

US EPA ARCHIVE DOCUMENT

Pesticide Programs Dialogue Committee (PPDC)
PRIA Process Improvement Workgroup Meeting Minutes
September 26, 2011

Meeting Attendees

Rick Keigwin (OPP/EPA)

Don Brady (OPP/EPA)

Cathy Eiden (OPP/EPA)

Ray McAllister (CLA)

Beth Law (CSPA)

Elizabeth Leovey (OPP/EPA)

Steve Covell (USDA/FS)

Anita Pease (OPP/EPA)

Amy Roberts

Elizabeth Buckley (Pesticide and Chemical News)

Kate Shenk (DCLRS/ISSA)

Caroline Kennedy (Defenders)

Greg Watson (CLA)

Perlsman Smith (United Fresh)

Ann Law (ABC)

Angela Somma (NOAA/NMFS)

Greg Lees (ISK Biosciences)

Julie Spagnoli (FMC)

Julie Schlekan (Valent USA/RISE)

Mike White (CPDA)

Tilghman Hall (CLA)

Agenda

- I. Introductions
- II. Meeting Purpose – Discussion on Timing ESA Consultations for Pesticides and Enhancing Public Participation Related to Endangered Species Assessments Conducted under Registration Review (continuation of July 27,2011 meeting)
- III. Industry Perspectives on ESA Consultations under Registration Review
- IV. Discussion
- V. Next Steps
- VI. Public Comments
- VII. Summary

Meeting Minutes

The Power Point presentations were posted on the internet at <http://www.epa.gov/pesticides/ppdc/pria/index.html> along with the agenda.

Introductions and Announcements

Elizabeth Leovey opened the meeting with general comments on the statutory provision in the Pesticide Registration Improvement Act (PRIA) 2 and process improvements and the Pesticide Program Dialogue Committee's (PPDC) role. A PPDC PRIA workgroup was formed to obtain stake holder input on process improvements related to pesticide registration activities. This particular meeting of that workgroup was convened to continue the dialogue started during the July 27, 2011 meeting regarding potential revisions to EPA's review processes related to its work on endangered species: 1) consultation initiation under the Endangered Species Act (ESA), and 2) opportunities for public participation. Ms. Leovey then described the ground rules for the meeting stating that PPDC members are the primary discussants followed by non-members.

Recap from July 27, 2011 Meeting

Don Brady started the meeting with a review of the discussion from the July 27, 2011 meeting. He reviewed the three options previously discussed as to when to consult with the National Marine Fisheries and Fish and Wildlife Services (the Services) on the Endangered Species Act (ESA) based on the July meeting. He presented a brief set of slides summarizing the options including pros and cons.

Option 1: Consult @ Proposed Registration Review Decision Stage. Pro: Formal consultation occurs later in process between the proposed and final registration review decisions, includes a

refined risk assessment, and proposed mitigation for listed species' protection. Con: Delays final decision as formal consultation proceeds.

Option 2: Consult @ "Interim" Registration Review Decision Stage. If a decision was considered an "interim" decision, it would be because OPP had not completed consultation. Pro: Consultation occurs at end of process, at the point when the Proposed Decision is completed, includes a final risk assessment, and reflects mitigation achieved for listed species' protection. Con: May be interpreted as a final decision in the absence of consultation making EPA vulnerable to lawsuits under the ESA. Caveat: EPA makes a decision of some kind in the absence of a final Biological Opinion with the ability to revisit the "interim decision" once the Biological Opinion becomes final.

Option 3: Consult informally on the preliminary risk assessment (PRA) and formally on the Proposed Decision, if needed. Pros: Provides additional information for the refinement of risk assessment because EPA and Services engage early and often. Provides greater opportunity to resolve issues before risk assessment is finalized and incorporate mitigation to protect listed species into the risk assessment. There is some success with this approach already. Con: May result in delays in the registration review schedule. This approach may not be a sustainable model given volume of actions necessary under registration review.

Consultation under Options 1 and 2 occur at different points during the registration review process. The intention of all these options is to incorporate mitigation before consultation. Option 3 emphasizes more frequent engagement with Services.

Tilghman Hall made the point that Option 1 may not allow enough time for registrants to weigh-in on mitigation. She emphasized the need to involve stakeholders before any kind of consultation. She supported the concept of allowing interim decisions where "no effects" determinations had been determined. Also supported that EPA and the Services need to work together closely.

