

US EPA ARCHIVE DOCUMENT

Registration Review Docket



CLOMAZONE

PPDC Registration Review Workgroup Meeting
March 8, 2007

**PPDC Registration Review Workgroup Meeting
Clomazone
Thursday, March 8, 2007
Potomac Yard South, 1st Floor Conference Center**

- I. Background— Casey Jarvis
- II. Human Health Scoping — Ray Kent
- III. Ecological Risk Assessment Problem Formulation-
Dana Spatz
- IV. Preliminary Work Plan- Casey Jarvis
- V. Questions/Comments

Clomazone Background

- ❑ Clomazone is an isoxazolane herbicide that causes bleaching or whitening of susceptible plants by inhibiting the formation of photosynthetic pigments.
- ❑ Pests controlled are annual grasses and broadleaf weeds.
- ❑ Technical registrant: FMC Agricultural Corporation
- ❑ First Registered: 1986
- ❑ No residential uses.
- ❑ Used for major crops such as cotton, tobacco, soybeans, rice, sugarcane, a variety of vegetable crops, and fallow land.

Clomazone Background

Use Information:

- ❑ Formulated as a wettable powder (WP), emulsifiable concentrate (EC), microencapsulated flowable (ME), and microencapsulated granule (MEG).
- ❑ Typically applied by ground equipment, band sprayer, soil incorporation equipment and aerial applications.
- ❑ Clomazone accounts for more than 50% of the crop treated for rice, cabbage, and pumpkins.
- ❑ Approximately 1,110,000 pounds active ingredient (lbs a.i.) of clomazone are used annually.
- ❑ Eleven Section 3 registrations, and twelve Section 24(c) registrations (Special Local Needs).

Human Health Problem Formulation

Where do we start?

The most recent comprehensive risk assessment(s) for:

- ❑ Dietary – food and water
- ❑ Residential application and post-application
- ❑ Occupational – handlers and reentry
- ❑ Aggregate – food + water + residential

Human Health Problem Formulation

What's new?

Potential sources of information, e.g.

- ❑ New data from registrants/others
- ❑ Changes in use patterns
- ❑ Literature reports
- ❑ Pesticide incidents
- ❑ Changes in policy

Human Health Problem Formulation

What's important?

- ❑ No new information = no review
- ❑ New information with minimal impact on risk = no review
- ❑ New information with significant impact on risk = full review
- ❑ New information with some risk implications = how much review?

Human Health Effects Scoping Document Conclusions

- ❑ Recent clomazone risk assessments are up to current standards
- ❑ No additional data are needed
- ❑ No further human health risk assessments are needed.

Information Sources

<u>Source of data</u>	<u>Clomazone results</u>
Recent assessments -	RAs in 2001 and 2002
New submitted data -	No new data
Changes in use -	Microencapsulation
Literature reports -	No useful data
Pesticide incidents -	Few incidents
Changes in policy -	Inhalation waivers, e.g.

Toxicity Database

Database essentially complete, but...

- ❑ Dermal toxicity study missing
- ❑ Inhalation study required
- ❑ Inadequate dosing in cancer studies

Issues were resolved in the scoping exercise

Exposure Database

Data are adequate for risk assessment

- ❑ No datagaps for residue chemistry
- ❑ Tier 1 dietary risks <1% of the acute & chronic PADs. Drinking water ok.
- ❑ No residential exposure
- ❑ Occupational handler scenarios are current and all MOEs are acceptable

FQPA Assessment

Database for FQPA assessment is complete

- ❑ Acceptable developmental studies in rats & rabbits
- ❑ Acceptable 2-gen repro study in rats
- ❑ No evidence of neurotoxicity in any study

Based on reliable data, the RA team recommends removal of the factor

Pesticide Incidents

- ❑ There are few poisoning incidents involving clomazone
- ❑ Incidents reflect irritation to skin, eyes, respiratory tract or gastro-intestinal tract

Policy Changes

- ❑ Interpretation of FQPA
- ❑ Drinking water risk – direct incorporation of water exposure in dietary assessments
- ❑ Inhalation risk – provision to waive requirement to test

