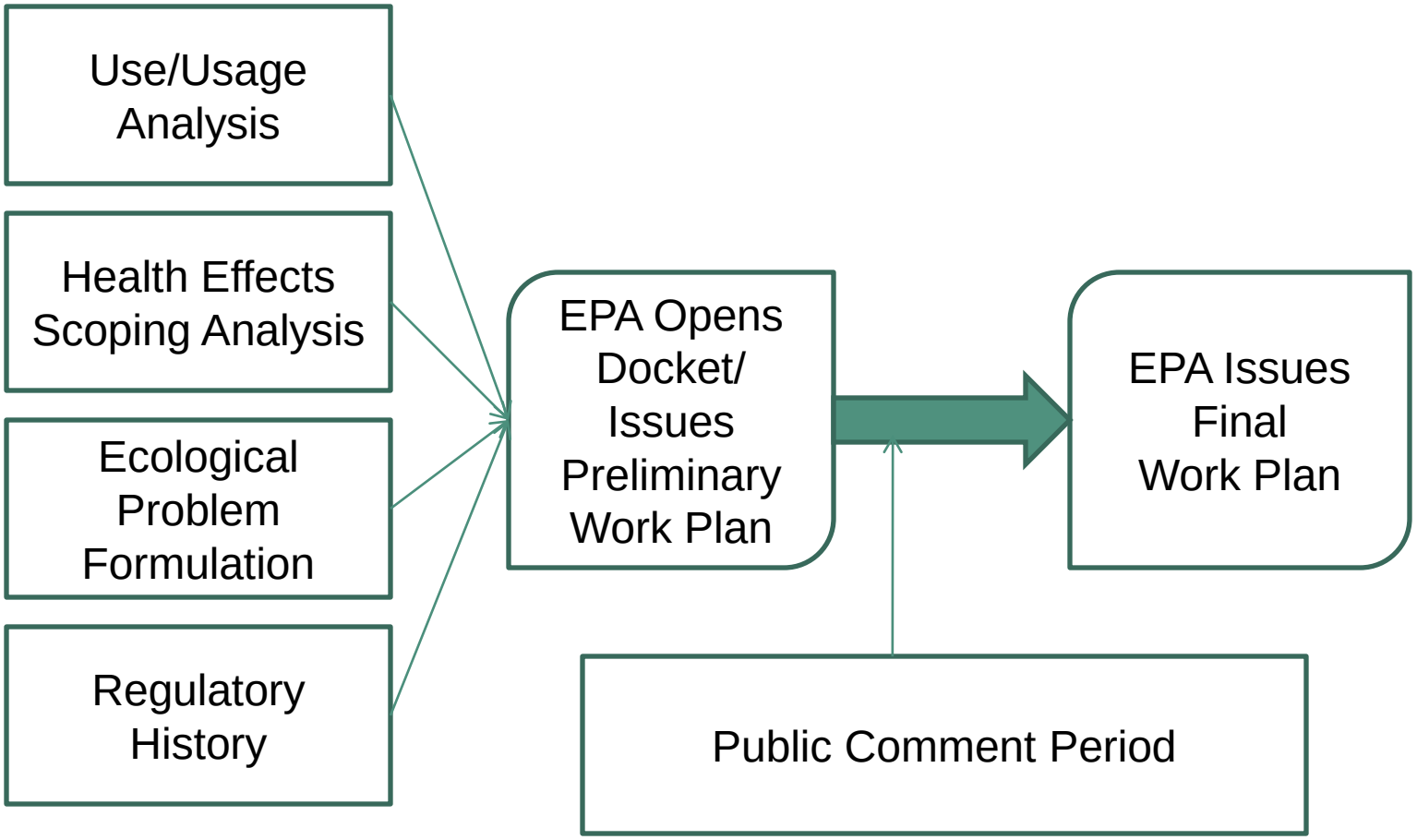
Stakeholder Input in the Registration Review Process

Kevin Costello
Pesticide Re-evaluation Division
United States Environmental Protection Agency
May 24, 2011

