



**Office of Prevention, Pesticides,
and Toxic Substances**

MEMORANDUM

PC Code: 125401
DP Barcode: 314307

SUBJECT: Section 24c Special Local Need Request for Clomazone
(Command[®] 3ME, EPA Reg. No. 279-3158) for Aerial Application to Rice in
Texas (SLN No. TX-050002)

FROM: James Breithaupt, Agronomist
Michael Davy, Agronomist
Michelle R. Embry, Ph.D., Environmental Toxicologist
Shannon Borges, Biologist
Dana Spatz, Senior Chemist

Environmental Risk Branch II
Environmental Fate and Effects Division (7507C)

TO: Tobi Colvin-Snyder
Registration Division (7505 C)

THRU: Tom Bailey, Ph.D., Branch Chief
Environmental Risk Branch II / EFED (7507C)

DATE: May 3, 2005

I. Executive Summary

The Texas Department of Agriculture is requesting a 24c Special Local Need Registration for the use of aerially-applied clomazone to no more than 5000 acres of rice for pre-emergence control of grass weed species (e.g., barnyard grass, broadleaf signalgrass, crabgrass, panicum, sprangletop). This memorandum presents the ecological risk assessment for clomazone (2-((2-chlorophenyl)methyl)-4,4-dimethyl-3-isoxazolidinone, PC Code 125401).

The proposed aerial use of clomazone in the rice-producing areas of Texas, excluding Harris and Fort Bend counties, for pre-emergence grass weed control in rice is not expected to pose acute or chronic risk to birds, fish, or beneficial insects, or acute risk to mammals. This proposed use does result in exceedances of Agency levels of concern (LOC) for the following taxa based on Tier I screening results:

Acute Risk

- Endangered and threatened (listed) terrestrial plants (monocots and dicots) at all application rates
- Listed freshwater invertebrates at the 0.6 lb ai/A application rate
- Non-listed marine/estuarine invertebrates at the 0.6 lb ai/A application rate
- Listed marine/estuarine invertebrates at all application rates

Chronic Risk

- Listed and non-listed small and medium-sized mammals that feed on short grass at the 0.6 lb ai/A application rate

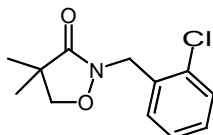
For those taxonomic groups where listed species LOC were exceeded, a county-level search using the LOCATES endangered species database was conducted to determine the presence of listed species inhabiting the proposed use areas. No listed freshwater or marine/estuarine invertebrates or small/medium mammals occur in the counties of proposed use. Aerial application of clomazone to rice in Texas may result in direct adverse effects to two terrestrial plant species, the Texas prairie dawn-flower (*Hymenoxys texana*) and the Texas trailing phlox (*Phlox nivalis ssp. texana*). Additionally, the Agency recognizes the potential for indirect effects on listed species resulting from this proposed clomazone use. Loss of terrestrial plants following clomazone application may indirectly affect species that utilize terrestrial environments near rice fields, including the Attwater's greater prairie chicken (*Tympanuchus cupido attwateri*) and the red-cockaded woodpecker (*Picoides borealis*). Loss of aquatic plant and unicellular algae may indirectly affect listed species that rely on these taxa as a food source, such as the Houston toad (*Bufo houstonensis*) and the interior least tern (*Sterna antillarum*). Further discussion of indirect effects on listed species resulting from the proposed clomazone use can be found in **Section VIII**.

II. Introduction

Clomazone is the only member of the isoxazolidinone family of herbicides currently in use. It is a pre-emergent systemic herbicide that is taken up by plant roots and shoots and moves into the xylem, inhibiting the formation of photosynthetic pigments.

A. Chemical Profile

| | |
|---------------------|---|
| Common Name: | Clomazone |
| Chemical Name: | 2-((2-chlorophenyl)methyl)-4,4-dimethyl-3-isoxazolidinone |
| Empirical Formula: | C ₁₂ H ₁₄ ClNO ₂ |
| Molecular Weight: | 239.7 |
| CAS#: | 81777-89-1 |
| PC Code: | 125401 |
| Solubility: | 1100 mg/L |
| Chemical Structure: | |



B. Use Information

| | |
|--------------|---|
| Formulation: | Command [®] 3ME Herbicide (31.4% active ingredient, microencapsulated) |
|--------------|---|

| | |
|-------------------------|--|
| Application Rate: | 0.4 lb ai/A (medium soils) 0.5 - 0.6 lb ai/A (fine soils) |
| Number of Applications: | Once per season |
| Method of Application: | Aerial spray |
| Area to be Treated: | ≤5000 acres |

According to the primary label, Command® 3ME is to be applied once per season at either 14 days before planting or up to 7 days after planting at the rates of 0.4 lb ai/A or 0.5 - 0.6 lb ai/A depending on soil type. Medium soils are defined as loam, silt, silt loam, sandy clay, and sandy clay loam and have an application rate of 0.4 lb ai/A. Fine or heavy soils, such as silty clay, clay loam, silty clay loam, and clay, have a recommended application rate of 0.5 to 0.6 lb ai/A. Use of clomazone in areas with coarse soils (sand, loamy sand, and sandy loam) is prohibited by the label. Other label restrictions include the following:

- no application within 1,200 feet of towns and housing developments, commercial fruits and nuts, vegetable production (excluding peppers, pumpkins, succulent peas, sweet corn, sweet potato, and winter squash), commercial greenhouses, and nurseries
- no application when winds are above 10 mph
- no application within 300 feet of desirable plants
- no application in rice fields in which concurrent crayfish or catfish farming occurs

It is important to note that the Texas SLN 24c label does not specify aerial spray droplet size and only states that “aircraft used to apply Command 3ME shall be configured and operated in such a manner as to minimize off-site spray movement to desirable species. As described in detail below, the use of medium to coarse droplet size, as opposed to fine to medium droplet size for aerial clomazone application significantly reduces risk from spray drift exposure to non-target plant species.

III. Environmental Fate Summary

Vapor phase transport and microbial degradation appear to be the major routes of dissipation in the environment. 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 FMC 65317 (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-m³/mol, clomazone is expected to remain in the water column as opposed to volatilizing. However, in the terrestrial environment, clomazone may volatilize from soil. In a laboratory study, up to 7% of the applied clomazone volatilized from soil in an 18 hour period. Volatility increased with application rate, wind velocity, temperature, soil moisture, and relative humidity.

Clomazone is stable to hydrolysis in acidic, neutral, and alkaline solutions and does not photodegrade in either water or on soil. In the aquatic environment, laboratory studies demonstrate that clomazone is more rapidly metabolized under anaerobic conditions than aerobic. This is consistent with the results of the metabolism studies conducted in soil. In an aerobic aquatic metabolism study conducted in a silt loam sediment-water system, clomazone degraded with a total system half-life of 75 days. The major metabolite was N-[(2-chlorophenol)methyl]-3-hydroxy-2,2-dimethyl propanamide, which reached a maximum of 11% of applied radioactivity on day 14. In this study there were six unidentified degradates that did not exceed 10% of applied radioactivity. Residues tended to partition to the sediment over the

course of the 30 day study. Volatility in this study was minimal.

