Clomazone Summary Document: Registration Review

January 2007

Docket Number: EPA-HQ-OPP-2006-0113
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Clomazone Summary Document
Registration Review: Initial Docket
January 2007

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I. Preliminary Work Plan

Introduction:

The Food Quality Protection Act of 1996 amendments to Federal Fungicide Insecticide and Rodenticide Act (FIFRA) mandated a new program: registration review. All pesticides distributed and sold in the United States must be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has begun to implement the new registration review program, and will review each registered pesticide approximately every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state clearly what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. Clomazone is one of the first chemicals going through the registration review process.

Anticipated Risk Assessment and Data Needs:

The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species assessment, for all clomazone uses. The Agency does not anticipate that a human health assessment will be needed for clomazone uses.

Ecological Risk:

- Ecological risk assessments for most clomazone uses were completed several years ago, and the Agency has not conducted a risk assessment that supports a complete endangered species determination.
- Further examination is necessary to refine acute risk to terrestrial plants, freshwater invertebrates (rice only), estuarine/marine invertebrates, and aquatic non-vascular plants. Also, potential chronic risk to small and medium-sized mammals and estuarine/marine invertebrates warrants additional analysis. Finally, analysis of potential indirect effects on listed species is required. Please refer to Section III—Ecological Risk Assessment Problem Formulation for a detailed discussion of the anticipated risk assessment needs.
- The Agency does not anticipate requiring data in order to conduct a complete ecological risk assessment including an endangered species assessment for all uses.
- Additional information provided prior to issuing a final work plan for clomazone will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. Please refer to Section III— Ecological Risk Assessment Problem Formulation for a detailed discussion of "other information needs."

Human Health Risk:

- The Agency believes that previously completed human health assessments are adequate and there is no dietary risk that exceeds the Agency's level of concern. In addition, there are no residential uses of clomazone and all worker margins of exposure (MOEs) are below the Agency's level of concern. Thus, no additional data are needed.
- Please refer to Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of previous human health assessments.

Timeline:

EPA has created the following estimated timeline for the completion of the clomazone Registration Review.

Activities	**Estimated Month/Year**
Phase 1: Opening the docket	
Open Public Comment Period for Clomazone Docket	Jan. 2007
Close Public Comment Period	April 2007
Phase 2: Case Development	
Develop Final Work Plan (FWP)	June 2007
Open Public Comment Period for Preliminary Risk Assessments	Dec. 2009
Close Public Comment Period	May 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

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the clomazone case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Stakeholders are also specifically asked to provide information and data in the following areas.

1. Were there any ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) or field studies not already reported to the Agency to support/confirm the estimated risk? If so, briefly describe them.
2. Are there any drinking water contamination, spray drift, or volatilization incidents not already reported to the Agency? Please provide specific details.
3. Are there any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets? If so, to what extent does this impact the export of crops treated with clomazone?
4. What is the frequency of application, application intervals, and maximum number of applications per season for use sites for which you have experience or knowledge?
5. What is the application timing, such as season and time of day for use sites?
6. Do you know of any emerging equipment or cultural practices that could reduce exposure to clomazone in the environment?
7. Neither clomazone nor FMC 65317, a degradate of clomazone, are identified as causes of impairment for any waterbodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of water quality data for these chemicals. To the extent possible, data should conform to the quality standards in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Water Quality & Impaired Water Body Data in OPP's Registration Review Risk Assessment & Management Process," included in the clomazone docket, in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Growers and other stakeholders with more detailed clomazone use information are asked to provide information addressing the "other information needs" in Section III— Ecological Risk Assessment Problem Formulation, page 23.

Next Steps:

After the comment period closes in April 2007, the Agency will prepare a Final Work Plan for this pesticide.

II. FACT SHEET

Background Information:

- Clomazone registration review case number: 7203
- Clomazone PC Code: 125401 CAS#: 77501-63-4
- Technical registrant: FMC Agricultural Corporation
- First approved for use in a registered product on February 27, 1986
- Clomazone degradate: FMC 65317
- Not subject to reregistration (no Reregistration Eligibility Decision (RED))
- Tolerances were reassessed under FQPA in the September 14, 2000 risk assessment for proposed uses on sugar cane, rice and cucurbit vegetables.
- Special Review and Reregistration (SRRD), Chemical Review Manager (CRM), Casey Jarvis: jarvis.casey@epa.gov
- Registration Division (RD), Product Manager (PM), Jim Tompkins: tompkins.jim@epa.gov

Use & Usage Information: (For additional details, please refer to the BEAD Appendix A document in the clomazone docket.)

- Clomazone is an herbicide used for major crops such as cotton, tobacco, soybeans, rice, sugarcane, a variety of vegetable crops, and fallow land.
- There are no residential uses.
- There are no pending new use registrations as of January, 2007.
- Approximately 1,110,000 pounds active ingredient (lbs a.i.) of clomazone are used annually.
- Clomazone accounts for less than 2% of the crop treated for green beans, cantaloupes, cotton, peas, potatoes, soybeans, sugarcane, and watermelons.
- Clomazone accounts for more than 50% of the crop treated for rice, cabbage, and pumpkins.
- Pests controlled are annual grasses and broadleaf weeds.
- There are eleven Section 3 registrations, and twelve Section 24(c) registrations (Special Local Needs).

Recent Actions:

- In February 2006, the Agency conducted an environmental fate and ecological risk assessment in response to a request from the registrants to remove coarse soil restrictions for use on rice in Texas.
- In May 2002, the Agency conducted a human health risk assessment in response to an IR-4 petition for the establishment of permanent tolerances for residues on peppermint and spearmint.
- On August 1, 2001 (67 FR 350489) tolerances that existed prior to August 1996 were reassessed under the FQPA as part of the consideration for establishing a tolerance on sugar cane.

Ecological Risk Assessment Status:

The following ecological outcomes are anticipated based on the limited data and risk assessments currently available. Please refer to Section III, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated ecological risk assessment needs. A summary follows:

- Acute risk to non-listed birds is unlikely to exceed the Agency's level of concern (LOC).
- Chronic risk to non-listed birds is unlikely to exceed the Agency's level of concern (LOC).
- Acute risk to non-listed mammals is unlikely to exceed the Agency's level of concern (LOC).
- Chronic risk to non-listed mammals may exceed the Agency's level of concern (LOC).
- Acute and chronic risk to non-listed fish is unlikely to exceed the Agency's level of concern (LOC).
- Acute risk to non-listed freshwater and estuarine/marine invertebrates may exceed the Agency's level of concern (LOC).
- Chronic risk to non-listed estuarine/marine invertebrates is uncertain, additional analysis is necessary.
- Acute risk to non-listed terrestrial and aquatic non-vascular plants is likely to exceed the Agency's LOC due to the compound's mode of action.