None of these issues were determined to impact dietary or occupational risk

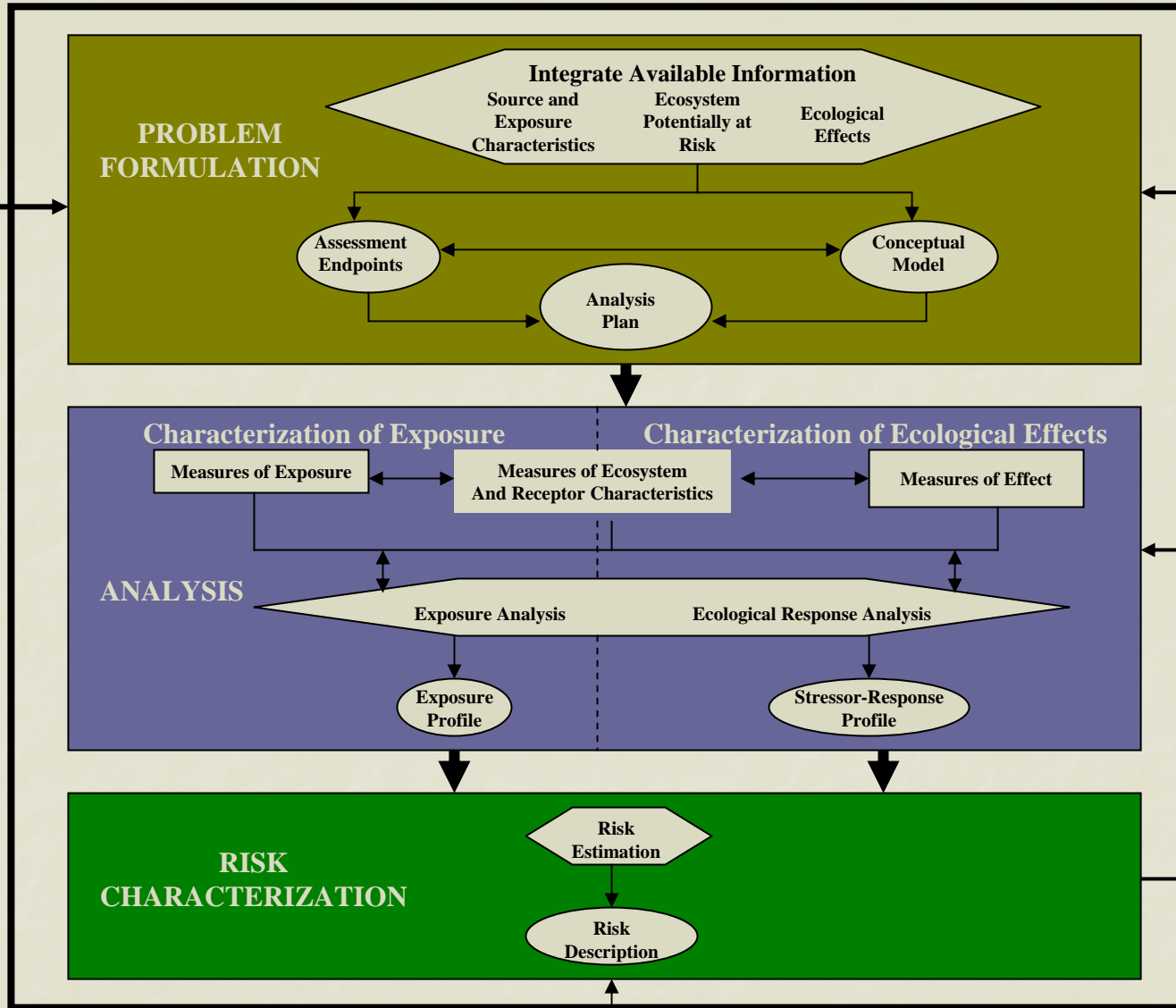
Ecological Risk Assessment

Planning Dialogue and Problem Formulation

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

**Planning
(Risk Assessor/
Risk Manager
Dialogue)**

- 1. Management Goals
- 2. Management Options
- 3. Scope, Complexity,
and Focus
- 4. Resources
- 5. Scheduling



As
Necessary

Acquire
Data,
Iterate
Process,
Monitor
Results

Communicating Results
to the Risk Manager

Risk Management

Risk Management Goals

(from Planning Dialogue discussions)

