PPDC PRIA Process Improvement Workgroup Meeting
Minutes – July 27, 2011

Meeting Attendees

Ray McAllister, Crop Life America (CLA)
Mike White, Chemical Products & Distributors Association
Laurie Flanagan, GCLRS
Jim Kunstman, PBI Gordon
Angela Reckords (Eversole Association)
Nneka T. Breaux, DOW AgroSciences
Susan Little, Consumer Specialty Producers Association (CSPA)
Bill McCormack, Clorox
Has Shah, American Chemical Council
Abby Trueblood, Dow Chemical Company
Lisa Amadio, Diversey
Caroline Kennedy, Defenders of Wildlife
Caitrin Martin, USDA – FAS
Sandra Hastings, Dynamac Corporation
Larry Pearl, Informa
John French, Arch Chemicals
Charlotte Sanson, BASF Corp. (CLA)
John Cummings, FMC Corp.
Jennifer Loda, Defenders of Wildlife
Ya-Wei Li, Defenders of Wildlife
Beth Law, CSPA
Julie Schlekau, Valent USA on behalf of Responsible Industry for a Sound Environment (RISE)
Sue Crescenzi, Steptoe & Johnson for ACC Biocides
Greg Watson, Monsanto
Catherine Eiden, OPP
Rick Keigwin, OPP
Don Brady, OPP
Elizabeth Leovey, OPP

Agenda

I. Introduction
II. Purpose of the Meeting
III. Overview of Registration Review Process
IV. Opportunities for Enhanced Stakeholder Participation
    Overview of MCFA Workshop, Results, and Next steps
V. Discussion
VI. Next Steps
VII. Public Comment
VIII. Summary and Next Workgroup Meeting

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 address 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.

Overview of Registration Review Process
Rick Keigwin (EPA) set the stage for the meeting by emphasizing the importance of obtaining stake holder input as early possible in the ESA review process. He reminded the workgroup that it is EPA's intention to meet our obligations under the ESA through the registration review program. He then provided an overview of EPA's current experience with ESA consultations on pesticides under the registration review program. Initially, EPA initiated formal consultation at the preliminary risk assessment stage of registration review. However, it is in the best interest of the Fish and Wildlife and National Marine Fisheries Services (the Services) to initiate formal consultation at a later date in the registration review process on a more fully formed risk assessment. Don Brady (EPA) explained the scientific and technical issues that currently confound the consultation process and described the National Academy of Sciences (NAS) review intended to clarify these issues and provide guidance to the federal agencies involved in and impacted by pesticide consultations under the ESA. He emphasized the commitment of the other federal agencies involved (Agriculture, Commerce, and Interior) to the successful outcome of this review. Discussion ensued related to the pending NAS review. Workgroup members expressed concern over resource constraints at the Services and their ability to handle the volume of pesticide consultations necessary to keep registration review on schedule, and the difficulties associated with national assessments versus localized assessments. They emphasized the importance of species-specific biological information in tailoring registration review decisions. Workgroup members expressed an interest in the possibility of consultations with regional offices rather than HQ offices of the Services. EPA indicated that discussions with the Services on that were ongoing.

EPA provided a set of slides summarizing points in the registration review process at which EPA could potentially initiate ESA consultation. These points included: 1) at the proposed risk decision and final risk assessment stage, 2) at an "interim" decision stage further along in the process when risk mitigation has been maximized, but prior to a final decision, and 3) initiate "informal" consultation on a preliminary risk assessment to obtain more biological information for risk assessment refinements, and initiate "formal" consultation (if warranted) at the proposed decision stage. Rick Keigwin provided an example of one case where EPA requested informal consultation and received information from a local Fish and Wildlife Services (FWS) office that was helpful in refining the EPA risk assessment.

A general discussion followed with various workgroup members expressing concern as to how consultation, whether it is informal or formal, would impact the registration review schedule. In particular it was noted that an informal consultation step might slow down the registration review process as additional time might be needed to update risk assessments based on information from the Services field offices. However, EPA emphasized that the end date for registration review is still 2022.

The workgroup was interested in the kinds of GIS databases needed to facilitate consultation and mentioned the FIFRA Endangered Species Task Force (FESTF) and Nature Serve databases as repositories of endangered species location information. There was a general consensus that once the available data were organized and made available, agreement was needed on how to use species location information in a risk assessment without making species vulnerable to species collectors. Workgroup members emphasized the importance of registrant-supplied data being used properly and transparently, so that "how" the data were used in risk assessments and biological opinions was easy to determine. European Union (EU) data were discussed as relevant to ESA consultations. The Services are requesting it and the registrants are providing it to inform biological opinions. Don Brady (EPA) responded to questions about the ESA standard versus the FIFRA standard. He explained that the ESA standard is risk-based and the FIFRA standard is based on risk versus benefit.

The Workgroup then returned to the discussion of options on when to consult. Greg Watson (CLA) expressed interest in the hybrid consultation option using informal consultation at the preliminary risk assessment stage followed by formal consultation, if warranted, at the final risk assessment proposed decision stage. There was general agreement on the importance of including localized information on species and agriculture in decisions and interest in some kind of informal conversation with the Services' local/regional field offices at the preliminary risk assessment stage to garner useful species-specific information. Members emphasized that proactive outreach on the part of EPA would be needed at this point to engage stake holders in the process. Concern was expressed that waiting to consult after a final decision was not legally defensible and consensus that there would be no decision on an action until consultation was complete.