Registration Review

- FIFRA requires review of each pesticide's registration every 15 years to ensure that all registered pesticides continue to meet the statutory standard for registration
- Re-evaluates all pesticides (1135 and rising)
- Each case has been the subject of at least one previous risk assessment
- Because certain classes of pesticides considered early in the process, only a few years may have passed since previous risk assessment

Informing Preliminary Work Plans



Inviting Comment on the PWP

- Intention of early comment period is the hope to refine the scope of the upcoming risk assessment
- Registrants can clarify labels with vague use instructions
- Growers can inform the focus of the risk assessment with guidance on which uses are most important (and which are not), and the actual use practices
- Broader scale geographic data more useful at this point, as the risk assessment is still several years off.
- Are other efforts in place (e.g. NRCS buffers or soil conservation measures) which would be relevant to our risk assessment?

ESA Requires Finer Focus

- Previous risk assessments considered risk to non-target organisms on a national scale
  - Ecological risk balanced against benefits of pesticide use under FIFRA
  - Mitigation generally applied broadly
- Risk assessments under registration review will also be compliant with the ESA
  - If possible risks to endangered species risks are identified, consultation with the Services required
  - Mitigation could be geographically specific

ESA Expands the Risk Assessment

- ESA assessment will be done on a national scale, but also considers the potential risk to each of 1300+ endangered species
- This requires an assessment of co-occurrence of pesticide residues with each species.
- This requires a more detailed understanding of
  - Biology and habitat of individual species
  - Use rates and use area of each pesticide

Preparing Risk Assessments

- Agency reviews public comments and additional information received
- Develops final work plan (FWP) stating if new risk assessments are required and if data call-in is needed
- EPA issues Data Call-In
- Risk assessments begin 2 ½ years after opening of docket; due 16 months later
- Risk assessments for FY07-FY09 in preparation stage

Refining Risk Assessments

- Draft risk assessments
  - 2nd point in process to engage stakeholders
  - Opportunity to discuss mitigation with registrants to reduce scope of consultation
- Users can help with more geographically specific data
  - No crops grown within a certain distance of the Tooth Cave Spider
  - Hops not grown beyond certain counties, and are very unlikely to be for specific reasons
  - Pesticide no longer used on certain crops except under very specific circumstances

Mitigation Discussions

- Mitigation measures could eliminate risk to some species (or even entire taxa)
  - Maximum rates could be reduced
    - Highest rates may no longer be needed
    - Highest rate might only be used against certain pests
  - Some uses may no longer be supported
    - Users could confirm if no longer needed
    - Users could identify specific scenarios where still important

Final Risk Assessment and Proposed Decision

- The Agency will finalize the risk assessment and publish Proposed Decision for public comment
  - 3rd point in process to engage stakeholders
  - Less effective point at which to provide use and usage information
- Agency makes safety finding under FIFRA
  - Human health
  - Non-listed species

Program Progress to Date

- EPA is continuing to meet all registration review targets consistent with overall program objectives