In an anaerobic aquatic metabolism study conducted in a silt loam sediment-water system, clomazone degraded with a total system half-life of 44 days. The primary metabolite was N-[(2-chlorophenol) methyl]-3-hydroxy-2,2-dimethyl propanamide, which reached 50% of applied radioactivity by 189-365 days. Another major degradate was 2-chlorobenzoic acid, which increased from 9.4% at 30 days to 14% at 189 days and then dropped to 12.5% by 365 days. Residues tended to stay in the water column, as opposed to the sediment and volatilization was minimal.

Clomazone is moderately mobile with K_d 's of 1.5, 2.6, 2.8, and 7.4 in fine sand, sandy loam, silty clay loam, and silt loam soils, respectively. Koc's in these same 4 soils were 203, 139, 196, and 608.

In the field, Command 3 ME applied to bare soil at a rate of 1.25 lbs. ai/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. Half-lives in surface water, based on laboratory aquatic metabolism studies, will range 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. A summary of clomazone fate properties are in **Table 1**.

Table 1. Environmental fate and chemical properties of clomazone

| Parameter | Value or Description |
|--|---------------------------------------|
| Solubility | water: 1100 mg/L @25 °C |
| Vapor pressure | 1.44E-4 mm Hg |
| Henry's Law constant | 4.14E-8 atm-m ³ /mol |
| Octanol water partition coefficient (K_{ow}) | log K_{ow} = 2.54 |
| Hydrolysis | stable @ pH 5,7, & 9 |
| Aqueous photolysis | stable |
| Soil photolysis | stable |
| Aerobic soil metabolism | $t_{1/2}$ = 28 - 173 days |
| Anaerobic soil metabolism | $t_{1/2}$ = 13 days |
| Anaerobic aquatic metabolism | $t_{1/2}$ = 44 days |
| Aerobic aquatic metabolism | $t_{1/2}$ = 75 days |
| Leaching (adsorption-desorption) | Freundlich K_{ads} = 1.5 - 7.4 ml/g |

| Parameter | Value or Description |
|--|--|
| Terrestrial field dissipation | t _{1/2} = 16 days (LA) t _{1/2} = 139 days (IA) |
| Bioconcentration in fish (bluegill sunfish) | 10X edible, 75X non-edible, 40X whole fish 97-99% depurated by 3 days |

IV. Aquatic Exposure Assessment

EFED performed a Tier I aquatic assessment for clomazone using the Interim Rice Model (Bradbury, 2002) to model aquatic exposure resulting from rice paddy water release. The model assumes uniform pesticide application to a one hectare field that has 10 centimeters of standing floodwater. Sorption is the only dissipation process used in the model. Due to the fact that clomazone will be applied aerially, 95% application efficiency was assumed to account for 5% spray drift. Discussion of aquatic exposure resulting from spray drift alone is discussed below. Floodwater release is assumed to occur immediately following pesticide equilibration, and EEC values are based on rice paddy discharge concentrations and do not account for dilution following release. Input parameters for the model are listed in **Table 2** below.

Table 2. Input parameters and assumptions for the Interim Rice Model

| Input Variable | Input Value | Comments |
|---|--|---|
| Application rate | 0.64 kg ai/ha (0.6 lb ai/A rate) OR 0.43 kg ai/ha (0.4 lb ai/A rate) | application rate adjusted to account for 5% spray drift resulting from aerial application |
| Soil bulk density | 1.3 g/cm ³ | Per Interim Rice Model |
| Area of field | 1 ha | Per Interim Rice Model |
| Mass of soil in field | 130,000 kg | Per Interim Rice Model |
| Depth of pesticide:sediment interaction | 1 cm | Per Interim Rice Model |
| Volume of water in the field | 1.016E6 liters | Per Interim Rice Model |
| Freundlich K _{ads} value | 2.8 ml/g (silty clay loam soil) 7.4 ml/g (silt loam soil) | MRID 00116619 |

The estimated peak concentrations in surface water predicted by the Interim Rice model are presented in **Table 3** below.

Table 3. Interim Rice Model Estimated Environmental Concentrations (EEC) of clomazone in the aquatic environment resulting from aerial use on rice

| Application Rate | Peak EEC (ppb)* |
|---------------------------------|-----------------|
| 0.64 kg ai/A (0.6 lb ai/A rate) | 463 |
| 0.43 kg ai/A (0.4 lb ai/A rate) | 215 |

*Interim Rice Model run with no degradation. Mean values were not calculated because the model does not consider degradation.

Aquatic EECs resulting from spray drift exposure to a pond adjacent to the rice paddy were calculated using the AgDrift model (v. 2.01, USEPA, 2004). The model was run to determine contribution that spray drift may have to aquatic exposure in nearby aquatic areas not subject to direct rice paddy discharge. Additionally, the model was run using both medium to fine and medium to coarse droplet size distributions in order to account for lack of specific label language as well as to consider the effects of droplet size on the resulting EEC values. Results of this model are presented in **Table 4** below.

Table 4. AgDrift EECs resulting from clomazone spray drift to a pond adjacent to the rice paddy

| Application Rate | Drop Size Distribution | Distance from Edge of Field (ft) | EEC (ppb) |
|---------------------------------|------------------------|----------------------------------|-----------|
| 0.64 kg ai/A (0.6 lb ai/A rate) | Medium to Fine | 0 | 4.3 |
| | | 10 | 3.7 |
| | Medium to Coarse | 0 | 3.0 |
| | | 10 | 2.4 |
| 0.43 kg ai/A (0.4 lb ai/A rate) | Medium to Fine | 0 | 2.8 |
| | | 10 | 2.5 |
| | Medium to Coarse | 0 | 2.0 |
| | | 10 | 1.6 |

EFED is aware of surface water monitoring data in small streams in rice-growing areas of Arkansas. The highest peak concentration of clomazone in the five years of monitoring was 38.2 ppb. These data have not yet been reviewed by the Agency, and the results are not included in this assessment. The monitoring data can be found at the following url: http://www.arkrice.org/research_results/

V. Terrestrial Exposure Assessment

A. Terrestrial Animal Exposure

The T-REX model (v1.1, USEPA, 2004) was used to estimate the terrestrial animal exposure values resulting from possible dietary ingestion of clomazone residues on vegetative matter and insects present in the rice field. This model is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). The EEC values were calculated based on the default foliar dissipation half-life of 35 days due to the lack of foliar dissipation data. The predicted maximum residues of clomazone that may be expected to occur on selected avian or mammalian food items immediately following application in the rice field are presented in **Table 5**.

