Response to PPDC Registration Review Implementation Work Group Recommendations and Issues from 2nd Meeting on July 24, 2007

Final: December 18, 2007

Background

This document provides the EPA Office of Pesticide Programs' responses to recommendations made by the Pesticide Program Dialogue Committee's Registration Review Implementation Work Group at its second meeting on July 24, 2007. These recommendations were endorsed by the full PPDC at its October 18, 2007 meeting.

The work group has provided input to the PPDC on several initial registration review dockets from among those opened in FY 2007. The July 24 meeting reviewed the docket information for one of the first biopesticide registration review dockets, linalool, and one of the first antimicrobial dockets, Busan 1024. Documents from the July 24 meeting are at: http://www.epa.gov/oppfead1/cb/ppdc/regisreview/implemen/july07/july07.htm.

The first work group meeting on March 8, 2007 provided comments on conventional pesticide dockets, using clomazone and hexythiazox as examples. The full PPDC endorsed these recommendations in May 2007. OPP provided responses to the recommendations at the July 24 work group meeting (ref. attachment) and to the full PPDC in October.

Work Group Recommendations and Issues from July 24, 2007 meeting

- There should be ***good documentation in the Summary Document of the nature of ecological incidents and how OPP judged their significance.*** For example, the presentation for this meeting made it clear that there were 140 minor incidents associated with linalool, but that almost all were incidents associated with products containing multiple active ingredients, and the other actives had higher risk profiles.
  Response: OPP agrees with this recommendation.

- ***Terminology should be clear.*** Acronyms like EUP (end use product) need to be spelled out.
  Response: OPP agrees with this recommendation.

- It is helpful to ***include the original registration documents*** as was done for linalool.
  Response: OPP will include original registration documents when they are available and still relevant.

- ***Clarifying when and how end use products will be addressed*** would be helpful. For example, efficacy issues associated with some linalool products are being addressed separately from registration review. In other cases, mitigation needs identified in registration review decisions will require follow up to ensure labels are revised.
  Response: Generally, mitigation needs identified in the risk assessment and proposed and final registration review decision will need to be implemented following the registration review decision. When issues are being addressed through a parallel process, as is the case with linalool, this will be explained in the Summary Document.

- OPP should ***ensure that scanned docket documents are legible*** to the extent possible. The legibility of some of the early linalool documents was poor.
  Response: OPP will include higher quality scans whenever possible.

- Work group members commended EPA for improvements in docket capabilities, including enhanced search capabilities and bookmarking. However, three areas still need attention:
  - The response time for accessing dockets can be very slow depending on the time of day. Michele Schulz reported she had contacted Regulations.gov staff and was told that the ***slowness resulted from having only one server for the whole Federal Docket Management System and that one or more additional servers were needed.*** She followed up on this concern after the meeting by doing further checks on docket usability and provided an email report to the work group on August 3, 2007
    Response: Kennan Garvey, work group chair, emailed Ms. Shulz and other members of the work group on September 24, 2007. Ms. Shulz had noted in her August 3 email that response times had become faster on Regulations.gov. Kennan reported that staff for the Federal Docket Management System (FDMS) that operates Regulations.gov had been adding servers and upgrading the production site as part of a high availability upgrade, including two additional Application Servers and an additional Documentum Content Server. FDMS staff expected these enhancements, along with earlier improvements, would greatly speed response times, as well as providing additional protection against outages.

  - Another work group member reported ***problems making submissions to dockets and getting confirmation*** that submissions had been made.
    Response: Upgrades to Regulations.gov reported above should reduce these types of problems. When problems are experienced, it is important to report them to Regulations.gov staff through the "Contact Us" icon at the bottom of each FDMS page. When confirmation of a comment submission is not provided, the submitter can confirm receipt with the chemical review manager responsible for the docket.

  - A member asked that OPP try again to ***get a zipped version of docket documents routinely included as part of the docket***, so that users could simply download the zipped file and open it, rather than individually downloading each file.
    Response: The bulk download item recommended by the PPDC Registration Review Implementation Work Group has been made a priority by OPP in discussions with FDMS staff. We understand that this enhancement is being worked on for possible release in 2008. In addition, a pending search engine enhancement may also have a bulk download feature for documents identified in the search.