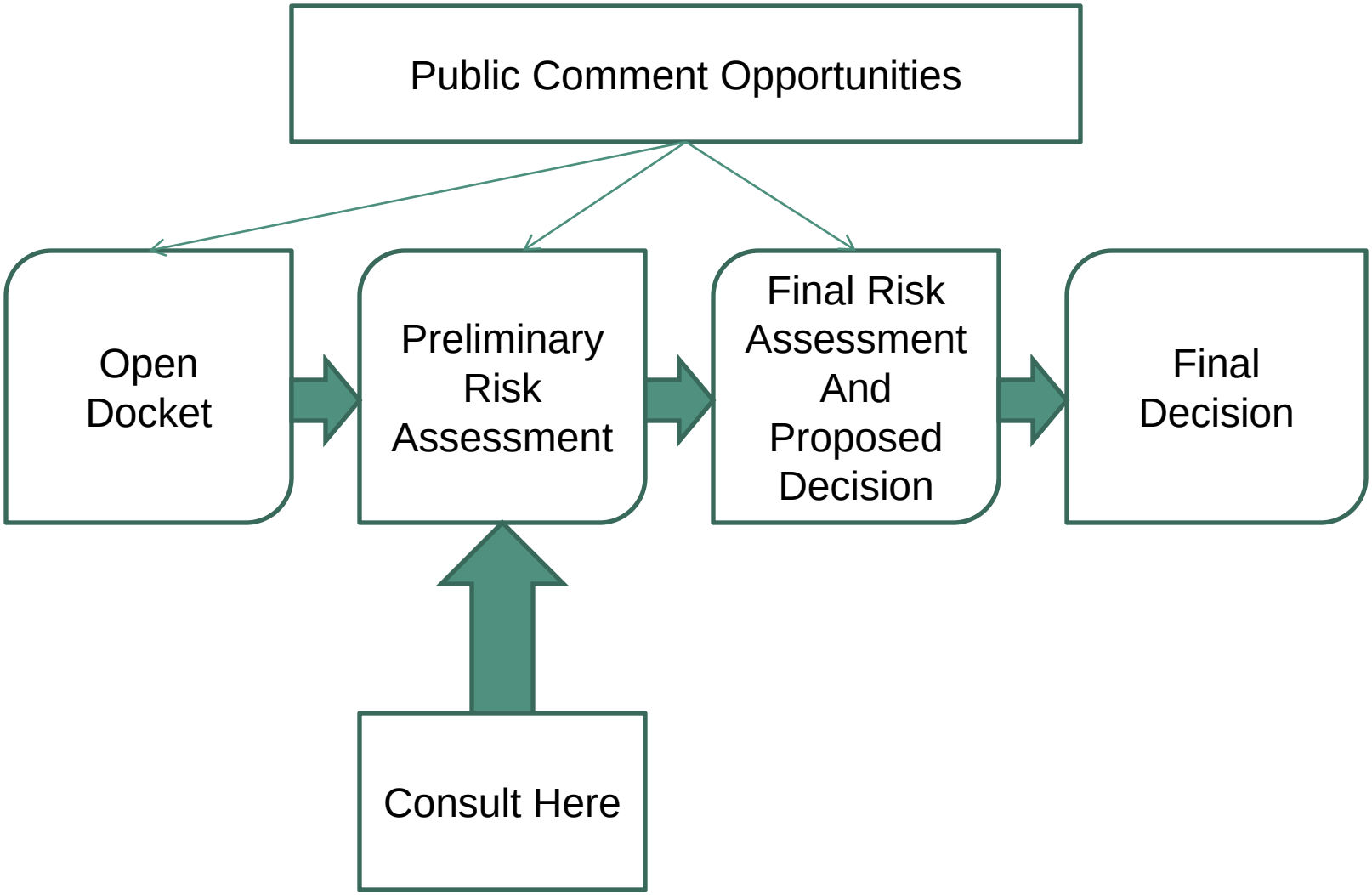
- By the end of March 2011
  - 253 cases were past the docket opening stage
  - 214 cases were past the FWP stage
  - 26 final decisions had been issued

- EPA will continue to open 70 new dockets (48 conventionals) each year through 2017. Nearly all pesticides registered at the start of registration review will have dockets opened by 2017, supporting decisions by October 1, 2022.