Table 5. Estimated Environmental Concentrations (EEC) of clomazone on avian and mammalian food items **within** the rice paddy

| Application rate | Estimated Environmental Concentration (EEC) (ppm) | | | |
|------------------|---|------------|--------------------------------|---------------------------|
| | Short grass | Tall grass | Broadleaf plants/small insects | Fruits/pods/large insects |
| 0.6 lb ai/A | 144 | 66 | 81 | 9 |

| | | | | |
|-------------|----|----|----|---|
| 0.4 lb ai/A | 96 | 44 | 54 | 6 |
|-------------|----|----|----|---|

In addition to the exposure values within the rice field, the EEC values on adjacent area food items resulting from spray drift were calculated using AgDrift (v. 2.01) and T-REX (v. 1.1, 2004). Values were modeled using AgDrift for edge of field, assuming a distance of zero feet from the edge of the rice paddy. As with the aquatic exposure assessment, the AgDrift model was run using both medium to fine and medium to coarse drop size distributions in order to account for lack of specific label language as well as to consider the effects of droplet size on the resulting EEC values. The application droplet size (fine to medium or medium to coarse) had no effect on the resulting EEC values. Calculations from AgDrift indicating the percent contribution of spray drift were then used as application rate inputs in T-REX to calculate EECs. Edge of field EEC calculations for specific avian and mammalian food items are presented in **Table 6**.

Table 6. Clomazone EECs on avian and mammalian food items at the **edge** of the rice paddy

| Application rate | Contribution from spray drift | Estimated Environmental Concentration (EEC) (ppm) | | | |
|------------------|-------------------------------|---|------------|------------------------------------|---------------------------|
| | | Short grass | Tall grass | Broadleaf plants/ small insects | Fruits/pods/large insects |
| 0.6 lb ai/A | 50% | 72 | 33 | 40.5 | 4.5 |
| 0.4 lb ai/A | 50% | 48 | 22 | 27 | 3 |

B. Terrestrial Plant Exposure

Terrestrial non-target plant exposure resulting from spray drift was calculated using AgDrift (v. 2.01). Edge of field, 100 foot, and 200 foot distances from the edge of the rice paddy were used to calculate the EEC values resulting from spray drift. Both medium to fine and medium to coarse droplet sizes were examined. EEC values are presented in **Table 7** below.

Table 7. EECs for terrestrial plants resulting from spray drift of aerially applied clomazone

| Application Rate | Drop Size Distribution | Distance from Edge of Field (ft) | % of applied | EEC (lb ai/A) |
|---------------------------------|------------------------|----------------------------------|--------------|---------------|
| 0.64 kg ai/A (0.6 lb ai/A rate) | Medium to Fine | 0 (edge of field) | 50 | 0.3 |
| | | 100 | 9.8 | 0.06 |
| | | 200 | 4.7 | 0.03 |
| | Medium to Coarse | 0 (edge of field) | 50 | 0.3 |
| | | 100 | 5.6 | 0.03 |
| | | 200 | 2.5 | 0.01 |
| 0.43 kg ai/A (0.4 lb ai/A rate) | Medium to Fine | 0 (edge of field) | 50 | 0.2 |
| | | 100 | 9.8 | 0.04 |
| | | 200 | 4.7 | 0.02 |
| | Medium to Coarse | 0 (edge of field) | 50 | 0.2 |
| | | 100 | 5.6 | 0.02 |
| | | 200 | 2.5 | 0.01 |

B. Ecological Risk Assessment

A. Summary

The proposed use of aerially-applied clomazone on rice in Texas is not expected to pose acute or chronic risk to birds, fish, or beneficial insects, or acute risk to mammals. However, this use poses acute risk to listed and non-listed terrestrial plants as well as freshwater and estuarine/marine invertebrates under certain scenarios described in detail below. There is also potential chronic risk to small and medium-sized mammals that feed on short grasses.

The Risk Quotient Method

The Risk Quotient Method is the means used by EFED to integrate the results of exposure and ecotoxicity data. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

$$RQ = \text{EXPOSURE} / \text{TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. EFED has defined LOCs for acute risk, potential restricted use classification, and for listed species.

B. Risks to Aquatic Organisms

1. Freshwater and Estuarine/Marine Fish - Acute

Based on the ecological effects data submitted by the registrant, the use of aerially-applied clomazone seems unlikely to pose acute risk to freshwater and estuarine/marine fish. Toxic effects of clomazone were seen in fish at concentrations significantly greater than those simulated by the Interim Rice Model (463 ppb - see **Table 3**) as well as spray drift to an adjacent water body (4.3 ppb). All RQ values fall well below the LOC of 0.05 for acute risk to listed species. Toxicity values are shown in **Table 8** below.

Further discussion of clomazone fish toxicity studies can be found in **Appendix A**.

Table 8. Clomazone fish acute toxicity values

| Species | % AI | LC ₅₀ /EC ₅₀ (ppb) | MRID # | toxicity category |
|---|------|---|--------------------------------|-------------------|
| Rainbow trout (<i>Salmo gairdneri</i>) | 88.8 | 19,000 | Acc# 248475 Rhoderick, 1982 | Slightly toxic |
| Bluegill sunfish (<i>Lepomis macrochirus</i>) | 88.8 | 34,000 | Acc# 248275 Rhoderick, 1982 | Slightly toxic |
| Sheepshead minnow (<i>Cyprinodon variegatus</i>) | 92.9 | 40,600 | Acc# 263081 Barrows, 1986 | Slightly toxic |

1. **Freshwater and Estuarine/Marine Fish - Chronic**

Based on the single chronic fish study submitted by the registrant, the use of aerially-applied clomazone seems unlikely to pose chronic risk to freshwater fish. The chronic toxicity of clomazone (NOAEC = 2290 ppb for rainbow trout) is well above the peak 56-day EEC of 443 ppb simulated by the Interim Rice Model, leading to RQ calculations well below the LOC of 1.0. No chronic estuarine/marine fish studies were submitted by the registrant.

Table 9. Freshwater fish clomazone chronic toxicity values

| Species | % AI | NOAEC (ppb) | MRID # |
|---|------|----------------|---------------------------|
| Rainbow trout (<i>Salmo gairdneri</i>) | 95.6 | 2290 | Acc# 073830 Anon, 1985 |

3. **Freshwater and Estuarine/Marine Invertebrates - Acute**

Based on the acute toxicity values for freshwater and estuarine/marine invertebrates, the use of aerially-applied clomazone on rice in Texas poses acute listed species risk to marine/estuarine species at both application rates (0.4 and 0.6 lb ai/A). Both listed and non-listed marine/estuarine shellfish species are potentially at risk from the application of clomazone at the high application rate (0.6 lb ai/A) as well as listed non-shellfish freshwater invertebrate species (**Table 11**). No LOC are exceeded based on the EEC values resulting from spray drift to an adjacent water body. Toxicity values are provided in **Table 10**.