- In the next antimicrobial case involving indirect food-use paper contact issues, the ***joint jurisdiction and coordination with FDA needs to be better explained***, based on what has been learned since opening the Busan 1024 docket. This will also be included in the Final Work Plan for Busan 1024.
  Response: AD has committed to do this for indirect food-use paper contact issues.

- ***Information on chemical characteristics*** for the active ingredient(s) in the case should be stated early in the Summary Document.
  Response: OPP will include information on chemical characteristics in future dockets, including chemical structure.

- OPP should ***clarify when and how stakeholders may submit data and ensure it is compensable*** when relied on by other registrants. Registrants are amenable to submitting data early in the registration review process but in some cases this could be an impediment to getting data compensation for it later.
  Response: The following describes EPA's general approach for addressing data compensation issues in connection with registration review:
  - The registration review program was structured to encourage and provide an opportunity for early stakeholder input following OPP's creation of an initial registration review docket. That docket includes information on what OPP knows about the pesticide as well as OPP's anticipated plan for conducting registration review for the pesticide (i.e., its preliminary work plan). In order for the review to proceed efficiently and in a timely way, it is in all stakeholders' interests to provide useful information as soon as it is available, including studies that OPP has identified as needed.
  - FIFRA Section 3(g)(2)(A) directs the Administrator to use the Section 3(c)(2)(B) Data Call-In (DCI) authority to require the submission of data when such data are necessary for registration review. Section 3(g)(2)(B) makes it clear that data compensation provisions apply to any data required for registration review. DCIs provide a mechanism to require precisely the data needed, ensure data compensation rights, and provide an enforceable mechanism should a registrant fail to respond to the DCI or fail to take other required or appropriate steps such as submitting required studies in a timely way.
  - In some cases, the Final Work Plan will identify the need for studies that a registrant has already voluntarily submitted in response to the preliminary work plan. OPP will review the submitted studies to determine their adequacy. OPP will also issue a data call-in to require the data regardless of study availability and determination of adequacy, since we have identified the need for studies in the specified areas. The data call-in will require registrants to take appropriate steps to satisfy the data requirement, including submitting the required data or citing the previously submitted data (assuming such data will satisfy the requirement) and offering compensation to the original submitter for use of the data in satisfying the DCI. As a result, issuance of the DCI ensures protection of the original data submitters' compensation rights.
  - In other cases, a registrant may submit studies that OPP has not identified as needed in either the preliminary or final work plan or in a subsequently issued DCI. In these cases, OPP may subsequently identify the need for the studies later

in the review process. OPP would then issue a DCI to impose the data requirement on non-submitting registrants and ensure protection of data compensation rights – as explained above -- for the studies relied on during the review process.

- Following issuance of a DCI, if there is not a registrant commitment to provide the needed data or if the registrant fails to take appropriate steps to satisfy the data requirement, OPP has authority to seek suspension of the affected pesticide registrations. EPA could also seek to cancel registrations if the absence of such data prevents EPA from making the necessary FIFRA Section 3(c)(5) finding in completing registration review.

- OPP needs to ***continue including all relevant documents in the docket***, including all previous decisions on the pesticide. This will be particularly important as OPP begins to open dockets for pesticides that have been through reregistration.
  Response: OPP agrees with this recommendation.

- ***Don't permanently archive earlier docket or website materials that may be useful references during registration review***.
  Response: FDMS allows dockets to remain open for at least 20 years provided there is periodic activity. This policy should safeguard against premature archiving of earlier materials that may be helpful later in the registration review process.

- When the same type of studies involving different species are needed, ***OPP should explain why similar studies involving two species are needed.***
  Response: OPP will provide better explanations in future Summary Documents of why additional studies are needed and what difference the data will likely make in the Agency's review.

- **Additional recommendations:** Michele Schulz mentioned in her follow up email after the July 24 meeting that:
  - OPP should work to ***standardize titles of registration review dockets***. This would help to improve searching capabilities.
    Response: OPP is working to standardize titles of registration review dockets to make "registration review" part of the title, along with the case name. In addition, OPP is providing current and historical information on each docket on its Registration Review Status Page at: http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm. This site provides the current status of registration review for each case and links to key documents, which are currently the Summary Document, including the Preliminary Work Plan, and the Final Work Plan, when available.