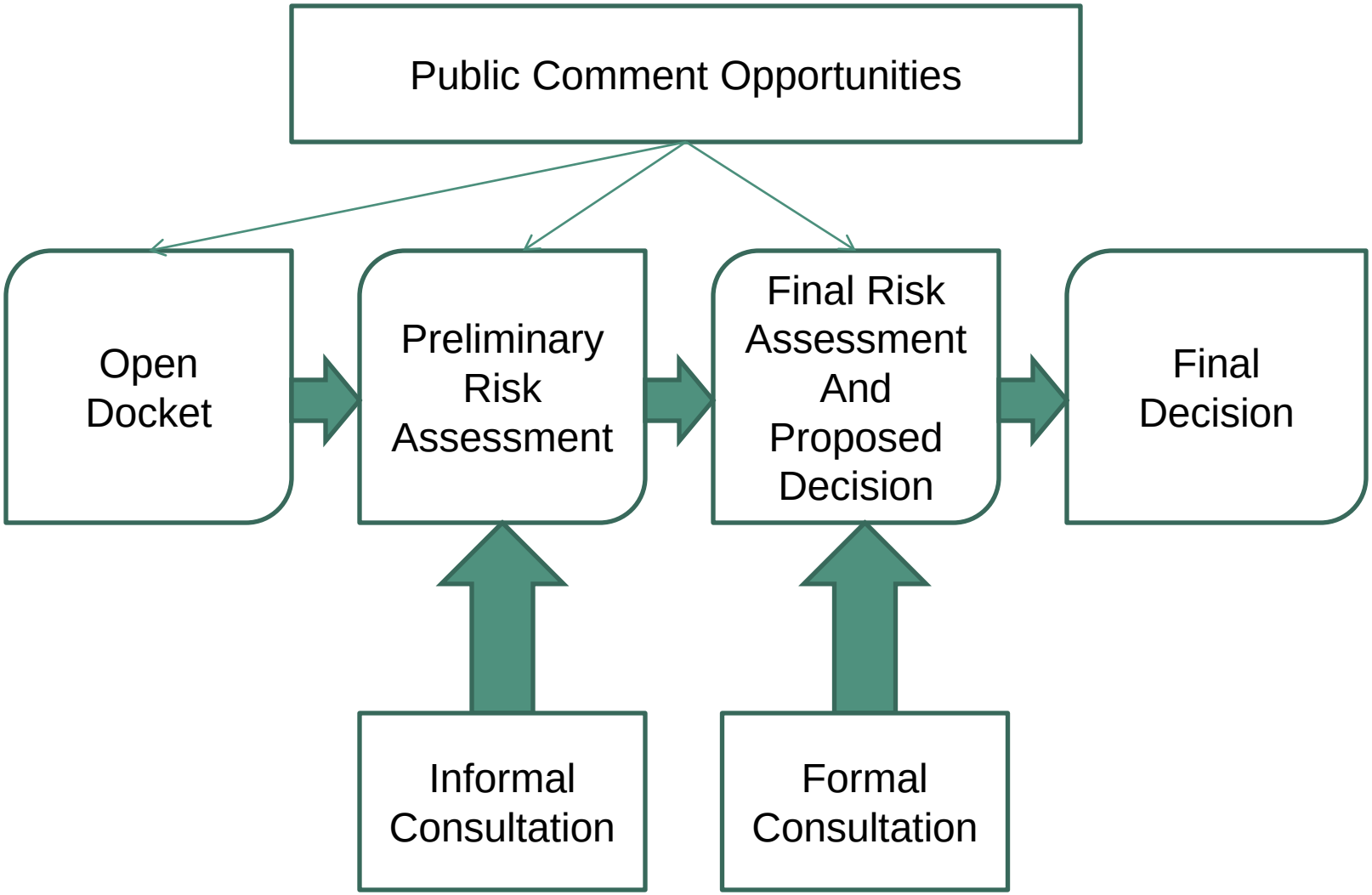
Collaboration Will Require Vigilance

- Agency will be simultaneously opening dockets, preparing risk assessments, and entering into dialog with stakeholders on dozens of cases every year
- Consultation with the Services will add additional complexity and effort
- Timely input from users critical to reduce scope of consultations and protect listed species
- Four-year schedule available on the web

When to Consult During Registration Review: Original Vision



When to Consult During Registration Review: Possible Alternative?



ESA Consultation

- Services will review Agency risk assessments to determine whether pesticide use will jeopardize continued existence of listed species
- Services issue Biological Opinions detailing Reasonable and Prudent Alternatives to preclude jeopardy
- Stakeholders can confer with Agency to suggest other RPAs which could also preclude jeopardy

Conclusion

- The Agency would appreciate stakeholder input at multiple points in the registration review process:
  - After posting of the Preliminary Work Plan
  - After posting of the Preliminary Risk Assessment
  - After posting of the Proposed Decision
  - After the Services propose RPAs
- The Agency always welcomes your input on specific or general registration review topics

An Overview of Pesticide Use and Usage Data In EPA's Office of Pesticide Programs

Diann Sims
Biological & Economic Analysis Division
United States Environmental Protection Agency
May 24, 2011

Discussion Topics

- Pesticide Label Use Overview
- Pesticide Usage Data Overview
- Challenges

Pesticide Label Use Data: Key Terms & Concepts

- **Use** data refers to information on allowable uses of pesticides in accordance with the EPA-approved label
- **Use** information answers the following questions:
  - What crops or sites may be treated with the pesticide?
  - How is a given pesticide used?
  - What pests drive the use of an active ingredient?
  - When is the pesticide used?