Table 10. Clomazone aquatic invertebrate toxicity values

| Species | % AI | LC ₅₀ ^{1/EC} (ppb) ₅₀ | MRID # | toxicity category | fulfills guideline requirements? |
|--|------|---|-------------------------------|-------------------|----------------------------------|
| Waterflea (<i>Daphnia magna</i>) | 88.8 | 5200 | Acc# 248475 Graney, 1982 | moderately toxic | Yes |
| Mysid shrimp (<i>Americanmysis bahia</i>) | 92.9 | 566 | Acc# 263080 Williams, 1986 | highly toxic | Yes |
| Eastern oyster (<i>Crassostrea virginica</i>) | 95.4 | 5300 | Acc# 260723 Carr, 1985 | moderately toxic | Yes |

Table 11. Aquatic invertebrate RQ values

| Application Rate | Peak EEC (ppb) | RQ values | | |
|---------------------------------|----------------|-------------|-------------|--------------------|
| | | FW1 | Mar/Est2 | Mar/Est shellfish3 |
| 0.64 kg ai/A (0.6 lb ai/A rate) | 463 | 0.09 | 0.82 | 0.09 |
| 0.43 kg ai/A (0.4 lb ai/A rate) | 215 | <0.05 | 0.38 | <0.05 |
| Max AgDrift value* | 4.3 | <0.05 | <0.05 | <0.05 |

Exceedances are indicated in bold type

*Based on 0.64 kg/ai, fine to medium spray, and a buffer of 0 feet

¹ *Daphnia* EC₅₀ = 5200 ppb

² Mysid shrimp EC₅₀ = 566 ppb

³ Eastern oyster EC₅₀ = 5300 ppb

4. Freshwater and Estuarine/Marine Invertebrates - Chronic

Based on the single chronic freshwater invertebrate study submitted by the registrant, the use of aerially-applied clomazone seems unlikely to pose chronic risk to freshwater invertebrates. The chronic toxicity of clomazone (NOAEC = 2200 ppb for *Daphnia magna*) is well above the EEC of 443 ppb simulated by the Interim Rice Model, leading to RQ calculations below the LOC of 1.0. No chronic estuarine/marine invertebrates studies were submitted by the registrant. However, an estuarine/marine invertebrate life-cycle toxicity test is required for clomazone because the end-use product is expected to be transported to the estuarine/marine environment from the intended use site, and the mysid shrimp acute toxicity value is less than 1 ppm (mysid shrimp clomazone EC₅₀ = 0.566 ppm). This represents a significant data gap in this risk assessment.

Table 12. Freshwater invertebrate clomazone chronic toxicity

| Species | % AI | NOAEC (ppb) | Endpoints | MRID # | toxicity category |
|---------------------------------------|------|----------------|--------------|-----------------------------|-------------------|
| Waterflea (<i>Daphnia magna</i>) | 95.6 | 2200 | reproduction | Acc# 073997, 073616 1985 | moderately toxic |

5.

Aquatic Plants

Based on the aquatic plant toxicity data submitted by the registrant, the use of clomazone applied aerially to rice fields in Texas does not pose acute risk to listed and non-listed vascular aquatic plants. The toxicity of clomazone to vascular aquatic plants (EC₅₀ = 12,000 ppb for duckweed) is well above the EEC of 443 ppb simulated by the Interim Rice Model, leading to RQ calculations below the LOC of 1.0. This use may pose acute risk to listed and non-listed aquatic non-vascular plants; however, there are currently no federally recognized listed non-vascular aquatic plant species. Aquatic plant toxicity data used to calculate risk quotients in this assessment are summarized in **Table 13** below. More detailed

toxicity study information is available in **Appendix A**. Based on the maximum aquatic EEC values from the Interim Rice model of 463 ppb and the freshwater diatom EC₀₅ of 159 ppb, RQ values for non-vascular aquatic plants exceed the LOC of 1.0 (See **Table 14**).

Table 13. Clomazone aquatic plant toxicity values

| Species | % AI | EC ₅₀ (ppb) | MRID # |
|--|------|------------------------|----------|
| Duckweed (<i>Lemna gibba</i>) | 90 | 12,000 | 44994803 |
| Freshwater diatom (<i>Navicula pelliculosa</i>) | 90 | 159 | 44994801 |

Table 14. Risk Quotient calculations for listed non-vascular aquatic plants (based on *Navicula pelliculosa* toxicity data)

| Application Rate | Peak EEC (ppb) | EC ₀₅ (ppb) | RQ |
|---------------------------------|----------------|------------------------|------------|
| 0.64 kg ai/A (0.6 lb ai/A rate) | 463 | 159 | 2.9 |
| 0.43 kg ai/A (0.4 lb ai/A rate) | 215 | 159 | 1.4 |
| Max AgDrift value* | 4.3 | 159 | <1.0 |

Exceedances are indicated in bold type

C. **Risks to Terrestrial Animals**

Based on the ecological effects data submitted by the registrant, the use of aerially-applied clomazone on Texas rice seems unlikely to pose acute or chronic risk to avian species, or acute risk to mammals, but may pose potential chronic risk to mammals. Acute and subacute toxic effects of clomazone were seen in birds at concentrations significantly greater than predicted dietary residues based on T-REX (v. 1.1, 2004) for both direct in-field exposure and adjacent field exposure resulting from spray drift. Additionally, acute toxic effects in mammals were higher than predicted residue values. Toxicity values are shown in **Tables 15-17** below.

Table 15. Clomazone avian and mammalian acute toxicity values

| Species | % AI | LD50 (mg/kg) | MRID # | Toxicity Category |
|---|------|------------------------------|------------------------------|----------------------|
| Northern Bobwhite (<i>Colinus virginianus</i>) | 88.8 | >2510 | Acc# 248475 Beavers, 1982 | Practically Nontoxic |
| Mallard Duck (<i>Anas platyrhynchos</i>) | 88.8 | >2510 | Acc# 248475 Beavers, 1982 | Practically Nontoxic |
| Laboratory Rat (<i>Rattus norvegicus</i>) | 88 | 2077 (male) 1369 (female) | 00117121 | Practically Nontoxic |

Table 16. Clomazone avian subacute toxicity values

| Species | % AI | LC50 (ppm) | MRID # | Toxicity Category |
|---|------|------------|------------------------------|----------------------|
| Northern Bobwhite (<i>Colinus virginianus</i>) | 88.8 | >5620 | Acc# 248475 Beavers, 1982 | Practically Nontoxic |

| | | | | |
|---|------|-------|------------------------------|----------------------|
| Mallard Duck (<i>Anas platyrhynchos</i>) | 88.8 | >5620 | Acc# 248475 Beavers, 1982 | Practically Nontoxic |
|---|------|-------|------------------------------|----------------------|

Table 17. Clomazone avian and mammalian chronic toxicity values

| Species | % AI | NOEC/NOEL | LOEC/LOEL | Comments | MRID # |
|---|------|--------------------|---------------------|---|----------|
| Northern Bobwhite (<i>Colinus virginianus</i>) | 90.7 | 1020 ppm (diet) | >1020 ppm (diet) | no toxicant-induced mortalities or pathological responses | 45178101 |
| Laboratory Rat (<i>Rattus norvegicus</i>) | 88 | 50 mg/kg bw | ----- | decreased parental body weight gain, body weight during gestation, and food consumption | 00151108 |

Based on mammalian and avian chronic toxicity values and estimated food-item residue data, use of clomazone poses potential chronic risk to listed and non-listed small (15g) and medium (35g) sized mammals that feed short grass at the high application rate (0.6 lb ai/A) based on a dose-based calculation of risk. The dose-based RQ calculations take into account the size of the animal and their food intake, and therefore the dose the animal actually receives. Diet based RQ values do not account for this variation. Risk quotient calculations are shown in **Table 18** below.