  - ***All comments may not be posted to the docket in a timely manner*** – what is the standard processing time?
    Response: Routine comments that are submitted electronically to Regulations.gov are normally processed and posted within 24 hours. More substantive comments and those submitted directly to the chemical review

manager rather than Regulations.gov may take up to four days to screen and process. For Registration Review dockets, comments are accessible after the close of the public comment period. It is OPP's intention that all documents in each docket will remain accessible throughout the registration review process so that each docket contains a running history of the case review.

Update on Diagnostic Biomarkers

- At its March 8, 2007 meeting, the work group stated that diagnostic biomarkers of pesticide exposure are needed. The following provides an update on OPP's consideration of this recommendation.

    - One of the major challenges faced by health care professionals in the diagnosis and treatment of ailments associated with pesticide exposure is the lack of tests to identify specific chemicals and/or exposure levels that may be linked to the reported illnesses. In response to the PPDC's recommendations that diagnostic tools are needed, the Agency continues to discuss internally the possible future course of action. The Agency hosted a workshop on diagnostic biomarkers on October 4, 2007 and reported the highlights at the October 17-18, 2007 PPDC meeting. The workshop provided valuable input on diagnostic biomarkers from a number of experts and many stakeholders. Further exploration on how the Agency may contribute to the advancement of diagnostic tools development is ongoing."

Next Steps

The chair thanked the work group for its work. The July meeting was the last meeting of the work group to provide feedback on dockets. The work group will likely be reconvened at a later date to provide feedback on subsequent stages of registration review.

Meeting Attendees

Work Group Members Present at Meeting

Caroline Cox, Center for Environmental Health
Michael Fry, American Bird Conservancy
Bernalyn D. McGaughey, Project Manager, FIFRA Endangered Species Task Force and President, Compliance Services International
Susan E. Little, Consumer Specialty Products Association
Ray McAllister, Crop Life Association
Michele Schulz, Syngenta
Dr. Hasmukh Shah, American Chemistry Council
Sue Crescenzi, Steptoe & Johnson
Dr. Warren Stickle, Chemical Producers and Distributors Association
James Wallace, S.C. Johnson & Sons, Inc.
Allen Jennings, USDA Office of Pest Management Policy

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Work Group Members Participating by Teleconference
Susan Kegley, Pesticide Action Network, North America
Mae Wu, Natural Resources Defense Council
Kristie Stoick, Physicians Committee for Responsible Medicine
Joseph Conlon, American Mosquito Association
Sam Jackling, NY Department of Environmental Conservation
Cindy Baker, Exigent Company
Gary Libman, GNL Consultation Services LLC

Others Present or Participating by Teleconference:
Christopher Pearce, S.C. Johnson & Sons, Inc.
Charlie Clark, Florida Dept. of Agriculture & Consumer Services (by phone)
Bob Moore, Florida Dept. of Agriculture & Consumer Services (by phone)
Carl Watson, Buckman Laboratories (by phone)
Dennis Barbie, Buckman Laboratories (by phone)

Debbie Edwards, OPP Director
Kennan Garvey, SRRD/OPP (Work Group Chair)
Amaris Johnson, SRRD/OPP (Work Group Coordinator)
Frank Sanders, Director, OPP Antimicrobials Division (AD)
Betty Shackleford, Associate Director, OPP/AD
Mark Hartman, Branch Chief, AD
Diane Isbell, AD
Kathryn Jakob, AD
Timothy Leighton, AD
Rick Petrie, AD
Najm Shamim, AD
Jenny Tao, AD
Srinivas Gowda, AD
Nader Elkassabany, AD
Janet Andersen, Director, OPP Biopesticides and Pollution Prevention Division
Stephen Morrill, BPPD
Roger Gardner, BPPD
Russell Jones, BPPD
Todd Peterson, BPPD
Shanaz Bacchus, BPPD
Philip Ross, OGC (by phone)

ATTACHMENT

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.