OPP Response to Initial PPDC Registration Review Implementation Work Group Recommendations on Registration Review Dockets

July 10, 2007

The first meeting of the Pesticide Program Dialogue Committee's Registration Review Implementation Work Group was held on March 8, 2007. The work group gave its initial recommendations on registration review conventional pesticide case dockets to the full PPDC on May 10, 2007. This document contains OPP's response to the work group's recommendations.

GENERAL DOCKET IMPROVEMENTS:

- Guidance on how to navigate and use the Federal Document Management System (FDMS) dockets.
  - The FDMS website (Regulations.gov) has a sub-page with User Tips on how to use the system. These tips can be accessed through a tab on the home page.
  - New features have improved FDMS navigation. Users can now go to Regulations.gov (http://www.regulations.gov/fdmspublic/component/main) and search on dockets using the pesticide case name to find the docket, rather than the full docket number. They can then use the "Bookmark Icon" feature to create a link back to the docket from their computers, making it faster to access the docket again and stay informed on changes to it.

- Organize dockets better and identify them more clearly, e.g., source, date and document descriptions.
  - In March 2007, OPP began posting a "Readers' Guide" document as the second document in each conventional pesticide docket. It lists the documents in order and describes what they are. OPP will also do Readers' Guides for biopesticides and antimicrobials in future dockets.
  - OPP also began including an initial Summary Document page with the division director's signature and date.

- Provide easier access to labels, i.e., list registration numbers within dockets. Include product/trade names in which each active ingredient is used
  - Beginning with the dockets opened in March 2007, OPP began including a listing of registration numbers, product names, and registrants in the Summary Document, if there were relatively few products, or in a separate document, if there were many products. This information will enable the public to access the Pesticide Product Label System to view the labels.

- Attempt to include all available background documents. Provide links to pertinent information on each active ingredient (since FDMS doesn't allow links from within the docket system).
    - OPP will include all available documents that aid in understanding the case status. OPP is also providing links to key FDMS documents, such as the Summary Document, on the Registration Review status for each case at: http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm. The case status pages on this site can link back to open or closed dockets and to any other documents that may be relevant in tracking progress of the review.

- Provide more detail on incidents: what is captured and what is not.
    - OPP will routinely include summary incident reports for human health and ecological incidents in the dockets. These will provide information on any significant incidents associated with use of the chemicals.

- There was a suggestion at the full PPDC meeting that all documents in the docket should also be contained in a zip file so that users can easily download all of them all at once rather than one by one.
    - The Federal Docket Management System does not currently support the posting of zip files. This feature is being considered for a future upgrade.

REGISTRATION REVIEW SUMMARY DOCUMENT SUGGESTIONS:

- Consider separating fact sheet and questions for comment as stand-alone documents; but another view was to have a single comprehensive summary document
    - There was not a consensus on the work group on this topic. OPP has considered the pros and cons and prefers to retain a single Summary Document that contains the critical information needed for the public to understand the basis for the preliminary work plan proposed for the case. OPP will strive to improve the organization and explanations in the Summary Document to make it more comprehensible to the public.

- Have more summary and highlighting of Agency conclusions up front. Highlight more the data requested and not requested with rationale. Less jargon, write in clear and understandable language. Better flow between sections of summary document. The clomazone and hexythiazox PowerPoint presentations for the March 8, 2007 work group meeting were very clear and could be used as a model for summarizing important points in future dockets. Don't go overboard with detail; awareness of Agency's limited resources.
    - OPP generally agrees with these recommendations and will seek to improve its presentation of information in future dockets.

- Provide more usage information, detail on geographic limitations, and the dates and sources of this usage information
  - All dates and sources for our usage data will be included in the *Explanation of the Source Data for this Screening Level Usage Analysis (SLUA)* page, which will accompany each SLUA in the public docket in the future.

- List Section 24(c) registrations and detail on their use patterns
  - OPP will begin listing information on Section 24(c) special local need products, including registration numbers and product names.
  - OPP includes use information on Section 24(c) registrations and label uses in the label use information report (Appendix A).

- More consistency in format between the ecological and human health sections
  - Based on the different kinds of information that need to be conveyed in each section, OPP doesn't see the value or feasibility in having a uniform format that applies to both the human health and ecological sections.

- Information about and/or Internet sites for analytical methods needed to aid states
  - Many pesticide methods are available on line.
    - Environmental Chemistry Methods are available at: http://www.epa.gov/oppbead1/methods/ecm12b.htm.
    - Residue Analytical Methods are available at: http://www.epa.gov/oppbead1/methods/ram12b.htm.
  - For those methods not available on-line, environmental chemistry methods can be requested from the OPP/BEAD Environmental Chemistry Branch and tolerance enforcement methods can be requested from the OPP/BEAD Analytical Chemistry Branch.
  - The Agency has long recognized that there are issues related to disseminating analytical methods developed by registrants. The Agency Forum for Environmental Measures (FEM), chartered by the Agency Science Policy Council, has been tasked with addressing both of these issues (see: http://www.epa.gov/OSA/fem/fem.htm). The FEM Website also has links to all Agency websites providing analytical methods (see http://www.epa.gov/OSA/fem/methcollectns.htm)
  - EPA will review and consider any comments regarding the need for additional analytical method development, including for specific degradates.

- Include the Pesticide Registration Improvement Act (PRIA) schedule for pending new use decisions and state whether these new uses are being evaluated within the registration review process
  - The formal review and decision making for new uses occurs in the context of PRIA and its mandates regarding timing. Any new uses approved at the time a registration review risk assessment begins will be folded into the registration review process. Uses approved subsequent to the opening of the registration review docket will be considered in any risk assessments that may be needed. PRIA schedule dates may change and OPP does not see the value of including

this transient information in the registration review dockets. We will continue to note pending new uses in the Summary Document.

GENERAL REGISTRATION REVIEW PROCESS RECOMMENDATIONS:

- For those pesticides lacking water quality benchmarks, develop benchmarks as part of the registration review process
  - OPP posted aquatic life benchmarks for many pesticides earlier this year at: http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm. The work group highlighted this as very useful information. OPP will consider opportunities and needs for developing additional water quality benchmarks as each case goes through registration review.

- Diagnostic biomarkers of pesticide exposure are needed
  - This issue is broader than Registration Review and was discussed at the full PPDC meeting on May 10, 2007.

- Clarify when and how stakeholders could provide information for endangered species assessments in registration review, e.g., pesticide usage, crop location and species location, and life history information.
  - OPP will initially seek endangered species information from stakeholders during the comment period on the docket that begins the registration review process. OPP may also seek additional input during the risk assessment process to help refine screening level risk assessments of concern for endangered species.