- ❑ Protect human health and the environment
- ❑ Efficient risk assessment process that minimizes refinement and re-work
- ❑ Make reasonable assumptions thus minimizing regulatory impact on users
- ❑ Put any needed mitigation measures in place in a timely manner

Problem Formulation

- ❑ Evaluate the nature of the problem, including the nature of the stressor and use characterization
- ❑ Assess the available information regarding the pesticide, effects, exposure, and ecosystem characteristics
- ❑ Prepare conceptual model and generate preliminary risk hypotheses
- ❑ Develop a plan for analyzing data and characterizing risk
- ❑ Identify data and information gaps

Stressor Source and Distribution

- ❑ Broad spectrum herbicide
- ❑ Control of annual grasses and broadleaf weeds
- ❑ Systemic herbicide taken up by roots and shoots
- ❑ Inhibits formation of photosynthetic pigments
- ❑ Only member of isoxazolidinone family of herbicides currently in use
- ❑ Generally applied pre-plant, pre-emergent or pre-plant incorporated
- ❑ Typically applied by ground equipment, but may also be applied aerially to rice

Agricultural Uses of Clomazone

<u>Crop</u>	<u>lbs. a.i.</u>	<u>Percent Crop Treated</u>	
		Avg.	Max.
Beans, Green	1,000	<1	<2.5
Cabbage	2,000	10	55
Cantaloupes	<500	<1	<2.5
Cotton	90,000	<1	5
Cucumbers	7,000	20	30
Dry Beans/Peas	1,000	<1	<2.5
Peas, Green	8,000	5	15
Peppers	2,000	5	10
Potatoes	2,000	<1	<2.5
Pumpkins	20,000	50	60
Rice	500,000	40	55
Soybeans	300,000	<1	<2.5
Squash	4,000	15	20
Sugarcane	20,000	<1	5
Sweet Potatoes (NPUD '02)	60,000	80	--
Tobacco	90,000	30	30
Watermelons	1,000	<1	5

Integration of Available Information

- ❑ May 31, 2000 assessment of existing and newly proposed uses:
 - 3ME formulation:
 - rice, sugarcane, cotton, pepper, soybeans, sweet potato
 - 4EC formulation:
 - cotton, soybeans, tobacco, fallow land, vegetables, tanager, cassava, yams, sweet potato, arracacha
- ❑ May 3, 2005 Section 24c for aerially applied clomazone to rice in Texas
- ❑ February 2, 2006 amendment for removal of coarse soil restrictions for rice in Texas

What We Know

- Vapor phase transport and microbial degradation appear to be the major routes of dissipation
 - Soil metabolism half-lives range from 28-173 days
 - Moderately high vapor pressure (1.4×10^{-4} mmHg)
 - High water solubility (1100 mg/L)
 - Moderately mobile in soil (K_d 's 1.5-7.4)