Table 18. Chronic mammalian and avian risk quotient calculations (based on rat NOEL of 50 mg/kg/day and mallard duck NOEC of 1020 ppm)

| Application Rate | Food Item | EEC (ppm) | Avian RQ | Mammalian RQ | | |
|------------------|-----------------------------|-----------|----------|--------------|-------------|---------------|
| | | | | body weight | dose based | dietary based |
| 0.6 lb ai/A | Short Grass | 144 | <1.0 | 15g | 1.24 | <1.0 |
| | | | | 35g | 1.07 | |
| | | | | 1000g | <1.0 | |
| | Tall Grass | 66 | <1.0 | 15g | <1.0 | <1.0 |
| | | | | 35g | <1.0 | |
| | | | | 1000g | <1.0 | |
| | Broadleaf plants/sm insects | 81 | <1.0 | 15g | <1.0 | <1.0 |
| | | | | 35g | <1.0 | |
| | | | | 1000g | <1.0 | |
| | Fruits/pods/lg insects | 9 | <1.0 | 15g | <1.0 | <1.0 |
| | | | | 35g | <1.0 | |
| | | | | 1000g | <1.0 | |

Exceedances are indicated in bold type

D. Risks to Terrestrial Plants

Non-target plant testing (seedling emergence) was conducted on clomazone formulated (Command® 3ME) product. No vegetative vigor studies were available, so risk was calculated using only seedling emergence toxicity values. This absence of vegetative vigor toxicity studies represents a significant data gap. Terrestrial plant clomazone typical end-use product (TEP) toxicity values used to calculate RQ values in this risk assessment are shown in **Table 19** below. For more detailed plant toxicity information, see **Appendix A**. Based on this data, the use of aerially-applied clomazone on Texas rice poses risk to non-target monocot and dicot plants (listed and non-listed). A summary of the RQ calculations is presented in **Table 20**. In addition, a number of non-target terrestrial plant incidents have been submitted to the Agency. These are presented in detail in **Appendix B**.

Table 19. Clomazone terrestrial plant toxicity values (formulated product)

| Study Type | Plant Type | Species | EC05 (lb ai/A) | EC25 (lb ai/A) | MRID# |
|----------------------------------|------------|---------|----------------|----------------|----------|
| Seedling Emergence (% emergence) | Monocot | Oat | 0.0154 | 0.076 | 45397701 |
| | Dicot | Lettuce | 0.0051 | 0.032 | 45397701 |

Table 20. Clomazone terrestrial plant risk quotient calculations

| Application Rate | Drop Size Distribution | Distance from Edge of Field (ft) | % of applied | EEC (lb ai/A) | RQ calculations | | | |
|------------------|------------------------|----------------------------------|--------------|---------------|-----------------|-------------|-------------|-------------|
| | | | | | Dicots | | Monocots | |
| | | | | | listed1 | non-listed2 | listed3 | non-listed4 |
| 0.6 lb ai/A | Medium to Fine | 0 (edge of field) | 50 | 0.3 | 58.8 | 9.4 | 19.5 | 3.9 |

| | | | | | | | | |
|-------------|------------------|-------------------|-----|------|-------------|------------|-------------|------------|
| | | 100 | 9.8 | 0.06 | 11.8 | 1.9 | 3.9 | <1.0 |
| | | 200 | 4.7 | 0.03 | 5.9 | <1.0 | 1.9 | <1.0 |
| | Medium to Coarse | 0 (edge of field) | 50 | 0.3 | 58.8 | 9.4 | 19.5 | 3.9 |
| | | 100 | 5.6 | 0.03 | 5.9 | <1.0 | 1.9 | <1.0 |
| | | 200 | 2.5 | 0.01 | 2.0 | <1.0 | <1.0 | <1.0 |
| | | | | | | | | |
| 0.4 lb ai/A | Medium to Fine | 0 (edge of field) | 50 | 0.2 | 39.2 | 6.3 | 13.0 | 2.6 |
| | | 100 | 9.8 | 0.04 | 7.8 | 1.3 | 2.6 | <1.0 |
| | | 200 | 4.7 | 0.02 | 3.9 | <1.0 | 1.3 | <1.0 |
| | Medium to Coarse | 0 (edge of field) | 50 | 0.2 | 39.2 | 6.3 | 13.0 | 2.6 |
| | | 100 | 5.6 | 0.02 | 3.9 | <1.0 | 1.3 | <1.0 |
| | | 200 | 2.5 | 0.01 | 2.0 | <1.0 | <1.0 | <1.0 |

Exceedances are indicated in bold type

¹Dicot EC₂₅ = 0.032 (lettuce)

²Dicot EC₀₅ = 0.0051 (lettuce)

³Monocot EC₂₅ = 0.076 (oat)

⁴Monocot EC₀₅ = 0.0154 (oat)

The AgDrift model was used to calculate the distance from the edge of a field required to bring spray drift deposition below the LOC of 1 for terrestrial plants. The spray drift buffer distances are described below for both fine to medium and medium to coarse droplet sizes, at both application rates, and for both listed and non-listed monocots and dicots (**Table 21**).

Table 21. Clomazone Spray Drift Buffers for Terrestrial Plants

| Application Rate | Drop Size Distribution | Spray Drift Buffer where LOC = 1 (feet) | | | |
|------------------|------------------------|---|--------------|--------------------|------------------|
| | | Listed monocot | Listed dicot | non-listed monocot | non-listed dicot |
| 0.6 lb ai/A | Medium to fine | 364.2 | >1000 | 75.5 | 177.2 |
| | Medium to coarse | 196.9 | 528.2 | 39.4 | 108.3 |
| 0.4 lb ai/A | Medium to fine | 242.8 | 856.3 | 36.1 | 121.4 |
| | Medium to coarse | 137.8 | 347.8 | 23.0 | 75.5 |

E. Risks to Non-target Insects

An analysis of the results show that clomazone is practically non-toxic to honeybees based on an acute contact toxicity test (LD₅₀ >25 ug ai/bee, MRID 45178102). Therefore, it is assumed that the use of clomazone will not pose significant risk to non-target insects.

VII. Listed Species

A. Direct Effects to Listed Species

The acute listed species LOC was also exceeded for freshwater and estuarine/marine invertebrates; chronic LOCs were exceeded for small (15 g) and medium (100 g) mammals that consume short grass.

However, no listed freshwater or estuarine/marine invertebrates inhabit rice-growing counties in Texas where aerial clomazone applications are proposed. The Louisiana black bear is the only listed mammal within these counties, but it is not included in the size and diet categories for mammals that are considered to be directly at risk.