Human Health Risk Assessment Status:

Please refer to Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. A summary follows:

Dietary (Food and Water):

- The most recent risk assessment (May 13, 2002) was in response to an IR-4 petition for the establishment of permanent tolerances for residues on peppermint and spearmint. The aggregate assessment included exposure to clomazone from both food and water. This Tier 1 assessment used tolerance level residues and 100% crop treated for all commodities.
- The acute dietary exposure estimates (females 13-50 years old) represented <1% of the aPAD (acute Population Adjusted Dose).
- The chronic dietary exposure estimates for the most highly exposed population subgroup (infants less than 1 year old) represented <1% of the cPAD (chronic Population Adjusted Dose).
- The May 13, 2002 risk assessment included both parent clomazone and FMC 65317 which is a degradate of clomazone. The agency concluded that residues of clomazone in drinking water do not contribute significantly to the acute and chronic aggregate human health risk. The acute surface water estimated environmental concentration (EEC) (95 ppb) is below the acute drinking water level of comparison (DWLOC) (30,000 ppb). The chronic surface water EEC (23 ppb) is below the chronic DWLOC (8,400 ppb).
- There are no dietary risks that exceed the Agency's LOC.

Residential:

- There are no residential uses of clomazone.

Occupational:

- The most recent occupational risk assessment was completed May 13, 2002 for a proposed new use on mint.
- Combined (dermal + inhalation) margins of exposure (MOEs) are above 100 for mixers and loaders with gloves (MOE = 2400) and for applicators at baseline attire (MOE = 4000).
- An occupational risk assessment was completed January 24, 2001 for a proposed use on sugarcane. This assessment measured exposure from the sugarcane use pattern that is comparable to the maximum application rate for all use sites (application rate was 1.25 lb a.i./acre and 200 acres treated per day for ground application).
- Combined (dermal + inhalation) MOEs are above 100 for mixers and loaders with gloves (MOE = 400) and for applicators at baseline attire (MOE = 1600).
- The restricted entry interval (REI) is 12 hours for clomazone.
- Although other established uses do not have current occupational risk assessments, the Agency expects occupational exposure estimates to be similar to those uses which have been assessed.
- Based on high MOEs and conservative assumptions, including high application rates and large acres treated per day, it is unlikely that any existing use of clomazone could pose an occupational risk.
- There are no occupational risks that exceed the Agency's LOC.

Tolerances:

- Please refer to the tolerance table, "Clomazone: A Comparision of U.S. tolerances and Canada, Mexico, and Codex Maximum Residue Levels (MRLs)," included in the clomazone docket.

Data Call-In Status:

- There has not been a data call in issued for clomazone.

Labels:

- A list of registration numbers may be found in the clomazone docket and the labels can then be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home.

III. Ecological Risk Assessment Problem Formulation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

PC Code: 125401
DP Barcode: D331933

MEMORANDUM

Subject: Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Clomazone

To: Dirk Helder, Team Leader
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Through: Thomas A. Bailey, Ph.D., Chief
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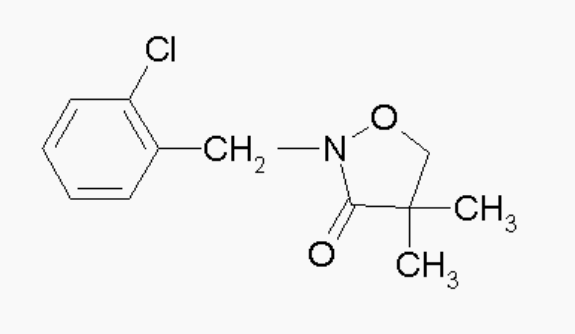
Attached is the preliminary problem formulation for the ecological risk assessment to be conducted as part of the Registration review of the herbicide clomazone.

REGISTRATION REVIEW

ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION FOR:

CLOMAZONE

2-(2-CHLOROPHENYL)METHYL-4,4-DIMETHYL-3-ISOXAZOLIDINONE



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STRESSOR SOURCE AND DISTRIBUTION

Clomazone is a broad spectrum herbicide used for control of annual grasses and broadleaf weeds in a wide variety of crops and locations. It is a systemic herbicide that is taken up by plant roots and shoots and moves into the xylem, inhibiting the formation of photosynthetic pigments. This results in bleaching or whitening of plants. Clomazone toxicity is believed to be caused by a plant metabolite, 5-ketoclomazone, and is dependant upon a plant's ability to oxidize the parent compound to this active metabolite. Clomazone is the only member of the isoxazolidinone family of herbicides currently in use. It is generally applied early pre-plant, pre-emergent or pre-plant incorporated, but may also be applied late season post-emergence on cotton and rice. Clomazone is typically applied by ground equipment (broadcast or banded), but may also be applied aerially to rice.

INTEGRATION OF AVAILABLE INFORMATION

The risk assessments available in the docket, and which serve as the basis for this problem formulation, include the following:

- 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, tanier, cassava, yams, sweet potato, and arracacha

- May 3, 2005 Section 24c for aerially-applied clomazone to rice in TX

- February 2, 2006 amendment for removal of coarse soil restrictions for rice in TX

ECOLOGICAL EFFECTS

TOXICITY STUDIES

The available acute toxicity data on the active ingredient indicate that clomazone is practically non-toxic to birds (LD_{50} >2510 mg/kg; LC_{50} >5620 ppm), practically non-toxic to small mammals (LD_{50} = 1369 mg/kg, female rat), slightly toxic to freshwater fish (LC_{50} = 19-34 ppm), moderately toxic to freshwater invertebrates (LC_{50} = 5.2 ppm), slightly toxic to estuarine/marine fish (LC_{50} =40.6 ppm), and highly to moderately toxic to estuarine/marine invertebrates (LC_{50} or EC_{50} = 0.567-5.3 ppm).

Chronic toxicity studies established the following NOAEC values: 1020 ppm (diet) for birds, 50 mg/kg/day for small mammals, 2.29 ppm for freshwater fish, and 2.2 ppm for freshwater invertebrates. The seedling emergence studies established the most sensitive plant EC_{25} to be 0.002 lbs. a.i./A.

INCIDENT REPORTS

The Agency has no incident reports in the Ecological Incident Information System (EIIS) for adverse effects to fish or wildlife that were attributed to clomazone use.

The Agency's EIIS contains 110 incident reports of damage to non-target plants attributed to the use of clomazone on various agricultural crops. All of these reported incidents occurred between 1985 and 1998. Pesticide registrants have reported 61 additional minor plant damage incidents linked to clomazone use that were not in the EIIS database. Most of the incidents report symptoms of whitening or discoloration of leaves on various crops, trees, and ornamental plants. Clomazone injures plants by inhibiting chlorophyll production, resulting in green tissue turning white or yellow following exposure. Most of the incidents were attributed to offsite movement of clomazone from treated fields via spray drift or movement of vapors. The majority of incidents, some of which have occurred at a distance of up to two miles from the treated fields, were attributed to volatility of the chemical that was broadcast onto the surface of the soil without incorporation, as allowed on the product labels. In addition, a few incidents apparently resulted from contaminated, wind-blown soil particles, runoff, and drift.

