

MCFA ESA Workshop

May 24 & 25, 2011

Denver Tech Center Marriott, Denver, Colorado

Workshop Summary

The Minor Crop Farmer Alliance ESA Workshop was held at the Denver Tech Center Marriott, Denver, Colorado over the two day period of May 24th and 25th, 2011. The workshop agenda is attached. (Appendix 1) More than 75 people participated (registration list attached, Appendix 2), including the US Environmental Protection Agency (EPA), US National Marine Fisheries Service (NMFS), US Fish and Wildlife Service (USFWS), US Department of Agriculture (USDA), State Agencies, grower groups, crop protection industry representatives and consultants involved in pesticide regulatory actions.

The primary purpose of the workshop was to focus on grower involvement in the Endangered Species review and regulatory activities surrounding the pesticide registration review process. The first day of the workshop involved technical presentations designed to provide a better understanding of each involved agency's role in the review process and the information needed to enhance the endangered species risk assessment process and possible mitigation measures. Copies of the workshop summary and individual presentations can be found on the following websites: Florida Fruit & Vegetable Association, www.ffva.com (click on "Resources" on the top banner); and California Citrus Quality Council, www.calcitrusquality.org.

The workshop included two case studies, one involving an insecticide and the other an herbicide. These were selected based on the registrant's cooperation and commitment to preparing a case study and broad geographic distribution and use patterns that included specialty crops. These chemicals were used to illustrate the diversity and types of information that may be needed at the grower level to adequately address the risk assessment issues described by the governmental entities. The focus of the workshop was on the registration review process at EPA in attempt to consider the process, including in particular, information needs and potential sources for that information, outside of the litigation currently driving the ESA review process. A short synopsis of each of the presentations follows.

Workshop Overview and Goals:

MCFA provided a short summary of the genesis of the workshop, and identified the planning committee and sponsors. The presentation also detailed the goals and objectives and process to be followed during the workshop.

EPA – Overview of Non-target Risk Assessment Process and Endangered Species Risk Determination.

This was a three phase presentation given by Kevin Costello, Pesticide Reevaluation Division, Office of Pesticides Programs (OPP); Diann Sims, Biological and Economic Analysis Division,

OPP; and William Eckel, Environmental Fate and Effects Division, OPP. Each of the presentations focused on a part of EPA's process to reassess, define and mitigate non-target impacts of pesticide use. The first presentation was a comprehensive look at the pesticide re-evaluation review process currently underway at EPA. It described the process and proposed several points in the timeline during which the Agency hoped to collect and review information necessary to provide a robust and meaningful endangered species assessment. It identified the tiered information needs which can trigger the need for more refined geospatial information about pesticide use. The presentation also proposed several points for informal consultations with both the stakeholder community and the Services to facilitate the endangered species risk assessment process. The second phase of the presentation described the scope and limitations of use and usage information as currently collected by the Agency. The sources for existing information were characterized and potential additional sources of information were identified. This presentation also detailed the critical importance of the label in the assessment process particularly the need to confirm the accuracy of use sites and clearly defined label use directions. The third phase of the presentation focused on EPA's Ecological Risk Assessment process with emphasis on the endangered species component. The presentation centered on the stages of the re-evaluation review process and how input from growers and registrants could make it more efficient and meaningful. It described a tiered process with broadly defined risk triggers at the initial stage of review keyed off label language, through the more refined and very local specific assessment at the individual species stage when a "may affect" trigger is exceeded. The presenter highlighted the importance of the initial "problem formulation" stage in helping ensure an efficient review and that appropriate information was identified and could be collected for the more refined risk assessment. The potential benefits from informal consultations during the assessment process also were highlighted. The importance of grower involvement during development of risk mitigation steps in the endangered species consultation process was also noted.

NMFS – Threatened and Endangered Species: An Overview of NMFS' Process for Assessing EPA Pesticide Registration Actions Pursuant to the ESA.

The NMFS presentation was made by Tony Hawkes, Endangered Species Division, Office of Protected Resources. This very comprehensive presentation provided a general overview of the consultation process between the action agency – EPA and NMFS. The consultation process is triggered by a decision document (proposed label) at EPA that defines the Agency action that requires consultation. Mr. Hawkes described NMFS's review process as dictated by regulations developed to implement the ESA. This requires an assessment of impacts beyond the individual organism, to include habitat and population level impacts on species survivability. His presentation characterized the types of data to be considered and the complexities involved in the analysis process. The broad scope of the definition of "take" under the ESA also increases the complexities of the process. The avoidance of "type 2" errors in the risk assessment leads to the addition of safety factors into the trigger levels to assure safety for threatened and endangered species. If the risk assessment identifies potential to either jeopardize the continued existence of the species or adversely modify or destroy critical habitat; NMFS also described the process they utilize to develop reasonable and prudent alternatives.