Pesticide Labels

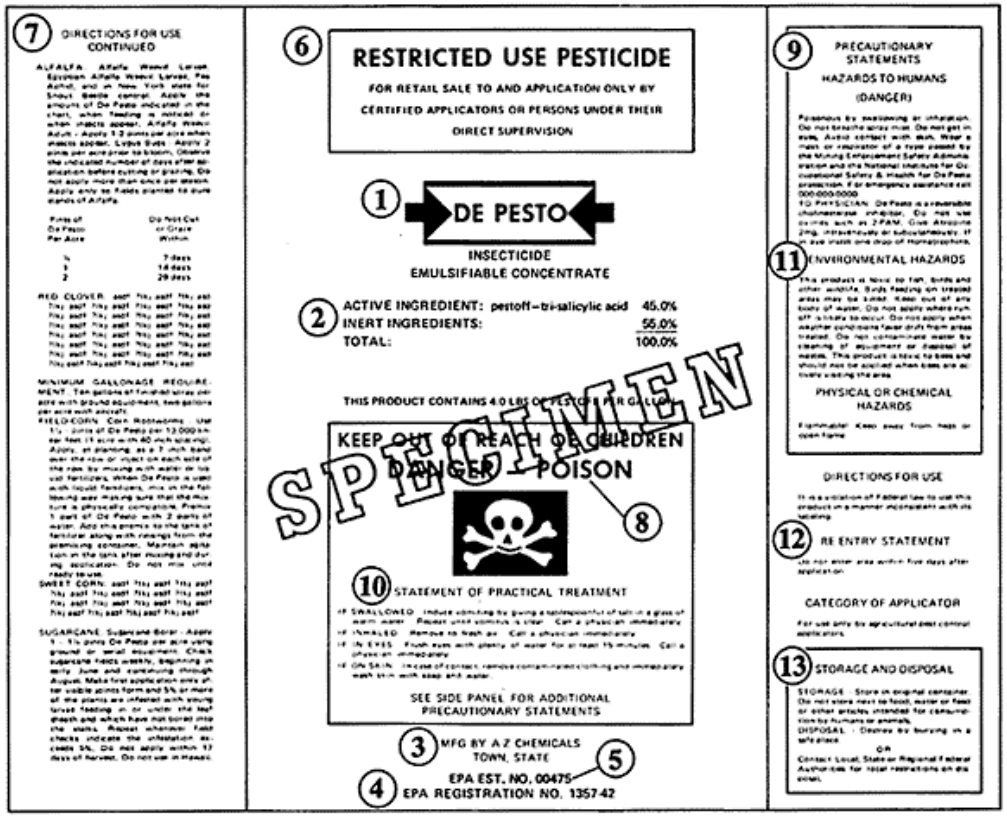
- Pesticide product labels:
  - provide critical information about how to safely and legally handle and use pesticide products
  - translate the results of scientific evaluations into a set of conditions, directions, and precautions that define who may use a pesticide, as well as where, how, how much, and how often it may be used
  - are legally enforceable

The Role of Pesticide Label Use Data in ESA

- Registration Review
  - Identify eligible uses
  - Identify use patterns
  - Identify label errors or opportunities for clarity
- Endangered Species Assessments
  - Characterize a pesticide's use
  - Identify use patterns

Importance of the Labels

- The LABEL is the foundation of the risk assessments
- Exposure assessments rely heavily on LABEL information



Importance of Labels in Assessing Risk

- Primary LABEL information used in modeling exposures:
  - Application method(s) (*e.g.*, ground vs. aerial)
  - Formulation type (*e.g.*, flowable vs. granular)
  - Use site(s)
  - Maximum single application rate (in lb a.i./acre)
  - Maximum number of applications/year
  - Maximum application rate/year (in lb a.i./acre)
  - Minimum application interval
  - Use restrictions (*e.g.*, geographic restrictions, buffers, spray drift restrictions)