EXPOSURE CHARACTERISTICS

Vapor phase transport and microbial degradation appear to be the major routes of dissipation in the environment. Clomazone is stable to hydrolysis in acidic, neutral, and alkaline solutions and does not photodegrade in either water or on soil. In soil, clomazone is metabolized under aerobic conditions with half-lives ranging from 28-173 days, depending on soil type. Carbon dioxide is the major degradate. Under anaerobic conditions, clomazone readily degrades ($t_{1/2}$: 13 days) to (N-[(2-chlorophenol)methyl]-3-hydroxy-2,2-dimethyl propanamide), which persists under anaerobic conditions.

Clomazone has a moderately high vapor pressure of 1.44×10^{-4} mmHg and a high water solubility of 1100 mg/L. Considering its Henry's Law Constant of 4.14×10^{-8} atm-m^3/mol, clomazone is expected to remain in the water column as opposed to volatilizing. However, in the terrestrial environment, clomazone may volatilize from soil. Clomazone is moderately mobile with K_d's ranging from 1.5 to 7.4 (lower in sandy soils) and K_{oc}'s from 139 to 608.

In the field, Command 3 ME applied to bare soil at a rate of 1.25 lbs. a.i./A dissipated with a half-life of 139 days in an Iowa silty clay loam and 17 days in a Louisiana silt loam. In both studies, parent clomazone was not detected below 6 inches. Degradates were analyzed for but were not detected (detection limit: 0.01 ppm). It is not clear what factor most contributed to the difference in dissipation rates at these sites, but one possibility might be that the conditions at the Louisiana site favored volatilization. Also a possibility is different soil metabolism rates in the two soils, as exemplified in the aerobic soil metabolism study.

Based on laboratory and field data, clomazone is not likely to contaminate ground water, however surface water contamination through runoff, spray drift, and vapor phase transport is possible. In surface water, clomazone will exist in the dissolved phase and bound to suspended particulates and sediment, and may persist with half-lives ranging from 1.5-2.5 months. The degradate N-[(2-chlorophenol) methyl]-3-hydroxy-2,2-dimethyl propanamide may be found in surface water and will persist, especially under anaerobic conditions.

Twenty-one incidents of clomazone contamination of surface and drinking water have been reported to the Agency. No incidents of ground water contamination have been reported.

CHARACTERISTICS OF ECOSYSTEMS POTENTIALLY AT RISK

For clomazone and pesticides in general, the ecosystems at greatest risk are those in close proximity to the use areas. These would include agricultural fields (surrounding non-agricultural terrestrial habitats) and water bodies directly adjacent to treated fields that may receive chemical residues via drift, volatilization, and/or runoff. Within water bodies, the water column, sediments, and pore water are all compartments of concern. **Table 1** below summarizes the agricultural use sites that clomazone is reported to be used on, the annual percent of crop treated (average and maximum) for each crop, and average annual pounds of clomazone applied for each crop. Based on these estimates, the sites where the majority of clomazone is used include rice, soybeans, cotton, tobacco, and sweet potatoes. These crops cover a large portion of the U.S. and a wide diversity of terrestrial and aquatic environments, as shown in the USDA crop maps (**Figures 1-6**) below. A single application is made at rates ranging from 0.25 – 1.75 lbs. a.i./acre, depending on the use site.

Organisms of concern include birds, mammals, reptiles, fish, and terrestrial and aquatic invertebrates, plants, and amphibians. The assessment endpoints are intended to reflect population sustainability and community structure within ecosystems and hence relate back to ecosystems at risk. If risks are expected for given species/taxa based on the screening-level assessment, then risks might be expected to translate to higher levels of biological organization.

TABLE 1

SCREENING LEVEL ESTIMATES OF AGRICULTURAL USES OF CLOMAZONE
SORTED ALPHABETICALLY
(04-19-06)

Crop	lbs. a.i.	Percent Crop Treated	
		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

All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.
'<1' indicates less than 1 percent of crop is treated.

Sources:

United States Department of Agriculture's National Agriculture Statistics Service – pesticide usage data from 1999-2004

Private Pesticide Market Research

National Center for Food and Agricultural Policy (1997) and National Pesticide Use Database (2002) are used only if data are not available from the other sources.

FIGURE 1. MAJOR SOYBEAN GROWING AREAS IN THE U.S.

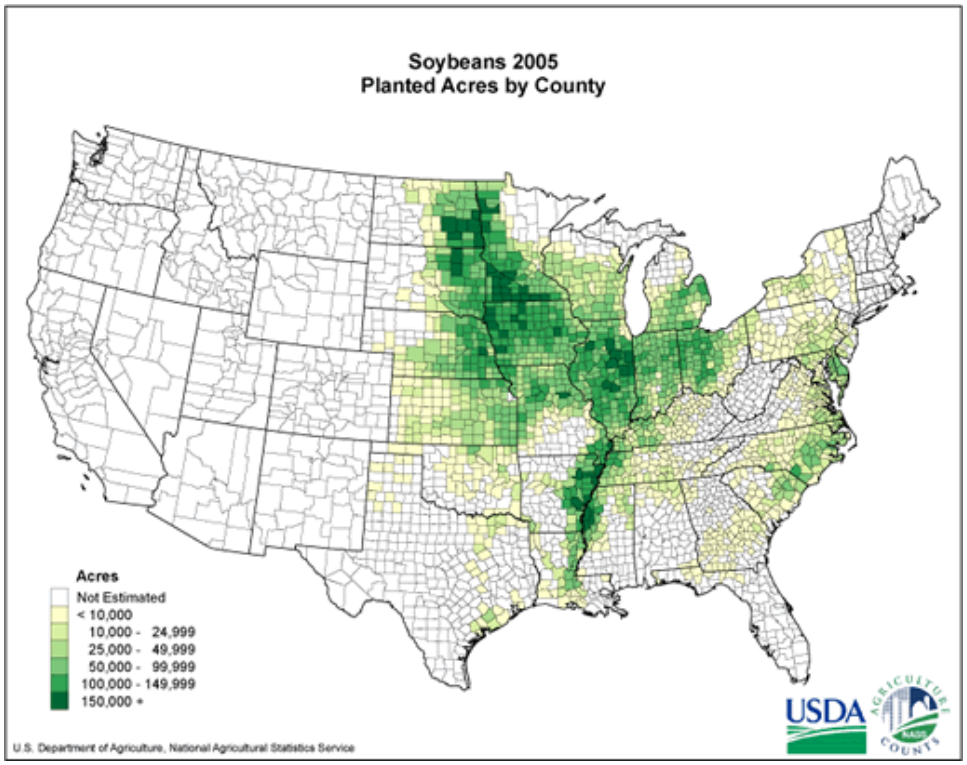


FIGURE 2. MAJOR RICE GROWING AREAS IN THE U.S.