USFWS – FIFRA and the ESA: U. S. Fish & Wildlife Service Perspective

Rick Sayers, Chief, Division of Consultations, HCP's, Recovery and State Grants, made the presentation for the USFWS. In his presentation the scope and magnitude of the potential consultation process became apparent. USFWS manages thirteen hundred listed species over a multitude of plant and animal taxa. The process of risk assessment and risk mitigation definition follows the process and complexity of the NMFS. USFWS detailed their use of surrogates to represent toxicity potentials for listed species which adds a level of uncertainty into the process. USFWS's analysis is more complicated in that several listed species share direct characteristics with organisms that are specifically being controlled by pesticidal products in question. Habitat impacts are also an important component of the USFWS's assessment.

USDA – Role in Endangered Species Risk Assessment and Mitigation

USDA provided an overview of information sources and programs that may be available to the specialty crop production segment to both help define potential impacts and to provide options for mitigation if needed. The USDA presentation was split into three components with Sheryl Kunickis, Director, Office of Pest Management Policy providing a general description across the spectrum of USDA activities that may impact this process. Shaun McKinney, Natural Resources Conservation Service followed with an overview of programs that can be used to help determine and model potential specific impact areas in addition to farm level planning services that can be directed at mitigation efforts. The third component was provided by Howard Hankin, also with the Natural Resources Conservation Service. He provided an overview of the targeted effort being conducted on a pilot basis in specific regions of the country to tailor conservation practices to address species conservation. This is a "best practices" process that can be partially supported through matching funds at the state conservation program level. This effort has been underway for over three years and has resulted in defined programs in several regions.

General Process Discussions:

In the discussion session after these four presentations there was a general agreement of the need for a better understanding of not only how FIFRA labeling is implemented across diverse cropping systems and regional pest complex differences, but also the need for better pesticide usage information at the species interface level. Grower groups were concerned over when to engage in data collection and the best means to assure that such collection effort was appropriately targeted resulting in quality information that would be used by EPA and the Services. EPA expressed concerns about timing of any efforts to assure the efficiency of the review process. They viewed the process along a continuum that would go from the broadest national consideration (i.e., label based) to locality specific temporal and culturally specific use patterns (crop specific farm level). Everyone was in agreement that a robust pesticide registration review process was preferable to the current litigation driven process.

Case Study Presentations:

To facilitate a more targeted discussion at the grower level two compounds were selected. The first of these, Phosmet (Imidan®) is a broad spectrum insecticide registered mostly for fruit and nut crops, and a few vegetables. The registrant for this product is the Gowan Company. It has been the subject of a Biological Opinion (BiOp) from NMFS in the current Salmonid Litigation on the West Coast and is also currently in registration review. The second product, Prometryn (Caparol®) is a broad spectrum pre- and post-emergent herbicide registered for use on several specialty crops and cotton. The registrant of this product is Syngenta Crop Protection, LLC. It will be the subject of a BiOp in the same litigation but has not yet started the ESA review process; it is also scheduled to start registration review in the near future.

Each of the registrants was asked to prepare a summary of the information available for consideration during the endangered species risk assessment and mitigation development process. The information included characterization of existing labels, general overview of relative toxicity, marketing and use information and any labeling language currently in place to limit off site impacts.

Phosmet:

The case study presentation for phosmet (Imidan®) made by Cindy Smith, Gowan Company, included basic information about the chemical and its non-target levels of concern, description of the labels and market information, relative importance in agricultural production, regulatory history, and the current biological opinion concerning salmonids in the northwest. Phosmet was first registered in 1966 and is one of the few broad spectrum organophosphate insecticides still registered for many fruits and nut crops. In her presentation, Ms. Smith identified information used both by EPA and the Services in their analysis of the risk associated with the use of phosmet which could substantially impact the assessment process. This included, in particular, the actual labels currently being marketed in the United States; the relative levels of use in key markets where concern for salmonids exist; and, trend analysis of future use of products. The last point triggered a lengthy discussion of the various use and usage databases and non-reported data retention requirements at the farm level. The use of monitoring data for risk assessments was also highlighted with the actual data suggesting a much reduced potential exposure than indicated in the models based on maximum use rates.