Industry Perspective - Suggested Process Improvements - CLA Presentation

Ms. Hall gave a Crop Life America (CLA) presentation. She emphasized that CLA's goal is for EPA and the Services to achieve a predictable consultation process, which includes a comprehensive risk assessment, is transparent and clear with well-documented risk management decisions. She said that the current Environmental Fate and Effects Division's (EFED) documents are not always clear as to why certain mitigation is needed. CLA wants a clear rationale for why mitigation is requested (i.e., buffers), and a mechanism for stakeholders to submit information relevant to the consultation. She continued that CLA seeks balance between protecting listed species and impacting agriculture and efficient and targeted interactions with the Services. CLA believes that information relevant to listed species risk assessment should be submitted before the problem formulation stage of registration review. CLA seeks to have "SMART" meetings reinstated before the problem formulation stage of registration review, and a

meeting after the Preliminary Work Plan (PWP) is available to ask clarifying questions. She emphasized CLA's desire for a mechanism for stake holders to get information into the registration review process as early as possible and a process or mechanism for potential interactions with the Services. CLA believes the most critical time is the next couple of years as EPA and the Services refine their working dynamic on ESA consultations.

Ms. Hall stated that all available studies and data should be included in the process. This would include studies and data available to the European Union (EU). Cathy Eiden asked what kind of mechanism was recommended to get the needed information into the process. A discussion around the types of data and information that would be useful proceeded. The types of data discussed included: monitoring data, EU data, usage information, species information. Ms. Hall said the CLA envisions a meeting where use information and available data are discussed initially, and a second meeting to discuss the PWP after the docket opens. She mentioned that IPM Centers can be used for information but you have to ask specific questions.

Greg Watson mentioned the historic use of SMART meetings and promoted the idea of reinstating the SMART meeting and using the same questions historically used at SMART meetings to obtain clarity on a pesticide product's use patterns and label information. Rick Keigwin said the questions used historically for SMART meetings are now put into the registration review summary documents and then made the point that EPA would be receptive to bringing back some version of SMART meetings, but that the current process includes those questions in the summary documents and the current process has not been fruitful in getting registrants to engage and provide answers to those questions. He emphasized that before EPA commits resources to reinstating SMART-type meetings, EPA would like some reassurance that the registrants would engage.

Ms. Hall emphasized the need to time information so it was accurate and useful for risk assessment. A discussion ensued as to of what kind of listed species' data EPA would rely on, where it might come from, and how current it would need to be.

The general point was made that increased involvement with stakeholders, with states in particular, was needed, and that there was a need to get more localized information into the process.

Tilghman Hall and Greg Watson commented that clarity around use patterns and an effort to clean-up older labels was needed. There was agreement that this effort was needed early in the process. Ms. Hall stated that data requirements in Final Work plan (FWP) should include a clear rationale supporting the data requirement.

Ms. Hall emphasized the need for improved communications across all parties, EPA, the Services, and the registrants and other affected stake holders. She emphasized the importance of identifying risk drivers, i.e., the use scenarios driving risk estimates, and gave some examples (aerial application, drift or runoff as the issue). She discussed working with USDA's Natural

Resources Conservation Service (NRC) to address risk drivers early and begin to address potential mitigation. She reiterated it is critical to know when consultation happens and expressed CLA's desire to discuss mitigation options ahead of consultation. CLA anticipates there will be refinements between the PRA and the final risk assessment. CLA wants full documentation of how a decision was reached, how mitigation decreases risk, and that any mitigation is feasible.

She expressed registrant's concern that they be "in the loop" and have been identified as applicants for the purposes of consultation. An ideal situation in her opinion (speaking for CLA) is to consult at the final decision stage on a final risk assessment reflecting maximum mitigation. Ms. Hall promoted the idea of "interim decisions", where decisions on "No Effects" determinations could move forward, but "May Affects" determinations would be part of a consultation. Don Brady asked for clarification on this approach where registration review decisions would potentially be parsed and move along separate tracks. CLA promoted the idea of frequent interaction with the Services particularly at the local office level of the Services. Greg Watson mentioned a case where early interaction with the Services local offices had been beneficial.

Ms. Hall then summarized her presentation on behalf of the CLA. She reiterated CLA's position and promoted using Option 2 and emphasized the need for allowing comment period on the "Interim" Decision to avoid legal challenges. She reiterated CLA's desire for a more open, reliable, and transparent consultation process, to consult formally as late in process as possible. She reminded EPA of the Counterpart Regulations and EPA's options under the portions of those regulations that survived the court challenge.