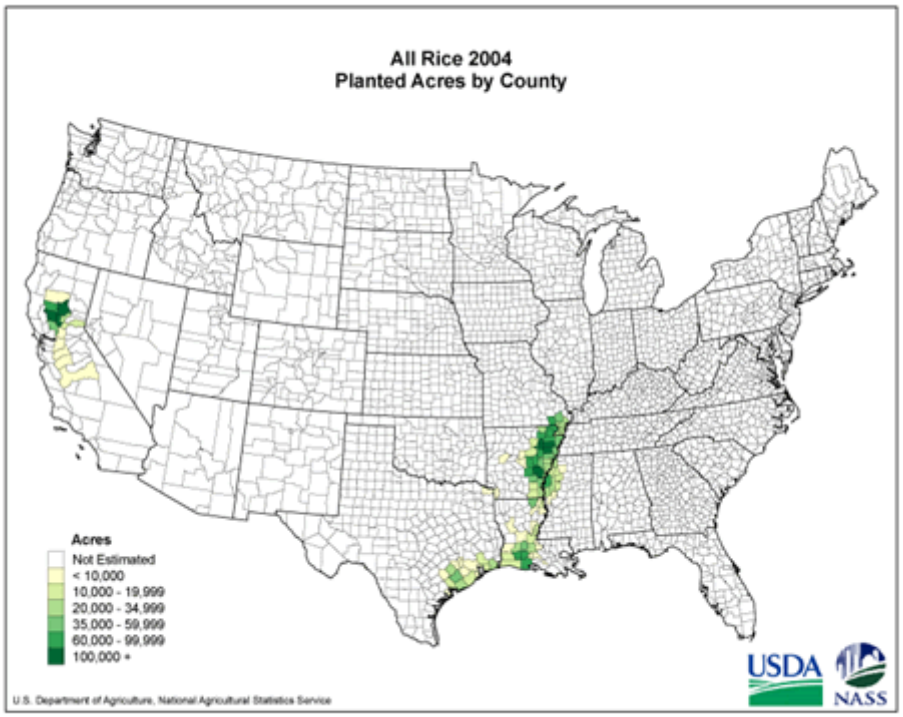


FIGURE 3. MAJOR COTTON GROWING AREAS IN THE U.S.

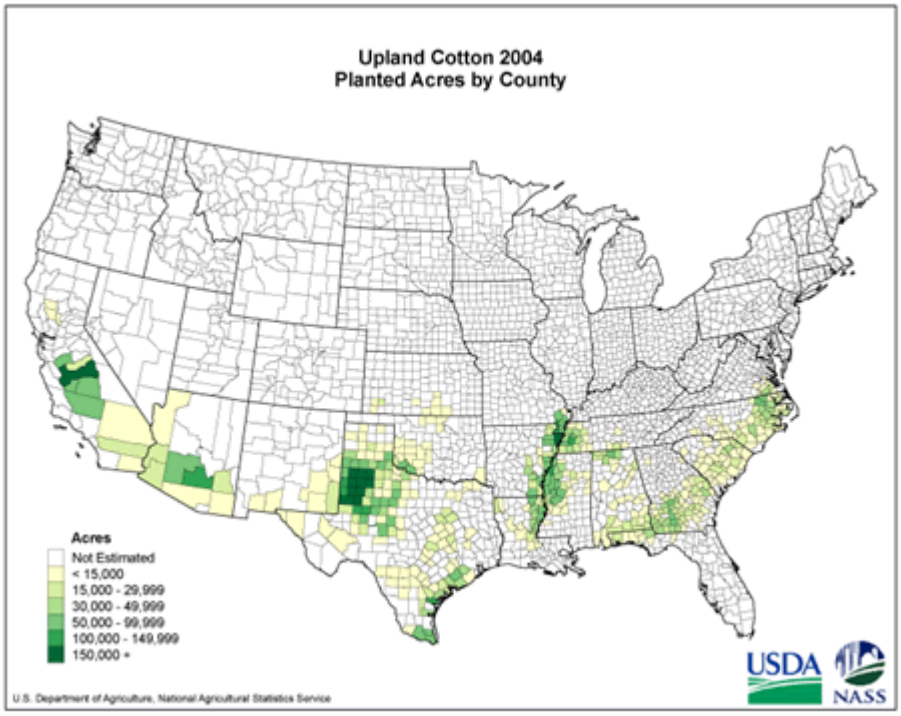


FIGURE 4. MAJOR SWEET POTATO GROWING AREAS IN THE U.S.

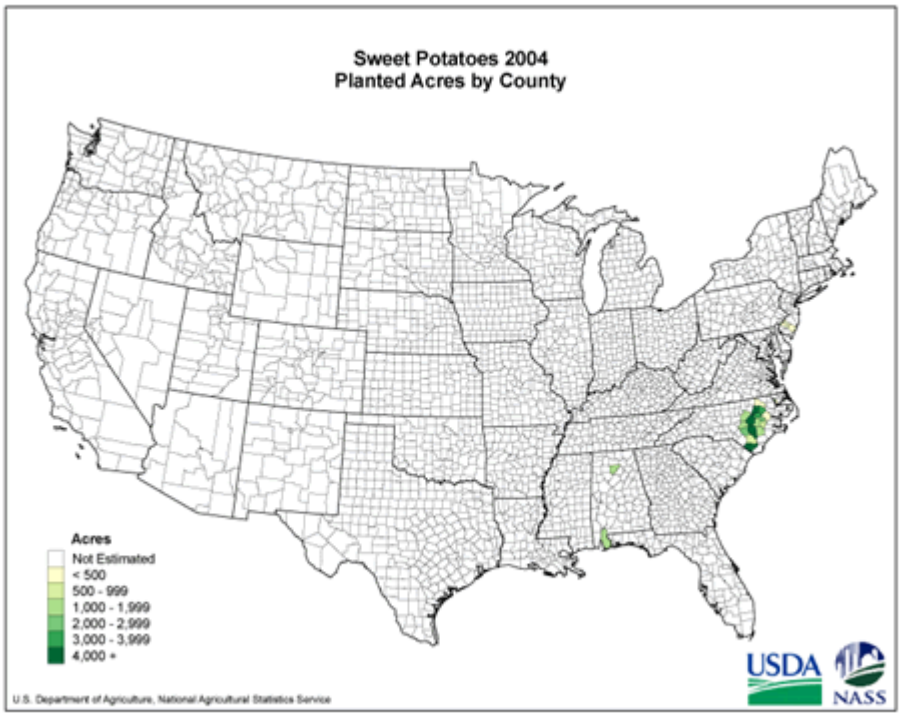


FIGURE 5. MAJOR TOBACCO (FLUE-CURED) GROWING AREAS IN THE U.S.