Prometryn:

The case study materials for prometryn (Caparol®) were presented by Dan Campbell, Syngenta Crop Protection, LLC. This triazine herbicide was first registered in 1964. Much of the same type of basic information that was provided for Imidan® was included in Mr. Campbell's presentation. Because of its registration on cotton, there appears to be much more information in the publically available databases across a more diverse geographical area. The presentation also highlighted the ability to use a GIS based system to determine co-location of pesticide use with counties that have been identified with habitat for endangered species. The ability to obtain more refined geospatial analysis was demonstrated in the presentation. Much interest was

expressed in the use of these tools and the need to develop a verifiable database on cropping locations and usage information.

General Discussions – Case Studies:

Several basic themes and questions emerged from the discussions around the information presented in the case studies:

- What are the appropriate points in the registration review process to initiate discussions with both the registrant and the user community to identify, describe and verify crop specific use and usage information?
- What data sources are most complete and relevant to the risk assessment process?
- How will commodity groups know when to engage in the process and how to ensure that information collected and submitted is considered?
- How would the need for informal dialogue and discussions take place prior to formal consultations between EPA and the Services?

The grower representatives indicated a need for additional information on EPA's risk assessment process and the Services biological opinion development process and resulting triggers used by the Services to drive reasonable and prudent alternatives development.

The consensus among all participants is that it would be in everyone's best interest to develop a comprehensive and transparent process during registration review rather than having the consultation process continue to be litigation driven.

To facilitate those discussions a matrix was developed to describe points in the process where specific information would be valuable and points where the process would most efficiently utilize the information. It was clear after the discussions that additional meetings to clarify the process would be necessary.

The Draft matrix is attached as Appendix 3.

Next Steps:

- Workshop Planning Committee, and MCFA Technical Committee Meetings in June to explore specific meeting outcomes and next steps.
- Coordinate website to post all presentations and workshop summary.
- Develop written workshop summary of major topics.

- Post proposed Draft matrix/discussion document developed at the workshop that could be used in the pesticide re-evaluation process.
- A review of USDA databases that EPA and the Services could potentially utilize in their review processes.
- Explore ways to maintain the dialogue including coordinating with other commodity groups and registrants.
- Determine the best route to communicate with MCFA members and others to follow up with recommendations of specific actions for growers during the ESA review process.
- Discuss ways to collect typical use data, typical tank mixes, etc., the data needs identified by the Agency and the Services during the workshop.
- Commitment by MCFA members to review existing BiOps and to thereafter appropriately follow up with the EPA and the Services on specific process issues, with a goal of developing a transparent, simple and common understanding of the process.
- Discuss the process defined in the Section 7 Consultation Handbook. Determine if the registration reevaluation Matrix can be accommodated.
- Find ways to gather and provide data in a consolidated way that can be used across multiple pesticide re-evaluation review dockets.
- Explore the use of webinars rather than face to face meetings for future discussions.

List of Appendices:

Appendix 1: MCFA ESA Workshop Agenda

Appendix 2: Registration List, MCFA ESA Workshop

Appendix 3: Draft Registration Review Information Matrix

Appendix 4: Links to Additional Information

Appendix 1

MCFA ESA Workshop Agenda

Agenda

MCFA ESA Workshop May 24-25, 2011

Goals for the Workshop:

- Provide grower representatives an understanding of the processes and analysis leading to identification of risk and mitigation options by each agency
- Identification of grower level data that would enhance the risk identification and risk mitigation decision process
- Initiate discussions on the mechanisms to provide such data

Tuesday, May 24

7:00 am – 8:30 am:

Registration and Check-in

8:30 am – 8:45 am:

Opening Comments and Meeting Description

Moderator: Daniel Botts, MCFA

8:45 am – 10:15 am:

**EPA Non-Target Risk Assessment Process and
Endangered Species Risk Determination**

Discussion of EPA OPP Risk Assessment Process
Endangered Species Specific Risk Assessment Process
Consultation
Pesticide Specific Risk Mitigation Option Determination

Presenters: William Eckel, EFED
Kevin Costello, PRD
Diann Sims, BEAD

10:15 am – 10:30 am:

Break

4:00 pm – 4:15 pm: Overview of Case Study Roundtable Discussion Process

Facilitator: Abby Dilley, Resolve

4:15 pm –5:45 pm: Registrant Presentations – Overview of Case Study Chemicals

Phosmet – Gowan (45 Min)