Pesticide Label Use Data Challenges

- Label Data Quality
  - Insufficient information on labels (missing max # of apps per year or season)
  - Unconvertible rates on labels (spray till wet, etc.)
  - Conversion factors for desired rates (lb ai/A)

Example of a Pesticide Label Report with Missing (Insufficient) Data Fields

Max App Rate Qty	Max App Rate Unit/Area	Max # Apps/Crop Cycle	Max # Apps / Year	Seasonal Max Dose/Crop Cycle	Seasonal Max Dose/Year	Min Retreatment	ReEntry Interval	Type	Equipment
0.167	gal (L)	NS	NS	NS	NS	NS	24 h	Soil band treatment	Sprayer

Pesticide Label Use Data – Challenges Continued

Resource limitations

- **Partial Reports**
  - For pesticides with many labels, a sub-set of those labels are extracted.
  - Partial reports are representative of:
    - Registrants who generate the studies and Technical Grade Active Ingredient (TGAI) labels for a particular pesticide
    - Formulations
    - Sites
    - %AI

Usage Data: Key Terms & Concepts

- **Usage** data provide **quantitative** information regarding how much of a pesticide is applied.
- **Usage** data answer the following questions:
  - How much of the pesticide is used?
  - Where are pesticides used and in what quantities?
  - What percent of the crop is treated?
  - What is the typical application rate?
  - What are the typical use patterns (number of applications, timing of application, method of application)?

Pesticide Usage Data Role in ESA

- Endangered Species Assessments
  - Characterize national, state, and county-level usage patterns
  - Inputs to aquatic, terrestrial, and atmospheric models

Importance of Usage Data in Assessing Risk

- Primary usage information includes:
  - Pounds applied
  - Typical or average application rate (in lb a.i./acre)
  - Area Treated
  - Crop Acreage Grown

Public Data Sources

- USDA's National Agricultural Statistics Service (NASS)
- California Department of Pesticide Regulation

Public Usage Data Sources

- **USDA-NASS** (National Agricultural Statistics Service)
  - Contains pesticide usage data from 1991 to 2009
  - Collects data via surveys (states that represent at least 85% of crop production)
  - Updates data annually for some crops and biennially for others

Public Usage Data Sources Continued

- CA Pesticide Use Reports (PUR)
  - Contains data on both agricultural crops/sites and some non-agricultural sites.
  - Type and amount of pesticide for every application
  - Data updated annually

Proprietary Databases

- GfK Kynetec Marketing Research, Inc.
  - Primary use is marketing/sales report for pesticide producers
  - Type of Information Available
    - Area treated
    - Lbs ai applied
    - Application rate
    - Number of applications
    - Limitations
    - Expensive; purchase is for access only
    - Limited in ability to cite the data

Limitations of Pesticide Usage Data

- Registered/labeled uses may exist but are not surveyed by the available data sources.
- Lack of reported usage data for the pesticide on a crop does not imply zero usage.
- Usage data on a particular site may be noted in data sources, but not quantified.
- Application timing information is usually very general.
- Survey respondents may not report usage.

Pesticide Usage Data - Challenges

- Rising cost of primary usage data sources
- Lack of usage data to support endangered species assessments
- Usage statistics by state, county, use site
- Sub-county usage statistics

Pesticide Usage Data - Challenges Continued

- Directly acquired county usage data
  - Maximum use rate
  - Percent crop treated
  - Median and 90th percentile number of applications
  - Total pounds per year
  - Year of the last use
  - Time span of use (years)

Summary

- Use and usage data are critical for registration review and endangered species assessments.