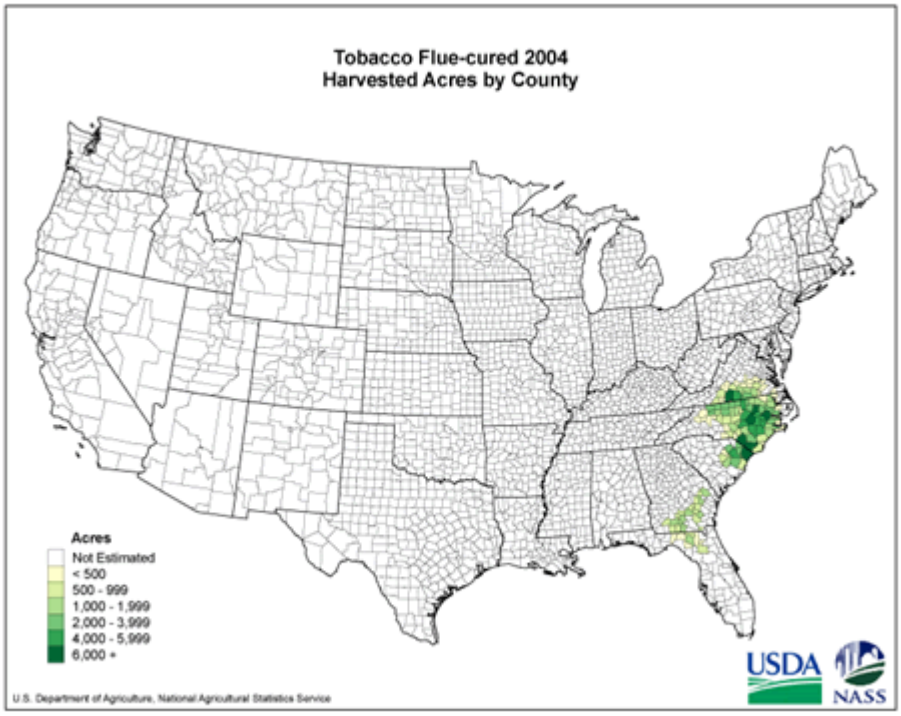
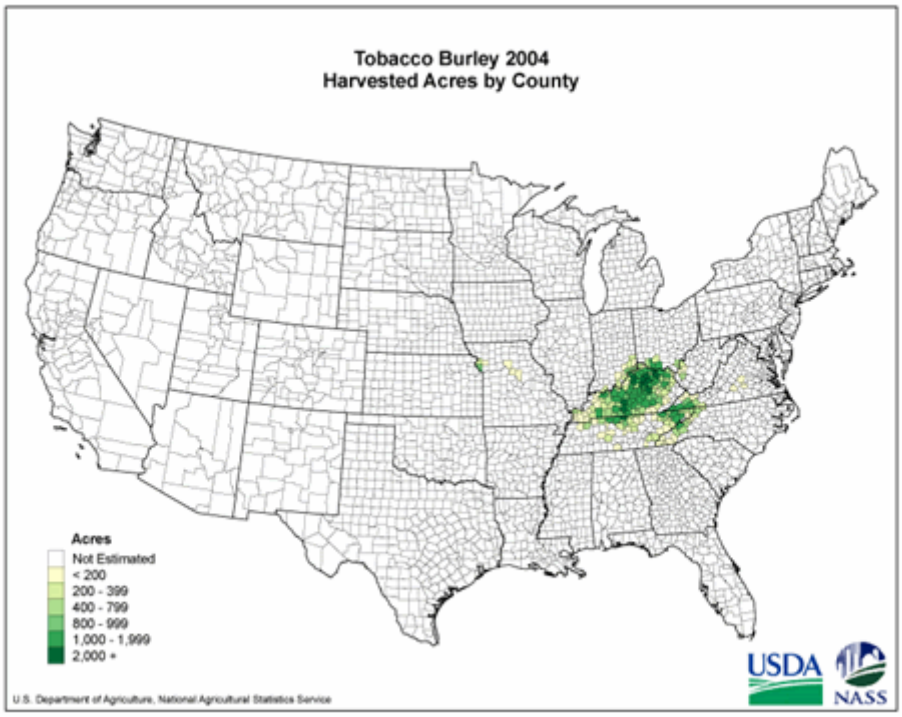


FIGURE 6. MAJOR TOBACCO (BURLEY) GROWING AREAS IN THE U.S.



ASSESSMENT ENDPOINTS

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to a pesticide, such as clomazone.

To estimate exposure concentrations, the ecological risk assessment considers a single application at the maximum application rate to fields that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

In terms of direct effects to terrestrial plants, both dicots and monocots are sensitive to clomazone. Tests performed using the 3ME formulation indicated that lettuce was the most sensitive dicot to clomazone, with shoot length as the most sensitive endpoint (NOEC = 0.0051 lbs. a.i./A, EC_{25} = 0.032 lbs. a.i./A). Oat was the most sensitive monocot, with an EC_{25} of 0.076 lbs. a.i./A and an EC_{05} of 0.0154 lbs. a.i./A. Observed phytotoxic effects on plants include stunting, bleaching, and plant death. Reductions in percent seedling emergence were also observed with increasing concentrations of clomazone.

Because of the potential risk to listed and non-listed plants, unicellular algae, aquatic invertebrates, and small and medium herbivorous mammals (short grass consumers only), should exposure occur, listed species in all taxa may potentially be affected indirectly due to alterations in their habitat (e.g., food sources, shelter, and areas to reproduce).