Public Comments

Angela Somma commented that all federal agencies can make "May Affect" determinations. She commented that the use of the Counterpart Regulations will make no difference to streamlining the consultation process because it does not address the differences of opinion on science issues related to pesticide consultations. Those differences of opinion are being addressed by the National Academy of Sciences (NAS) National Research Council (NRC) review. Ms. Somma cautioned against using Option 2 because the approach may be interpreted as lacking consultation. She said that given legal history on the ESA, parsing the decision would be difficult to implement. Ms. Hall responded that if not the Option 2 route, then there needed to be some mechanism to move decisions forward because consultations are taking too long.

Mr. Keigwin asked for some discussion on when the optimum time would be to submit information relevant to a listed species risk assessment into the process. He also mentioned the value of including stake holders represented by the Minor Crop Farmer's Alliance (MCFA).

Don asked for comments from group.

Don mentioned that Endangered Species County Bulletins can be very specific. Ms. Hall reiterated that USDA IPM Centers could be a good source of information but they need targeted questions to provide the most useful information.

Greg Watson thanked Don for the opportunity to present.

Summary and Next Steps

Don Brady summarized the main themes of the discussion. He noted that many of the ideas coming out of the work group mimicked themes from the Minor Crop Farmer Alliance (MCFA). He noted that all the ideas discussed were useful and would contribute to EPA's refinements of its public process for ESA consultations. He noted the "split" federal action concept and posed the question what legal standing would a split decision have? He commented that whatever EPA does in the next few years, it is likely to change as the process and thoughts evolve and mature, and as the NRC review concludes.

Ray McCallister & Julie Spagnoli emphasized the need to get our process going and formalized to reduce uncertainty. They asked what effect the process would have on products already going through registration review. Don Brady acknowledged the validity of the question, its importance, but responded that he had no answer at this point in time.

Rick Keigwin asked if the group would offer some chemical candidates to try some of these ideas related to process changes. Greg Watson responded that that would take some thought.

Don asked for additional thoughts. There were none. He then moved on to next steps. He stated that EPA should do some thinking on what was heard from the group and discuss the recommendations and consider refinements to them. EPA and the Services need to discuss options. Rick Keigwin mentioned the existing ESA petitions and that they need to be factored in to the discussion and any potential process changes.

It was decided that the workgroup would report out to the next full PPDC meeting. Greg Watson offered to provide a summary of the CLA presentation. Julie Spagnoli commented that the group seemed to be in consensus that consultation should occur as late in the registration review process as possible in order to capture as much relevant information and mitigation as possible in the final risk assessment.

Ray McAllister asked for clarification on the reason to consult as late as possible in the process.

EPA must determine what process would work for consultation and then get with the Services and have a dialogue as to what process would work for all the agencies, FWS, NMFS, and EPA.

Don Brady continued that EPA must continue to reregister products and prepare risk assessments for consultation where warranted. In addition, EPA would have to consider the NRC report and then reconsider the process in light of that report.

Julie Spagnoli asked Rick Keigwin if EPA could prioritize which pesticides will need ESA consultation. He responded, "All of them". He further commented that EPA could test out the idea of getting pre-problem formulation information via meetings and make registration review schedules for specific chemicals available at least 8 to 9 months before problem formulation begins.

Ray McAllister asked about the status of clomazone and fomesafen and the relevance of this discussion to those chemicals. Don Brady responded that the lesson learned from clomazone and fomesafen is that the Services are interested in consulting on a more fully formed and mature risk assessment. That experience also made clear that stake holders need to be a part of the process prior to consultation. Mr. McAllister followed with another point echoing one made by Ms. Hall earlier regarding the impracticality of putting a "freeze" on a reregistration while the chemical goes through consultation. Don Brady acknowledged the validity of the point but offered no answer.

The discussion returned to labels and the need to clean them up, clarify the language on them, particularly for older product labels. Don Brady cited the "typical" use versus "maximum" use issue and how to handle that issue. He commented that he is hearing some common ideas, concepts, and concerns, and believes we are starting to get some clarity on the issues. Don mentioned the history of the program

He identified follow-up steps to include: 1) a discussion with Marty Monell regarding a report on the proceeds of the July 27 and September 26 work group meetings at the next full PPDC meeting, and 2) CLA will provide a summary of their presentation points.

Greg Watson mentioned use information and species location information as the two big items to consider relevant to ESA consultations: 1) multiple actives in one product and how that will be handled as an issue needing further thought, and 2) the availability of species location information.

Don asked for more comments and questions and got none. He adjourned the meeting.