Ya-Wei Li (Defenders of Wildlife) asked about the use of the FWS' Information, Planning, and Conservation (IPAC) database and whether EPA has looked into using it. Don Brady (EPA) responded that EPA had inquired about using IPAC, but that the species location information is best when used for the border-states with Mexico. EPA has concerns with how current the data are in IPAC and on keeping it current. Caroline Kennedy (Defenders of Wildlife) asked what geographic area EPA would accept as the area to consider for mitigation. She raised the issue of scope and range for listed species and how EPA would handle uncertainty around a species location.

Opportunities for Enhanced Stakeholder Participation

EPA discussed the Minor Crop Farmer Alliance (MCFA) ESA Workshop held in May 2011 in Denver giving the workgroup members some background and an update on the workshop proceedings. MCFA is an organization of growers of minor crops; minor crops generally include all crops except corn, rice, soybeans, wheat, and cotton. MCFA members have expressed

concern over the lack of opportunity for grower participation during ESA consultations on pesticides. During the workshop EPA, the Services, MCFA members, industry representatives, and the public discussed opportunities for grower participation, and the kinds of information growers might bring to the consultation process to help refine both EPA's risk assessments and the Services biological opinions.

A general discussion among the workgroup members ensued covering a wide variety of topics, including:

- Lack of transparency around consultations,
- Concern that EPA should not require data for data's sake and the hope expressed that the NAS review would help put some bounds on what data were actually needed for an ESA assessment,
- Current ESA consultation process as experienced under litigation is a poor model because of the court-ordered time constraints, which do not allow enough time for stakeholder information to be considered
- Availability and use of studies from the EU registration process for use in ESA consultations
- Evolution of biological opinions for the Pacific Northwest Salmonids lawsuit
- Importance of getting agreement on what constitutes a screening-level ESA risk assessment
- EPA's preliminary risk assessment is the point at which the dialogue with the Services field offices should begin, and where robust outreach is needed to engage the stake holder community
- Lack of resources at the Services HQ to effectively deal with the volume of consultations required under the registration review program
- Lack of clarity on labels as language is often ambiguous and responsible for overly conservative risk assessments

When to Consult with the Services

The workgroup then returned to a discussion of where and when to consult during registration review. PPDC members suggested initiation of informal consultation on the preliminary risk assessment and formal consultation if needed at the proposed decision stage. EPA mentioned that there have been situations where initiation of informal consultation (cartridges) resulted in valuable information from field offices that resolved potential concerns for listed species. Concern was expressed that proposing consultation after an EPA decision was a non-starter and created legal vulnerability under the ESA. There was a general group consensus that there is no decision without consultation, where required by the ESA. Workgroup members expressed concern that the consultation process for pesticides was broken and there was no legislative fix in the near future.

Members attending the meeting from the public (Defenders of Wildlife) asked about the Information, Planning and Conservation System (IPaC) database and whether the Agency has looked into using it to facilitate consultations. EPA (Don Brady) responded that EPA has considered using it and has had conversations with the Services about using it, but that the most robust information is for species located at the border-states with Mexico. EPA has some concerns about quality control of the data being entered into the system and how that information

is updated. Ya-Wei Li (Defenders of Wildlife) asked how much certainty EPA needs as to species locations to move forward on consultations. Caroline Kennedy (Defenders of Wildlife) asked what geographic area EPA would accept as an area of mitigation.

Public Participation under Registration Review Program

EPA (Rick Keigwin) explained that the Services view consultation as between two federal agencies, and that it is up to EPA to bring other agencies and the public into the process. He described the current consultation process and points where public input is solicited and then discussed expanding opportunities for public input during registration review. Consideration was given to expanding the registration review schedule to include a date or quarter when a chemical will go into registration review and when the docket containing the Preliminary Work Plan (PWP) will open, as well as deadlines for submission of information. PPDC member (Susan Little) requested the name of the Chemical Review Manager (CRM) assigned to a specific chemical be included. EPA offered the name of the branch as an alternative since individual CRMS may change. PPDC members were interested and agreeable to these potential changes.

EPA (Rick Keigwin) proposed receiving stake holder input during the 8 to 9 months before a chemical docket opens, and once the docket is open and the PWP available for public comment, organize and hold additional public meetings with stake holders to discuss the accuracy of information in the PWP. The point was made that this would be particularly helpful for chemicals with multiple technical registrants and end-use product manufacturers. There was some concern expressed by PPDC members (Nneka Breaux) that confidential business information might be compromised, but was assured that sensitive information could be protected.

PPDC members recommended that the PWP be used to garner information on use patterns and labels. EPA (Rick Keigwin) explained that the questions included in the PWP come straight from “SMART” meetings held previously under tolerance reassessment and re-registration programs and are intended to garner exactly that type of information, but that relatively few to no comments or input are received on the PWP questions. PPDC members (Greg Watson) discussed the importance of accurate label language and suggested EPA could consider using a “GAP” table in the PWP, similar to the one included in the EU dossier. There was general agreement that registrants and end users should get involved in the process earlier to clarify use patterns, a master label would be useful, on the need for an industry task force to organize an effort to clean-up labels, and the value of using the PWP to tighten up loose label language. There was consensus among the work group members that an agreed to set of uses is the key to successful consultations and that there is a 3 year time frame in which to work this issue occurring between the PWP and before work begins on the preliminary risk assessment. EPA emphasized the need for deadlines for submission of information in support of an endangered species assessment. There was some concern that not all registrants would agree to tighten label language and some sort of incentive or policing among registrants might be necessary. There was an interest in having “SMART” meetings timed to coincide with the PWP stage of registration review, allowing time to resolve label issues prior to starting a risk assessment. Consideration was given to the volume of meetings needed and the resource impacts and to inviting the Services to the “SMART” meetings.