CONCEPTUAL MODEL

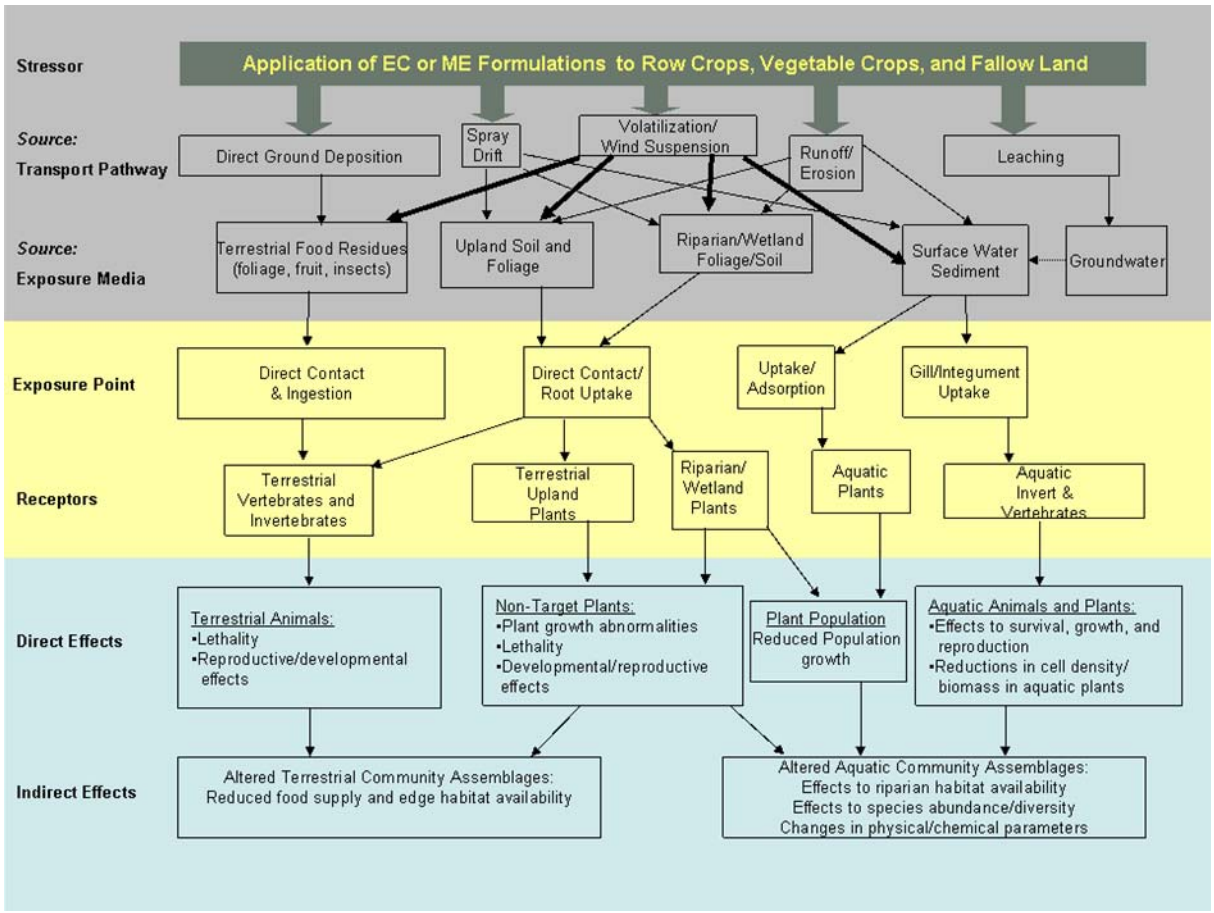
In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological exposure pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

The conceptual model (**Figure 7**) depicts the potential pathways for ecological risk associated with clomazone use. The conceptual model provides an overview of the expected exposure routes for organisms within the clomazone action area. For terrestrial organisms, the major route of exposure considered is the dietary route; consumption of food items such as plant leaves or insects that have clomazone residues as a result of spraying, drift, and volatilization. For aquatic animal species, the major routes of exposure are considered to be via the respiratory surface (gills) or the integument. Direct contact and/or root uptake is the major route of exposure for terrestrial and wetland (riparian) plants, while aquatic plants may be exposed via direct uptake and adsorption. Estimated exposure concentrations for all organisms are obtained through the use of several Agency exposure models.

RISK HYPOTHESIS

Based on an examination of the physical/chemical properties of clomazone, the fate and disposition in the environment, and mode of application, a conceptual model was developed that represents the possible relationships between the stressor, ecological receptors, and the assessment endpoints. A major transport pathway for clomazone is volatilization, resulting in exposure to various terrestrial and aquatic receptors. Ecological incident reports since the registration of clomazone have documented effects to non-target crops and ornamental plants up to two miles away from the site of application. These incidents have been reported for both the emulsifiable concentrate and microencapsulated formulations. Plants are bleached white and damaged plants can die from exposure to clomazone. Since volatilization is the major route of dissipation, soil incorporation should be explored as an option for mitigating offsite movement.

FIGURE 7. ECOLOGICAL CONCEPTUAL DIAGRAM FOR CLOMAZONE



ANALYSIS PLAN OPTIONS

In registration review, pesticide ecological risk assessments will follow the Agency's Guidelines for Ecological Risk Assessment, will be in compliance with the paper titled "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency" ("Overview Document") (January 2004), and will be done in accordance with Section 7 of the Endangered Species Act.

Previously completed screening level risk assessments and exceedences of Agency levels of concern indicate a need to further examine and refine acute risk to terrestrial plants, freshwater invertebrates (rice only), estuarine/marine invertebrates, and aquatic non-vascular plants. Also, potential chronic risk to small and medium-sized mammals and estuarine/marine invertebrates warrants additional analysis. Finally, analysis of potential indirect effects on listed species is required.

The Agency wishes to better understand 1) which environmental and product specific factors contribute most to the off-site movement and phytotoxicity of clomazone, 2) plant recovery, 3) the effectiveness of current buffer restrictions, and 4) options for additional mitigation, where required. Recent incident surveys would be extremely helpful in understanding the current situation with regards to potential risk to non-target species.

Table 2 shows the current status of risk assessments for registered uses of clomazone. In addition to refining the terrestrial plant risk assessment, other uncertainties and potential paths forward are described below.

- The assessment of chronic risk to birds is based upon a single avian reproduction study with the Bobwhite quail. Normally, these studies are conducted with two species, an upland game bird (Bobwhite quail) and a waterfowl (Mallard duck). However, a closer inspection of the available data indicates that with, albeit some uncertainty, reproductive effects in birds are unlikely and, therefore, a study with the Mallard is not expected to provide any information to the contrary. An examination of the quail reproduction study showed that at the highest dose tested, 1020 ppm (diet), there were no observed effects. Assuming the highest application rate of 1.75 lbs. a.i./acre, the Mallard duck would have to be over twice as sensitive to clomazone as the Bobwhite quail in order to potentially result in an LOC exceedence. Considering avian chronic effects due to herbicides in general, our database shows that the Bobwhite quail is the more sensitive species, compared to the Mallard duck, 75 percent of the time. Also important to consider are the results of the 2-generation rat reproduction study, where the affected endpoint (NOAEL = 1000 ppm) was parental body weight gain, body weight during gestation, and food consumption. Given this information and the fact that no marked reproductive effects were seen in either the quail or the rat, the Agency believes it is unlikely that clomazone presents a chronic risk to birds and that a new avian reproduction study with the Mallard duck would not be of particular value.

- A screening level assessment of chronic risk to mammals has not been completed for all uses. However, no additional data are needed at this time.

- The tier I screening level assessment showed acute risk quotients for some clomazone uses to be slightly above levels of concern for freshwater and estuarine/marine invertebrates, and aquatic non-vascular plants. Since these assessments were conducted using tier 1 exposure models, the Agency will refine the risk assessment by first estimating EECs using tier II models. It is expected that refinement will result in no LOC exceedences.

- An assessment of chronic risk to estuarine/marine invertebrates has yet to be completed because of a lack of data. However, based on the acute and chronic data for freshwater invertebrates, and the acute data for estuarine/marine invertebrates, an acute to chronic ratio can be calculated and applied in order to estimate the NOAEC value for estuarine/marine invertebrates. Doing so results in a mysid shrimp NOAEC of 0.24 ppm. There is some uncertainty surrounding this estimated value, however the acute to chronic ratio method is commonly used in these types of circumstances and is a reasonable approach using the best available data. For clomazone, a NOAEC of 0.24 ppm for estuarine/marine invertebrates will be used in the risk assessment. The Agency does not believe a new study would change the overall risk conclusions.