Presenter: Cindy Baker Smith, Gowan Corporation

Prometryn – Syngenta (45 Min)

Presenter: Dan Campbell, Syngenta Crop Protection

5:45 pm – 6:00 pm: Logistics for Day 2

Facilitator: Abby Dilley, Resolve

Wednesday, May 25th:

8:00 am – 8:10 am Overview and Logistics

Facilitator: Abby Dilley, Resolve

8:10 am – 8:20 am NMFS Response to Case Study Products

Presenter: Angela Somma, NMFS

8:20 am – 8:30 am USFWS Response to Case Study Products

Presenter: Rick Sayers, USFWS

8:30 am – 8:40 am EPA Response to Case Study Products

Presenter: Donald Brady, EPA - EFED

8:40 am – 8:50 am USDA Response to Case Study Products

Presenter: Harold Coble, USDA
David Epstein, USDA

8:50 am – 10:15 am

Round Table Discussion – Grower Data

Facilitator: Abby Dilley, Resolve

Is there grower level information that is of value in the risk assessment and mitigation step development process at EPA? Or with the Services during specific consultations?

10:15 am – 10:30 am

Break

10:30 am – 12:30 pm

Round Table Discussion – Collection, Verification and Utilization of Grower Use Data

Facilitator: Abby Dilley, Resolve

If grower information is useful --

- What information is most desirable?
- How is it collected?
- How is it entered in the process?
- Who screens the data for completeness and accuracy?

12:30pm – 1:30 pm

Lunch

1:30 pm – 2:45 pm

Round Table Discussion – Points of Entry for Grower Data

Facilitator: Abby Dilley, Resolve

What are the appropriate points of entry for grower and producer group's data in the EPA or Services endangered species risk determination and risk mitigation processes?

2:45 pm – 3:30 pm

Next Steps

Facilitator: Abby Dilley, Resolve

3:30 pm – 4:00 pm

Concluding Remarks

Presenters:

- Donald Brady, EPA - (5 Min)
- Angela Somma, NMFS - (5 Min)
- Rick Sayers, USFWS - (5 Min)
- Sheryl Kunickis, USDA - (5 Min)
- Chris Schlect, MCFA - (5 Min)

Appendix 2:

Registration List, MCFA ESA Workshop

	Name	Organization	Email
1	Baker Smith, Cindy	Gowan	cbakersmith@gowanco.com
2	Balling, Steve	Del Monte Foods	steve.balling@delmonte.com
3	Becker, Jonathan	USEPA-Office of Chem Safety and Pollution Prevention	becker.jonathan@epa.gov
4	Bell, David	Wild Blueberry Commission of Maine	dkbell@maine.edu
5	Berger, Lori	CA Specialty Crops Council	lori@specialtycrops.org
6	Blankenship, Brett	Washington Assoc. of Wheat Growers	michelle@wawg.org
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14	Costello, Kevin	EPA OPP, Pesticide Re-evaluation Division	costello.kevin@epa.gov
15	Cowles, Jim	Washington Department of Ag	jim.cowles@agr.wa.gov
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24	Feken, Max	FDACS	max.feken@freshfromflorida.com
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32	Hancock, Gregg	Waterborne Environmental, Inc	hancockg@waterborne-env.com
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46	Maier, Eric	Washington Assoc. of Wheat Growers	michelle@wawg.org
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56	Ruckert, Edward	McDermott Will & Emery	eruckert@mwe.com

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Appendix 3:

Draft Registration Review Information Matrix

**Draft
Registration Review Matrix
MCFA ESA Workshop**

May 24 & 25, 2011

This table reflects the discussion at the MCFA ESA Workshop to describe opportunities for grower input and dialogue during registration review that could help refine EPA's and the Services' ESA Pesticides risk assessment and risk mitigation development process. **IT IS A WORK IN PROGRESS.** It will serve as a focus point for future discussions.