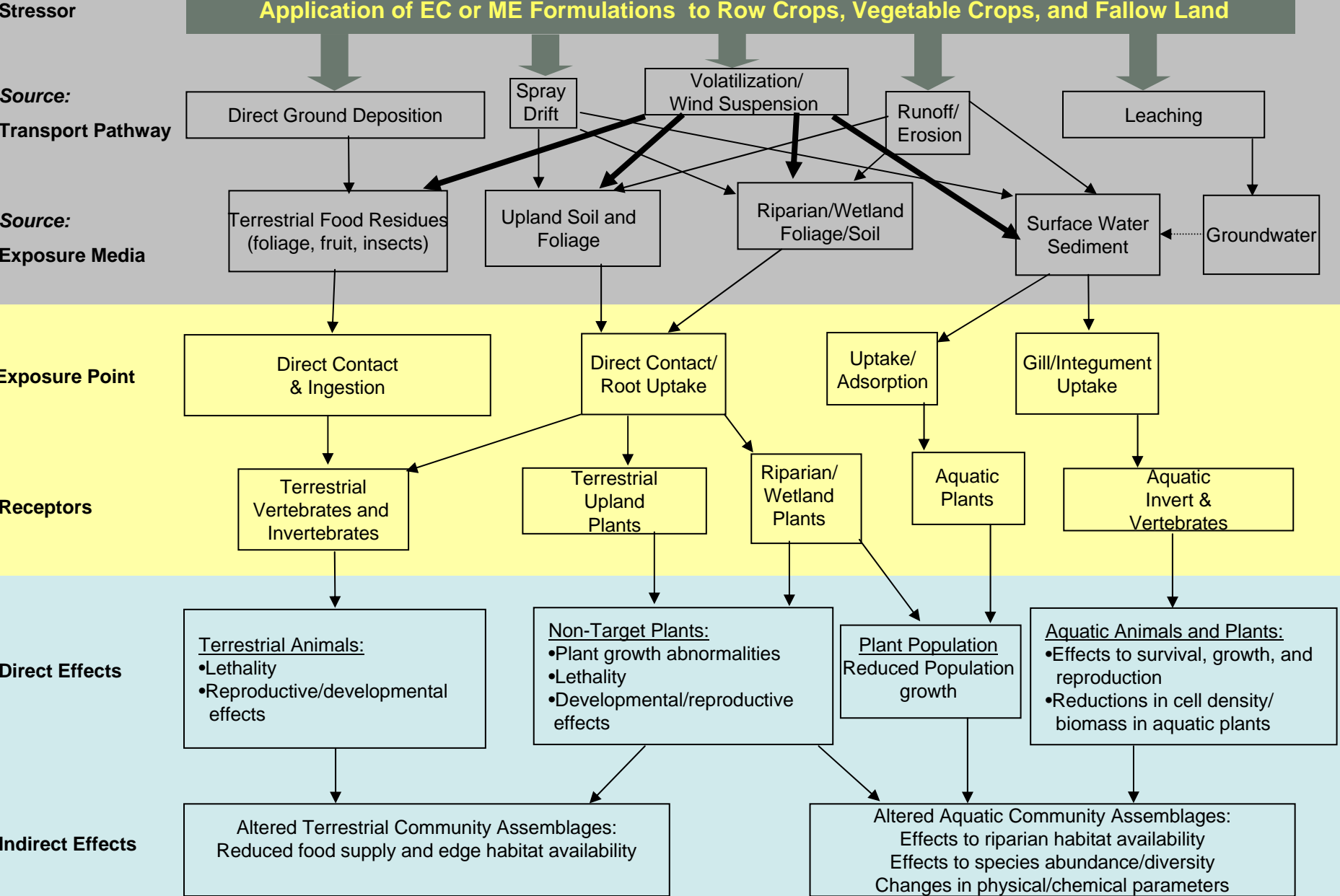
What We Know

- Terrestrial Plant Risk
 - RQ's from risk assessment
 - Incident reports of crop damage
 - Tomatoes, fruit trees, corn, pecans.....
 - Attributed to volatilization
 - Incidents as far as 2 miles away from application
 - Both the older EC formulation and the newer microencapsulated formulation

What We Know

- ❑ Tier I screening level risk assessments show slight LOC exceedences
 - acute risk to:
 - Freshwater invertebrates
 - Estuarine/Marine invertebrates
 - Aquatic non-vascular plants
 - chronic risk to:
 - Small mammals
- ❑ Fairly straightforward refinements should result in no LOC exceedences

Application of EC or ME Formulations to Row Crops, Vegetable Crops, and Fallow Land



Conceptual Model Risk Hypotheses

A major transport pathway for clomazone is volatilization, resulting in exposure to various terrestrial and aquatic receptors. Plants are bleached white and damaged plants can die from exposure. Since volatilization is the major route of dissipation, soil incorporation should be explored as an option for mitigating offsite movement.

Analysis Plan

- In Registration Review, ecological risk assessments will:
 - follow the Agency's Guidelines for Ecological Risk Assessment
 - be in compliance with the document titled "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. EPA, January 2004"
 - address obligations under Section 7 of the Endangered Species Act.

Analysis Plan (continued)

- Further examine and refine acute risk to terrestrial plants, freshwater invertebrates, estuarine/marine invertebrates, and aquatic non-vascular plants.
- Further examine potential chronic risk to small and medium-sized mammals and estuarine/marine invertebrates.