With regard to buffer zones to protect non-target plants and listed species from direct and indirect effects, the Agency will be exploring the possibility of using EPA's Office of Air volatilization models to predict offsite movement of clomazone. Data already collected in laboratory and field volatility studies on clomazone will be used as inputs to the model. Should this approach prove to be workable, the results of this modeling exercise may be used to evaluate the buffer distances currently on product labels. In addition to the air modeling, the Agency will also be examining the available incident data and will assess whether the buffer zones currently on the label are appropriate given the distances clomazone traveled described in the incident reports. There are cases reporting plant damage caused by clomazone applied up to 2 miles away. The 1,200 feet and 300 feet setbacks required in certain cases on some clomazone labels should be reexamined in light of the incident reports.

If the planned ecological risk assessment continues to indicate that clomazone may potentially impact, either directly or indirectly, listed species or critical habitat, and therefore does not support a "not likely to adversely affect" determination, further refinements will be made. This will involve determining whether use of clomazone "may affect" a particular listed species, and if so, whether it is "likely to adversely affect" the species, or in the case of critical habitat, whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat, and if so, whether the expected impacts are "likely to adversely affect" the critical habitat. The first step in the process is to improve the exposure estimates based on refining the geographic proximity of clomazone's use and the listed species and/or critical habitat. If there is no geographic proximity, this information would support a determination that clomazone use will have no effect on the species or critical habitat. If after conducting the first step of this analysis the Agency determines that geographic proximity exists, both potential

direct effects and any potential indirect effects of the pesticide use will be examined. This process is consistent with the Agency's Overview Document. The Agency will consult as necessary with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (Services), consistent with the Services' regulations.

If the screening level risk assessment identifies potential concerns for indirect effects on listed species for those organisms dependent upon terrestrial plants, the next step for EPA and the Services would be to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether clomazone's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by clomazone. Then EPA would determine whether the use of clomazone overlaps the critical habitat or the occupied range of those listed species.

Anticipated Data Needs

The Agency does not foresee requiring any additional ecological effects or environmental fate studies listed in 40 CFR Part 158 prior to conducting the planned assessments. The Agency will however conduct a search of the open literature to ensure that all best available science is utilized. The Agency uses the ECOTOX database as its mechanism for searching the open literature for ecological effects information. ECOTOX integrates three previously independent databases - AQUIRE, PHYTOTOX, and TERRETOX - into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife, respectively.

Other Information Needs

There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is very much interested in obtaining the following information:

1. confirmation on the following label information
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates
    e. frequency of application, application intervals, and maximum number of applications per season
    f. geographic limitations on use
2. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
3. use history

4. median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county
5. application timing (date of first application and application intervals) by crop – national, state, and county
6. sub-county crop location data
7. usage/use information for non-agricultural uses (e.g., forestry, residential, rights-of-way)
8. directly acquired county-level usage data (not derived from state level data)
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
9. typical interval (days)
10. state or local use restrictions
11. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
12. monitoring data

The analysis plan will be revisited and may be revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration review docket.

TABLE 2
CURRENT STATUS OF ECOLOGICAL RISK ASSESSMENT FOR REGISTERED USES OF CLOMAZONE
(CROP AND USE INFORMATION PROVIDED BY BEAD)

Crop	Form	Application rate (lbs. a.i./A)	Included in Previous EFED Screening Risk Assessment?	LOC's Exceeded in Tier I Screening Risk Assessment (?: not determined) RQ is in parenthesis
cotton	ME EC	1.25 1.75	Yes No	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (321) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.08), ?chronic Aquatic Plants: none
tobacco	ME EC	1 1	Yes Yes	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (255) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.06), ?chronic Aquatic Plants: none
fallow land	EC	1	Yes	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (321) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.08), ?chronic Aquatic Plants: none
arracacia	ME	1.3	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (382) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.09), ?chronic Aquatic Plants: none
beans, succulent	ME	0.25	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (66) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
cabbage	ME	0.49	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (127) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none

Crop	Form	Application rate (lbs. a.i./A)	Included in Previous EFED Screening Risk Assessment?	LOC's Exceeded in Tier I Screening Risk Assessment (?: not determined) RQ is in parenthesis
				E-M Invertebrates: ?chronic Aquatic Plants: none
cucumber	EC ME	0.375 0.375	Yes – EC @ 0.1875 lbs. a.i./A	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (46) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
cassava	ME	1.275	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (382) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.09), ?chronic Aquatic Plants: none
melons, musk	ME	0.25	No	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (66 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
melons, water	EC	0.375	No	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (95 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
peas, succulent	ME EC WP	0.4875 0.5 0.5	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (127) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
pepper	ME EC	1 1	Yes	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (255) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.06), ?chronic Aquatic Plants: none

Crop	Form	Application rate (lbs. a.i./A)	Included in Previous EFED Screening Risk Assessment?	LOC's Exceeded in Tier I Screening Risk Assessment (?: not determined) RQ is in parenthesis
pimento	EC	1	No	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (255 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.06), ?chronic Aquatic Plants: none
pumpkin	ME EC WP	0.75 1 1	No	Birds: ?chronic Mammals; ?chronic Terrestrial Plants: acute (255 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.06), ?chronic Aquatic Plants: none
rice	ME	0.6	Yes	Birds: ?chronic Mammals: chronic (1.24) Terrestrial Plants: acute (153) Freshwater Fish: none Freshwater Invertebrates: acute (0.09) Estuarine/Marine Fish: none E-M Invertebrates: acute (0.82), ?chronic Aquatic Plants: acute (2.9, non-vascular)
soybeans	EC ME	1.25 1.25	Yes	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (321) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.06), ?chronic Aquatic Plants: none
squash, summer	ME	0.50	Yes – EC @ 0.1875 lbs. a.i./A	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (127 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none

Crop	Form	Application rate (lbs. a.i./A)	Included in Previous EFED Screening Risk Assessment?	LOC's Exceeded in Tier I Screening Risk Assessment (?: not determined) RQ is in parenthesis
squash, winter	ME	0.75	Yes – EC @ 0.1875 lbs. a.i./A	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (191 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: ?chronic Aquatic Plants: none
sweet potato	ME	1.5	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (382) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.09), ?chronic Aquatic Plants: none
Yam	ME	1.275	Yes – EC	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (382) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.09), ?chronic Aquatic Plants: none
Yautia	ME	1.275	No	Birds: ?chronic Mammals: ?chronic Terrestrial Plants: acute (382 est.) Freshwater Fish: none Freshwater Invertebrates: none Estuarine/Marine Fish: none E-M Invertebrates: acute (0.09), ?chronic Aquatic Plants: none

IV. Human Health Effects Scoping Document

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

January 5, 2007

SUBJECT: Clomazone (PC 125401) – Human Health Risk Assessment Status Update in Support of Registration Review Case 7203.