- Key challenges
  - Obtaining appropriate and adequate pesticide use data
  - Ensuring that the label use information is accurate and complete

Ecological Risk Assessment Process in EPA's Office of Pesticide Programs

William P. Eckel, Ph.D.
Environmental Fate & Effects Division
US Environmental Protection Agency
May 24, 2011

EPA's Risk Assessment Process

- Problem Formulation: scope of Federal Action (sum of all labels for an active ingredient)
- Effects Assessment (toxicology) by taxon
- Fate Assessment (exposure) by media
- Risk Characterization: RQ = exp./tox. Compared to Levels of Concern (LOC)

EPA's Risk Assessment Process

- Establish Action Area and extend to Effect Area: Where does exposure exceed LOC?
- Identify Taxa at risk
- Consider Direct and Indirect risks
- Identify Listed species that may be at risk (MA/LAA and MA/NLAA)
- Describe Uncertainties in exposure, toxicology, geography, etc.

EPA's ESA Effects Determination

- May Affect or No Effect
- Species in Action (Effect) Area are May Affect (MA)
- If MA, Likely (LAA) or Not Likely (NLAA) to Adversely Affect, based on further analysis (body wt., diet, habitat, etc.)
- Modification of Critical Habitat (yes/no)
- Handoff to Services for Jeopardy call under ESA

EPA's Goals for Endangered Species Act in Registration Review

- Achieve Protection for Listed Species by:
  - Geographically-specific mitigation
  - Focused Consultation with Services
  - Increased Efficiency & Consistency with automation of Biological Assessment
  - Providing multiple opportunities for stakeholder input

Problem Formulation (PF)

- Identify footprint of use (ag, forestry, residential, etc.) by associating label use sites with NLCD classes to define Action Area
- Identify data gaps (toxicity, fate/exposure)
- Role of stakeholders: In Public Comment period, review PF to refine EPA's understanding of use patterns, formulations, use intensity, application methods

Problem Formulation (PF) (continued)

- EPA attempts to determine scope of Federal Action; labels often incomplete or vague
- Clarification of label(s) tightens Federal Action, reduces uncertainty and conservative assumptions, MA calls
- What crops, application rates, frequencies, intervals?...actual versus label-allowed if lower
- Possibly eliminate unneeded use patterns on labels to focus risk assessment

Problem Formulation (PF) (continued)

- At this early stage, data sets of national scope are needed, because EPA is working from general to specific (national to local)
- “Use” and “Usage” information
- Data sets that cover an entire crop also useful

Draft Risk Assessment Stage

- EPA identifies species for which there is no concern (“No Effect”)
- EPA identifies species that are “May Affect,” and will require further analysis or mitigation before proceeding to ESA Consultation
- EPA publishes Risk Assessment for public comment at this stage

Post-Draft Risk Assessment Stage

- EPA investigates mitigation opportunities with industry & growers, to minimize number of species proceeding to ESA Consultation

- EPA is interested in obtaining mitigation to reach as many No Effect and Not Likely to Adversely Affect determinations as possible before initiating Consultation

Post-Draft Risk Assessment Stage (continued)

- Stakeholder role: Offer specific regional or local geographic use limitations, or pesticide use modifications that result in No Effect or Not Likely determinations

- Stakeholders can supply information to reduce uncertainties in risk assessment: may make mitigation unnecessary locally

- Regional & local information more appropriate at this stage (e.g., actual crop areas)

Final Biological Assessment

- Incorporate all agreed-upon refinement and mitigation efforts (from stakeholder input) into final Federal Action (labels)
- Compile Consultation package for submission to Services
- Services prepare Biological Opinion; EPA publishes BO for public comment
- Timing of final FIFRA action vs. BO is uncertain

Formal or Informal Consultation

- Stakeholders may provide information during Consultation to define Pesticide Use Limitation Area (Endangered Spp. Protection Bulletin)
- Stakeholders have opportunity to offer methods to achieve Reasonable & Prudent Alternatives
- Grower-level data is most relevant at this stage (county-level framework)

Examples of Local Data

- Actual crop locations (not all crop land)
- Local pesticide use practices (timing, frequency, method)
- Runoff water management practices
- Mitigations (buffers, etc.) already in place due to soil conservation practices, etc.
- Other relevant inter-governmental agreements

Conclusion

- There are numerous pieces that make up the process of risk assessment and management
- We welcome your questions
- We look forward to our discussions tomorrow