The RQs for terrestrial plants (both monocots and dicots) exceed the listed and non-listed species levels of concern. A county-level search (LOCATES database) indicated that listed plant species occur in or near areas proposed for aerial clomazone use. Listed species found in these counties are the Texas prairie dawn-flower (*Hymenoxys texana*) in Fort Bend County and Texas trailing phlox (*Phlox nivalis* ssp. *Texensis*) in Hardin County. In areas proposed to receive aerial applications of clomazone, current information and analyses have identified a potential for direct effects to these listed plants. Label restrictions prohibit aerial applications of clomazone in some areas of Fort Bend County (North and East of State Highway 36). However, since EFED predicts with high certainty that clomazone will volatilize and move off site, these restrictions may offer limited protection to Texas prairie dawn-flower in Fort Bend County.

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 lb ai/A, EC₂₅ = 0.032 lb ai/A). Oat was the most sensitive monocot, with an EC₂₅ of 0.076 lb ai/A and an EC₀₅ of 0.0154 lb ai/A. Observed phytotoxic effects on plants included stunting, bleaching, and plant death. Reductions in percent seedling emergence were also observed with increasing concentrations of clomazone.

The acute listed species LOC was also exceeded for freshwater and estuarine/marine invertebrates. However, no listed estuarine/marine invertebrates inhabit rice-growing counties in Texas where aerial clomazone applications are proposed.

Lastly, the chronic LOC was exceeded for small (15g) and medium (35g) mammals that feed on short grass. There are no endangered small or medium sized mammals that inhabit rice-growing counties in Texas where aerial clomazone applications are proposed.

B. Indirect Effects to Listed Species

Current analyses do not indicate concerns for direct acute and chronic effects to other listed taxa inhabiting Texas rice-producing counties. However, because of the risk to listed and non-listed plants, unicellular algae, non-listed marine/estuarine invertebrates, and small and medium herbivorous mammals (short grass consumers only), listed species in all taxa may be affected indirectly by aerial applications of Clomazone to rice in the proposed areas of use. According to a county-level search, twelve listed animal species inhabit these counties: whooping crane (*Grus americana*), bald eagle (*Haliaeetus leucocephalus*), Attwater's greater prairie chicken (*Tympanuchus cupido attwateri*), Houston toad (*Bufo houstonensis*), interior least tern (*Sterna antillarum*), brown pelican (*Pelecanus occidentalis*), piping plover (*Charadrius melodus*), loggerhead sea turtle (*Caretta caretta*), Eskimo curlew (*Numenius borealis*), Kemp's ridley sea turtle (*Lepidochelys kempii*), red-cockaded woodpecker (*Picoides borealis*), and Louisiana black bear (*Ursus americanus luteolus*). None of these are considered to be obligates on the listed plant species indicated above, but RQs indicate direct risk to all terrestrial plants. Symbionts with the plant species listed above are not known.

Significant amounts of clomazone may be present in waters draining rice fields, especially after large rainfall events. Depending on the amount of rainfall, these concentrations will decrease with increasing

distance from the fields because of dilution, and can also decrease through volatilization from surface water. LOCs for aquatic plants were not exceeded; however, volatilization and aerial transport of clomazone may cause deposition of clomazone on emergent aquatic vascular vegetation. EFED does not require testing on emergent aquatic vascular plants, and further information on the effects of clomazone on these species would clarify the potential indirect effects due to their loss. Without this information, and because clomazone can affect the plant through contact with above ground vegetation, a risk to emergent aquatic vascular plants is assumed. Indirect effects to listed species are expected to occur through runoff and/or volatilization that causes the loss of emergent aquatic vascular plants, terrestrial plants, and unicellular algae. Based on the record of incidents involving damage to plants by volatilized clomazone, plants may be affected by offsite movement of clomazone up to 2 miles away from the site of application.

Chronic LOCs are exceeded for small and medium sized mammals that consume short grass. None of the listed species in the counties of the proposed clomazone use are obligates on small or medium herbivorous mammals. The Louisiana black bear may consume mammals as carrion, and the bald eagle may include small mammals in its diet. However, both of these species forage opportunistically, and have preferences for other food items (the bald eagle primarily consumes fish; the Louisiana black bear depends more on plants). Therefore, the loss of small and medium sized herbivorous mammals is not expected to cause indirect effects to listed species in the proposed areas of aerial clomazone use.

1. Listed Species in Freshwater Environments

Listed species that inhabit freshwater environments in the areas of proposed aerial clomazone use include the interior least tern and the Houston toad. These species may utilize freshwater areas near rice fields or downstream from drainage sources during the time of clomazone use. The interior least tern inhabits streams and rivers in this region, and may be affected by losses of emergent aquatic vascular vegetation and unicellular algae that provide food and/or habitat for prey (fish and freshwater invertebrates). This species nests on open sandy stream banks and islands, requiring no vegetation for this component of its life cycle. The Houston toad occupies ponds and wetlands during its breeding season. Losses of emergent aquatic vascular plants and unicellular algae could affect food resources and/or cover for the Houston toad during its aquatic phase. Loss of riparian vegetation may also affect water temperature, which could lead to losses of prey for terns or could affect tadpole survival for Houston toads.

2. Listed Species in Marine and Estuarine Environments

Listed species inhabiting marine and estuarine environments and/or nearby areas include Kemp's ridley sea turtle, loggerhead sea turtle, and brown pelican. These species of sea turtles should not be affected heavily by losses of terrestrial or emergent aquatic vegetation, since they require no vegetation for nesting and are not exclusively plant eaters. However, they do feed on marine/estuarine invertebrates in shallow waters along the Gulf Coast. Should clomazone reach these waters along the Texas coast and cause losses of invertebrate food resources, then the potential would exist for indirect effects to these sea turtle species. The brown pelican nests among dense vegetation on isolated islands off the Texas coast, and feeds exclusively on fish. Losses of vegetation could affect nesting if volatilized clomazone were to move into these areas.

The likelihood that clomazone will reach the Texas Gulf Coast via runoff or volatilization is minimal. This conclusion can be made because: 1) the percentage of rice-containing cropped area in Texas coastal counties is low, ranging from <1% to ~3% of the total acres in the county, 2) rice production in these counties occurs at a distance at least 15 miles from the coast, and 3) volatilization of clomazone is not

expected to occur at a distance greater than 2 miles from the sites of application. As a result, indirect effects to these listed species in marine and estuarine environments are expected to be unlikely.

3. Listed Species in Terrestrial Environments

Listed species in Texas rice-growing counties that are mainly dependent on terrestrial systems include the Louisiana black bear, red-cockaded woodpecker, and Attwater's greater prairie chicken.

The Louisiana black bear requires a large home range and generally inhabits lowland forests, though it can range into a variety of habitats. The main threat to this species is encroachment of agricultural land on their habitat, so its range may include or abut rice-cropped areas. Following winter hibernation, this species depends heavily on plants for food, and clomazone applications could cause indirect effects if it reached their home ranges during this critical period. However, the potential for indirect effects to the Louisiana black bear is expected to be low, because 1) their home ranges are large and require large areas of undisturbed forest, 2) according to the LOCATES database, they are present only in Lavaca and Victoria Counties within the proposed area of aerial clomazone application, and their presence there is possible but not confirmed, and 3) < 1% of total acres in Lavaca and Victoria Counties are cropped in rice.