FROM: Ray Kent, Chief
Reregistration Branch 4
Health Effects Division (7509P)
Office of Pesticide Programs

TO: Casey Jarvis, Chemical Review Manager
Reregistration Branch 2
Special Review and Reregistration Division (7508P)
Office of Pesticide Programs

Attached is a health effects risk assessment update for the herbicide clomazone, which has entered into the registration review process. HED has considered recent clomazone risk assessments, updates to toxicity, exposure and usage databases, open literature data, poisoning incident data, and changes in science policy in its review. HED has determined that recent risk assessments meet current standards for science, that toxicity or exposure databases for clomazone are complete and that there are no material changes in science policy that would warrant the submission of new data or a revision of risk assessments.

Registration Review – Clomazone (PC 125401)
Human Health Risk Assessment Status

HED's Clomazone Registration review team has updated the risk assessment status of clomazone. The team looked at the current use profile, and the toxicity and exposure databases for clomazone and determined whether there were deficiencies in the databases or changes in science policy that would affect the overall risk picture. The team consisted of Sue Hummel and Ray Kent, with assistance from other RRB4 members.

Information Sources. The primary sources for the status update were the two most recent risk assessments (February, 2001 and May, 2002), the last HIARC report (January, 2001) and an OPPIN bibliography of master record identification number (MRIDs). In addition, a 21-day dermal study, submitted since the last risk assessment, was reviewed. A screening Google search (Google Scholar) and a Science Direct search indicated very little information relevant to human health risk assessment has been published on this herbicide. Incident databases were also reviewed.

Toxicity database. The toxicity database for clomazone is generally complete.

The previous risk assessments for clomazone identified three data needs: 1) a 21-day dermal study in rats; 2) a 28-day inhalation study; and 3) new cancer studies. The 21-day dermal study has been received and reviewed. There were no effects observed at the limit dose of 1000 mg/kg/day. Consistent with usual practice for chemicals that are not toxic by the dermal route at the limit dose and do not have developmental toxicity concerns, a dermal risk assessment is not required.

Since the last risk assessment on clomazone, HED has implemented an inhalation toxicity study waiver policy. Clomazone meets one of the criteria for a waiver under the policy, exhibiting low inhalation toxicity (Category 4 in an acute inhalation study) with an inhalation MOE of >1000 (based on oral toxicity data) for all occupational scenarios. Thus, the previous requirement for a 28-day inhalation study no longer applies.

Although the existing negative cancer studies in rats and mice are not considered acceptable because of inadequate dosing, repeat studies are not required at this time. Clomazone is currently classified as "not likely to be carcinogenic to humans". In addition to the two rodent studies, this classification is based on the lack of mutagenic concern and a lack of data in the literature or information on structure-activity relationships (SAR) to indicate carcinogenic potential.

While the highest dose in the rat cancer study, 84 mg/kg/day, did not produce adverse effects, there were adverse effects in parental animals in the two-generation reproduction study at 100 mg/kg/day. Thus, the 84 mg/kg dose closely approached an adverse dose and there is no need to repeat the study.

In the mouse cancer study, clomazone was tested for two years at doses up to 300 mg/kg/day with no response observed at any dose. HED has estimated a "provisional" cancer risk from current uses of clomazone assuming higher doses of clomazone (600 mg/kg/day and 1200 mg/kg/day) would elicit a tumor response in mice. With the current use pattern for clomazone, and the associated low exposures, cancer risks are unlikely to be a concern. Thus, HED sees no need for additional mouse data at higher doses unless new uses are submitted which will significantly increase dietary and/or worker exposure.

The toxicity database required to perform an FQPA assessment is complete. Acceptable developmental studies in rats and rabbits and a two-generation reproduction study in rats are available. Clomazone exhibits no neurotoxicity in toxicity studies of various durations.

There are few poisoning incidents associated with the use of clomazone, and the few that are available suggest that exposure to clomazone is unlikely to result in serious health effects. Symptoms of exposure to clomazone are consistent with irritation to skin, eyes, respiratory tract or gastro-intestinal tract.

Dietary exposure database. With respect to the assessment of dietary risks, the dietary exposure database is complete. There are adequate residue data reflecting the use of all existing formulations on representative commodities with the possible exception of the microencapsulated formulation layby use on cotton described below. For both acute and chronic dietary risks, dietary exposures (food only) were less than 1% of the PAD assuming tolerance level residues and 100% crop treated (Tier 1 assessment).

Drinking water risks were last assessed using the DWLOC approach. DWLOCs were well in excess of 1 mg/liter and screening level groundwater and surface water concentrations were < 0.4% of the DWLOC for acute aggregate exposure and <0.3% of the DWLOC for chronic aggregate exposure. HED believes that nothing is to be gained by reassessing drinking water risks using the current practice of directly incorporating drinking water exposures into the probabilistic acute assessment. Risks from consumption of drinking water will continue to be negligible.

Residential exposure. There are no residential uses for clomazone**,** and therefore no residential risk assessment is required.

FQPA factor. The FQPA factor was removed (1x) by the old FQPA Committee in September, 2000 based on the completeness of the data, no indications of susceptibility or sensitivity in developmental and reproduction studies and no residual concerns for pre- or postnatal toxicity to infants and children. Even though there have been changes in the policies determining an appropriate FQPA factor since 2001, the same decision on the FQPA factor conclusion would be reached today, i.e. there are reliable data to remove the factor.

Occupational exposure. As noted above, a dermal toxicity study was received since the last risk assessments on clomazone and, based on review of the study, dermal exposure to workers is not of concern. Inhalation exposure for handlers is also of no concern as the MOEs, based on

extant uses, are in excess of 18,000.

Other issues.

Residue data. There has been a trend toward microencapsulated formulations for clomazone because of its volatility. For the most part, there are adequate residue data reflecting use of microencapsulated formulations; however, there is one use, a layby use on cotton, with no data on the microencapsulated formulation. It is theoretically possible that the layby use could result in over-tolerance residues. Although, HED suspects that, since clomazone residues are typically below the limit of detection at harvest for all other uses regardless of formulation clomazone would not be detected at harvest following the layby use of the ME product. In order to confirm this point, the residue study should be required. It should be noted that this is a tolerance issue and not a risk issue. Risks from the layby use on cotton are considered negligible.

Spray drift. Because clomazone is somewhat volatile, it is possible that there could be bystander exposure by analogy to the soil fumigants. HED believes that inhalation risks to bystanders would not exceed those of applicators, and the minimum MOE for applicators is 18,000 (target 100).

Harmonization issues. There are no Codex MRLs for clomazone. Canada has a 0.05 ppm MRL for clomazone on soybeans – the same as the US tolerance. Mexico has tolerances for clomazone that agree with U.S. tolerances.

Conclusion: HED does not need any additional data to confirm our earlier conclusions regarding the exposure and resultant risks from the use of clomazone. The risk assessments on file are up to current standards and no further human health risk work is needed.

V. Glossary of Terms and Abbreviations

ai	Active Ingredient
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval

ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard