 2013, four chemicals that would have otherwise required a formal risk assessment were deemed to be de minimis. This determination saved resources for risk assessment as well as allowing the agency to close registration review cases without expending additional resources.

Water Quality Monitoring Data. An important goal of the agency's pesticide registration review process is to prevent or resolve water quality issues related to the use of pesticides. Easy access to and consideration of water monitoring data can help OPP characterize pesticide exposures to water resources, design effective risk mitigation and evaluate whether risk

mitigation has been achieved. Effectively addressing pesticide water quality concerns through the pesticide registration review process reduces the need for other EPA programs and state/tribal pesticide and water programs to use their limited resources to address pesticide-impaired waters under the Clean Water Act (CWA), and more efficiently protects human health and the environment from pesticide risks.

OPP routinely considers publicly-available sources of water monitoring data, such as the U.S. Geological Survey and the EPA's Storage and Retrieval Data Warehouse (STORET), in its human health and ecological risk assessments. State/tribal data can also be useful for characterizing pesticide exposure and informing re-evaluation efforts. At the beginning of registration review, OPP established a public process for the submission of state/tribal water quality monitoring data, including but not limited to CWA 303(d) & 305(b) data (http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm). In FY'13, in an effort to receive additional data, we sought feedback from states on the water quality data guidance and submission process. OPP expects to issue revised guidance in FY'14. In addition, we have been coordinating with the EPA Office of Water to distribute information through its regional and state water monitoring networks regarding pesticide cases currently under review. We are beginning to receive additional data in response to these outreach efforts.

OPP has been working also with various external stakeholders to locate water monitoring information that is not publicly available. In FY'13, we have been collaborating with the National Water Quality Monitoring Council to plan a pesticides and water session at its April 28-May 2, 2014 National Monitoring Conference in Cincinnati, Ohio. We solicited and received a number of abstracts pertaining to the use of models and monitoring data to assess pesticide risk to water resources. We are also coordinating with the Association of Clean Water Administrators to further broadcast OPP's message about interest in state/tribal water monitoring data to help resolve current pesticide and water issues and prevent future problems.