Process Point	Information Needs	Potential Providers	Comments
Pre Docket (Problem Formulation)	<p>Clarification and confirmation of Use/usage (characterized) data and label statements</p> <p>Characterization of tank mixes for environmental risk assessments</p> <p>Crop distribution Information (where grown today and where could be or couldn't be)</p>	<p>Registrants Growers States USDA</p>	<p>Grower Action: Know the schedule</p> <p>EPA action: identify schedule to let people know critical timing for receiving information</p> <p>EPA and Services Action: Definition of data needs</p>
Docket Opens/First Public Comment Period (90 days)	<p>Preliminary work plan issued</p> <p>Comments sought on scope of registration review and data needs</p> <p>Opportunity to address or refine data needs identified above or created by synthesis done by EPA</p>	<p>Registrants Growers States USDA</p>	<p>Grower action: Review preliminary work plan and problem formulation to provide comments to correct or inform</p> <p>Possible information Needs:</p> <ul style="list-style-type: none"> • Tank mixtures • Environmental mixtures <p>Registrant Action: Possible mechanisms for reviewing information to develop a final work plan:</p> <ul style="list-style-type: none"> • Label review

Process Point	Information Needs	Potential Providers	Comments
Final work plan and Data Call-in issued (about 2 years in this phase)	<p>Comments received and addressed</p> <p>Revised scoping document</p> <p>No comment period</p>	<p>Registrants</p> <p>Growers</p> <p>USDA</p>	<p>EPA Action:</p> <p>Identify a process step (draft risk assessment) where they have enough information to identify species of concern and where more information could be provided to refine.</p> <p>Place for informal consultation –technical input from the Services</p>
Preliminary Risk Assessment/Second Public Comment Period	<p>Integrating data received into risk assessments</p> <p>Human health and eco risk assessments released for comment.</p> <p>Species of concern identified at this phase.</p> <p>Discussion of possible mitigation based risk assessment</p>	<p>Registrants</p> <p>Growers</p> <p>States</p> <p>USDA</p>	<p>EPA Action:</p> <p>Potential informal Consultation with Services</p>
Proposed Registration Review Decision/ Third Public Comment Period	<p>Finalization of proposed mitigation</p> <p>Revised labels submitted</p>	<p>Registrants</p> <p>Growers</p> <p>USDA</p>	<p>Grower Action:</p> <p>Response to proposed mitigation</p>
Final Decision Issued (if no need for consultation)			

Consultation Required

Process Point	Information Needs	Potential Providers	Comments
EPA Request Initiation of Consultation Services Request for Clarification	Identify applicants	Registrants Growers USDA	
Final Biological Opinion			
Reasonable Prudent Measures and Alternatives			
Implement Reasonable Prudent Alternatives			

Appendix 4:

Links to Additional Information

Links to Additional Information

ESA Section 7 -- Endangered Species Consultation Handbook:

http://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf

Environmental Protection Agency:

EPA's Office of Pesticides Programs Endangered Species Site

<http://www.epa.gov/espp/>

Registration Reevaluation Division Sites

Schedules:

http://www.epa.gov/oppsrd1/registration_review/schedule.htm

Status of Pesticide Registration Review

http://www.epa.gov/oppsrd1/registration_review/reg_review_status.htm

Environmental Fate & Effects Division Sites

Basic Information on the Pesticide Programs Endangered Species Program

<http://www.epa.gov/oppfead1/endanger/basic-info.htm>

Endangered Species Effects Determinations and Consultations and Biological Opinions

<http://www.epa.gov/oppfead1/endanger/litstatus/effects/>

National Marine Fisheries Service

General Information

<http://www.nmfs.noaa.gov/pr/laws/esa/>

Listed Species

<http://www.nmfs.noaa.gov/pr/species/esa/>

Critical Habitats

<http://www.nmfs.noaa.gov/pr/species/criticalhabitat.htm>

Biological Opinions

<http://www.nmfs.noaa.gov/pr/consultation/opinions.htm>

U. S. Fish & Wildlife Service

General Information

<http://www.fws.gov/endangered/>

Listed Species

<http://www.fws.gov/endangered/species/us-species.html>

Critical Habitats

<http://www.fws.gov/endangered/what-we-do/critical-habitats.html>

U. S. Department of Agriculture

Agricultural Chemical Use Program

http://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/

Agricultural Statistics Annual

http://www.nass.usda.gov/Publications/Ag_Statistics/index.asp

Pesticide Recordkeeping Program (PRP)

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateQ&navID=PesticideRecordkeepingProgram&rightNav1=PesticideRecordkeepingProgram&topNav=&leftNav=ScienceandLaboratories&page=PesticideRecordkeepingProgram&resultType=>

Safe Harbor Policy

http://www.nrcs.usda.gov/technical/ECS/environment/safe_har.pdf

NRCS PROGRAMS

<http://www.nrcs.usda.gov/programs/>

Other Sites

USGS Land Cover Information

<http://landcover.usgs.gov/uslandcover.php>