Analysis Plan (continued)

- The Agency wishes to better understand:
 - Environmental and product specific factors that contribute most to off-site movement and phytotoxicity
 - Plant recovery
 - Effectiveness of current buffer restrictions
 - Options for additional mitigation, where required

ESA

- ❑ If potential to impact, either directly or indirectly, listed species or critical habitat, further refinements will be made.
 - Improve exposure estimates based on refining geographic proximity
- ❑ If geographic proximity exists...
 - Potential direct and indirect effects will be examined

Data Gaps and Uncertainties

- ❑ Chronic risk to birds
 - Only have Bobwhite quail avian repro study
- ❑ How important is it to require the study with the Mallard duck?
 - Is there a potential for exposure?
 - Yes, clomazone is fairly persistent and used in a wide variety of crops
 - What did we learn from the Bobwhite study?
 - No effects at the highest dose tested
 - Mallard would have to be over 2x as sensitive to reach LOC
 - What else do we know about reproductive effects?
 - Rat study showed no marked repro effects at high dose
 - For herbicides, Bobwhite is more sensitive 75% of the time

Decision

- ❑ Given what we know, unlikely that we will learn anything new
- ❑ Reasonable to assume no chronic risk to birds
- ❑ Decision is consistent with risk management goals

Data Gaps and Uncertainties

- ❑ Chronic risk to estuarine/marine invertebrates
 - No mysid shrimp life cycle study

- ❑ How important is it to require the mysid study?
 - Is there potential for exposure?
 - Yes, many uses near estuarine/marine environments
 - What did we learn from the other aquatic invertebrate studies?
 - We have freshwater invertebrate acute and chronic studies
 - We have estuarine/marine acute study
 - Appears that estuarine/marine inverts are more sensitive
 - Is there an alternative to requiring a study?
 - Yes, can use acute to chronic ratio to estimate chronic NOAEC for mysid
 - Is this a reasonable approach?
 - Yes, method is commonly used in these kinds of situations

Decision

- ❑ Given what we know about risk to aquatic organisms, unlikely to learn anything new from a study
- ❑ Use acute to chronic ratio to estimate NOAEC and calculate RQ's

Data Gaps and Uncertainties

- How far does clomazone volatilize, is there any difference between the formulations, and are the current buffers appropriate?
 - Incident reports up to two miles for both the EC and ME formulations
 - Current buffers:
 - 1,200 ft. from towns and housing developments, commercial fruit/nut or vegetable production, commercial greenhouses or nurseries
 - 300 ft. from desirable plants
 - Will a Field Volatility study answer the question?
 - Possibly, but would be very expensive and study really isn't designed to measure volatilization far distances from the site of application. Too many variables (temp., wind, rainfall, humidity, etc.) that will confound the results.
 - So how can we get at this question?
 - May be able to use Office of Air volatilization models
 - Can use currently available data as inputs into the model

Decision

- Attempt to use air models
- Investigate incident reports to glean as much information as possible to look for trends and adequacy of current buffers

Clomazone

Preliminary Work Plan

Next Steps

Phase 1: Opening the docket

- Close Public Comment Period

Phase 2: Case Development

- Develop Final Work Plan (FWP)
- Begin Developing Preliminary Risk Assessments
- Open Public Comment Period for Preliminary Risk Assessments
- Close Public Comment Period

Clomazone

Preliminary Work Plan (con't)

Next Steps

Phase 3: Registration Review Decision

- Open Public Comment Period for Proposed Reg. Review Decision
- Close Public Comment Period
- Final Decision and Begin Post-Decision Follow-up

Preliminary Work Plan Timeline

Activities	Estimated Month/Year
Phase 1: Opening the docket	
Open Public Comment Period for Clomazone Docket	Feb. 2007
Close Public Comment Period	May 2007
Phase 2: Case Development	
Develop Final Work Plan (FWP)	June 2007
Begin Developing Preliminary Risk Assessments	June 2007
Open Public Comment Period for Preliminary Risk Assessments	Dec. 2008
Close Public Comment Period	March 2009
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	June 2009
Close Public Comment Period	Sept. 2009
Final Decision and Begin Post-Decision Follow-up	Jan. 2010
Total (years)	3

Question and Answer Session