The red-cockaded woodpecker is also heavily dependent on plants, since it inhabits mature living pines during the breeding period (occurring April - June) and consumes arboreal insects and seasonal wild plants. If areas containing red-cockaded woodpecker habitat are near rice fields, loss of nesting and feeding habitat could occur through contact with clomazone. Incidents involving volatilized clomazone include cases in which defoliation and mortality of nearby trees have occurred. Since this species occupies a relatively small habitat niche (e.g., it prefers older pine trees with decaying heartwood), indirect effects due to tree losses could have a large impact on individual survival. The LOCATES database lists this species in four counties within the proposed area of clomazone use, and its presence is possible but not known. Information about the location of current populations would aid in characterizing the risk of indirect effects to this species.

Attwater's greater prairie chicken nests in tallgrass prairie along coastal and nearby counties in Texas. Grassland vegetation is required for nesting (occurring April - May), and although the food habits of the prairie chicken include insects, leaves and seeds of plants also make up a portion of the diet. These species is known to occur in rice-producing counties, and could be indirectly affected if clomazone reached its habitat.

4. Listed Species Utilizing Multiple Environments

The bald eagle utilizes both terrestrial and aquatic environments, and its habitat preferences vary widely. While its diet consists mainly of fish, it also consumes small mammals and carrion. It is possible that plant losses could affect eagle prey, but since they forage opportunistically and on a variety of animals, the impact of indirect effects is likely to be low. Nesting occurs often in tall, mature trees, sometimes near agricultural areas. Volatilization could affect trees for nesting, especially since eagle pairs reuse nesting trees over several years. However, given the size of their territory and varied habitat preferences, the potential for indirect effects is probably low.

5. Species Inhabiting Texas During Winter or Migration

Piping plovers and whooping cranes are winter inhabitants of coastal and inland Texas. During their breeding season, piping plovers nest on beaches in shoreline and inland areas; however, little is known about their winter habitat requirements. Whooping cranes utilize a variety of habitats, including wetlands and prairies. Neither of these species is present in Texas during the proposed time of clomazone use, so no immediate indirect effects are expected to occur. If plant losses affect their required wintering habitat, indirect effects are possible. However, further information on piping plovers is necessary to fully assess the potential for indirect effects. Wintering populations of whooping cranes inhabit coastal areas, islands, and wildlife refuges along the Texas coast, so few indirect effects are expected to occur to this species.

The Eskimo curlew breeds in extreme northern latitudes and historically only utilized this area of Texas as a migration stopover. Recent sightings of this species have been reported, though some sources report that it is probably extinct. If it still exists, it is unlikely to be present during the time of clomazone application, since it is on its breeding ground at that time of year. If plant losses affect migration stopovers, then indirect effects would be possible. However, further information on this species is needed to fully assess the potential for indirect effects.

The above discussion provides only a general account of possible direct and indirect effects to listed species that may result from aerial applications of clomazone to rice. Refined analyses of risk to listed species using geographic information of use sites and species occurrence (available in the LOCATES database), “species profiles” provided by the Services and other sources, and information regarding the temporal nature of aerial clomazone applications is necessary to determine the true indirect effects to listed species. The greater the probability that aerial clomazone applications will produce effects on plants, the greater the concern for potential direct and indirect effects for listed species in this region, and therefore, the more intensive the analysis on the potential listed species of concern. Because of the high probability that clomazone will volatilize and move off site, these intensive analyses may need to be expanded to include counties neighboring areas proposed for aerial clomazone applications to rice.

C. Listed Species Critical Habitat

Critical habitat has not yet been established for any listed plant species that may be directly affected. Critical habitat has been established for other listed species that may be affected indirectly, including the whooping crane and the Houston toad.

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening-level taxonomic analysis (risk quotients, RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening-level risk assessment has identified potential concerns for indirect effects on listed species for those organisms dependent upon terrestrial plants. In light of the potential for indirect effects, the next step for EPA and the Service(s) is 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 the pesticide'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 the pesticide. Then EPA would determine whether use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that is potentially impacted directly by the use of the pesticide. EPA and the Service(s) are working together to conduct the necessary analysis.

This screening-level risk assessment for critical habitat provides a listing of potential biological features that, if they are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include the following: mammals, birds, amphibians, reptiles, freshwater and estuarine/marine fish, and freshwater and estuarine/marine invertebrates. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above, should additional work be necessary.

VIII. Probit Slope Response Relationship on the Listed Species Levels of Concern

The Agency uses the probit dose response relationship as a tool for providing additional information on the listed animal species acute levels of concern (LOC). The acute listed species LOCs of 0.1 and 0.05 are used for terrestrial and aquatic animals, respectively. The interpretation of acute listed species LOCs is presented in terms of the chance of an individual event (i.e., mortality or immobilization) should exposure at the estimated environmental concentration actually occur for a species with sensitivity to clomazone on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency assumes a probit dose response relationship, and uses the slope of the dose response calculated from the toxicity study used to establish the acute toxicity measurement endpoints for each taxonomic group.

In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope. The upper and lower bounds of the effects probability are based on available information on the 95% confidence interval of the slope. Studies with good probit fit characteristics (i.e., statistically appropriate for the data set) are associated with a high degree of confidence. Conversely, a low degree of confidence is associated with data from studies that do not statistically support a probit dose response relationship. In addition, confidence in the data set may be reduced by high variance in the slope (i.e., large 95% confidence intervals), despite good probit fit characteristics.

If information is unavailable to estimate a slope for a particular study, a default slope assumption of 4.5 is used as per original Agency assumptions of typical slope cited in Urban and Cook (1986). The 95% confidence intervals for the slopes are unavailable in cases where slope is based on a default assumption of 4.5.

Individual effect probabilities are calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by Ed Odenkirchen of the U.S. EPA, OPP, Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the LOC (0.1 for terrestrial animals and 0.05 for aquatic animals) is entered as the desired threshold. The following is the summary of screening assessment of listed terrestrial and aquatic species Levels Of Concern using probit slope relationship.

The estimates of probability of individual effects to each taxonomic group considered in this risk characterization are presented in **Table 22** below.

Table 22. Probit Slope Relationships

| Listed Species | Bobwhite quail | Rat | <i>Daphnia</i> | Rainbow trout | Mysid | Sheepshead minnow |
|---|-------------------------|---------------------------|---------------------------|---------------------------|---------------------------------------|---------------------------|
| Acute Tox. End Point LC50 | > 5620 ppm ¹ | 1369 mg ai/kg bw | 5.2 ppm | 19 ppm | 0.566 ppm | 40.6 ppm |
| Mean Slope | NA | 4.5 ² | 4.21 | 4.5 ² | 9.79 | 4.5 ² |
| Slope 95% Confidence Interval | NA | NA | 0.15 - 8.27 | NA | 5.82 - 13.77 | NA |
| Approximate Chance of Individual effect | NA | ~1 in 2.9x10 ⁵ | ~1 in 4.6x10 ⁷ | ~1 in 4.2x10 ⁸ | ⁴ ≤1 in 1x10 ¹⁶ | ~1 in 4.2x10 ⁸ |

¹Practically nontoxic without mortality

²Default value

³Some mortality occurred at 4 of the 5 dosage levels

⁴Actual probability is beyond the reporting limit for Excel

Based on these data and assumptions, the results show chance of individual effect appears minimal to all taxa. The estimated chance of individual effect ranges from ≤ 1 in 1x10¹⁶ to 1 in 2.9x10⁵.

A. Terrestrial listed species

4. Birds

Because there were no demonstrable effects in acute toxicity tests with birds, a slope cannot be calculated to use in estimating the probability of individual effects on birds.

5. Mammals

The results show that the chance of individual effect to listed mammal species is very small. The effect probability $p(z)$ is 3.4×10^{-6} or ~1 in 2.9×10^5 , assuming a listed species LOC of 0.1. Given the low probability of occurrence, it is recognized that this estimate is likely associated with considerable uncertainty. However, raw data were not provided to determine the true slope of the dose response, and hence, no estimates of the upper and lower 95% confidence limits are available to estimate the uncertainty. The individual mortality associated with the highest calculated RQ value for clomazone TGAI in mammals (0.04) is estimated to be 1 in 6.3×10^9 . This RQ is calculated using a scenario with the highest application rate (0.6 lb ai/A), and 15g mammals consuming short grass.

B. Aquatic Animals

4. Freshwater invertebrate (waterflea)

Based on an assumption of a probit dose response relationship with a mean estimated slope of 4.21 (95% CI = 0.15 - 8.27), the corresponding estimated effect probability associated with the listed species LOC of 0.05 is 2.2×10^{-8} or approximately 1 in 4.6×10^7 . Upper and lower estimates of the effects probability associated with the listed species LOC are 1 in 2.37 and ≤1 in 1×10^{16} , respectively. Using the EEC calculated from the Interim Rice Model assuming the maximum application rate, the RQ for *Daphnia mgana* (0.09) results in a probability of individual mortality estimated at 1 in 2.05×10^5 .

5. **Freshwater and marine/estuarine fish (rainbow trout and sheepshead minnow)**

Based on an assumption of a probit dose response relationship with a mean estimated slope of default 4.5, the corresponding estimated chance of individual mortality associated with the listed species LOC of 0.05 is 2.40×10^{-9} or one in 4.17×10^8 for both freshwater and marine/estuarine fish. Because raw data are not available to estimate the slopes for each of these groups of fish, default inputs were required for estimating the probability of individual effect. Since the inputs were identical for each group, the estimated probability of an event occurrence is the same. Given the low probability of occurrence, it is recognized that this estimate is likely associated with considerable uncertainty. Raw data were not provided to determine the true slope of the dose response, and hence, no estimates of the upper and lower 95% confidence limits are available to estimate the uncertainty. Using EECs calculated from the Interim Rice Model assuming the highest application rate, the RQs for the rainbow trout (0.02) and the sheepshead minnow (0.01) result in probabilities of individual mortality estimated at 1 in 6.36×10^{12} and ≤ 1 in 1×10^{16} (beyond the reporting value for Excel) for freshwater and estuarine fish, respectively.

6. **Marine/estuarine invertebrates (Mysid shrimp)**

Based on an assumption of a probit dose response relationship with a mean estimated slope of 9.79 (95% CI = 5.82 - 13.77), the corresponding estimated effect probability associated with the listed species LOC of 0.05 is $\leq 1 \times 10^{16}$ or ≤ 1 in 1×10^{16} . The estimated probability is beyond the reporting limit for Excel, so the estimated probability cannot be known using this version of the model. However, it is clear that the probability is small. Upper and lower estimates of the effects probability associated with the listed species LOC are 1 in 5.39×10^{13} and ≤ 1 in 1×10^{16} , respectively. However, using the mean slope and the EEC calculated from the Interim Rice Model using the maximum application rate, the RQ for the mysid (0.82) results in a probability of individual mortality estimated at 1 in 5.09. This estimate implies that the probability of individual mortality is high, which corresponds to apparent concerns throughout this risk analysis for estuarine invertebrates.

Appendix A: Ecotoxicity Tables

I. Toxicity to Terrestrial Animals

A. Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of clomazone to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below.

| Avian Acute Oral Toxicity | | | | | |
|---|------|---------------------------|----------------------|----------------------------------|-----------------------------------|
| Species | % ai | LD50 (mg/kg) | Toxicity Category | MRID No. Author/Year | Study Classification ¹ |
| Northern bobwhite quail (<i>Colinus virginianus</i>) | 88.8 | > 2510 mg/kg ² | practically nontoxic | Acc. No. 248475 Beavers, 1982 | Acceptable |
| Mallard duck (<i>Anas platyrhynchos</i>) | 88.8 | > 2510 mg/kg ² | practically nontoxic | Acc. No. 248475 Beavers, 1982 | Acceptable |

1 Acceptable (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)

2 No mortalities were observed at the highest dose.

Since the LD₅₀ is >2510 mg/kg, clomazone is categorized nontoxic to avian species on an acute oral basis.

Two subacute dietary studies using the TGAI are required to establish the toxicity of clomazone to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

| Avian Subacute Dietary Toxicity | | | | | |
|---|------|-------------------------------|----------------------|----------------------------------|----------------------|
| Species | % ai | 5-Day LC50 (ppm) ¹ | Toxicity Category | MRID No. Author/Year | Study Classification |
| Northern bobwhite quail (<i>Colinus virginianus</i>) | 88.8 | > 5620 ppm ² | practically nontoxic | Acc. No. 248475 Beavers, 1982 | Acceptable |
| Mallard duck (<i>Anas platyrhynchos</i>) | 88.8 | > 5620 ppm ² | practically nontoxic | Acc. No. 248475 Beavers, 1982 | Acceptable |

1 Test organisms observed an additional three days while on untreated feed.

2 No mortalities were observed at the highest dose.

Since the LC₅₀ is > 5620 ppm, Clomazone is categorized practically toxic to avian species on a subacute dietary basis.

B. Birds, Chronic

Avian reproduction studies using the TGAI are required for clomazone because the birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, and the pesticide is stable in the environment to the extent that potentially toxic

amounts may persist in animal feed. The preferred test species are mallard duck and bobwhite quail.

Avian Reproductive Toxicity

| Species | % ai | NOAEC (ppm a.i.) | Treatment Effects | MRID No. Author/Year | Study Classification |
|---|------|---------------------|---|--------------------------------|-------------------------|
| Northern bobwhite quail (<i>Colinus virginianus</i>) | 90.7 | 1020 | No toxic-induced mortalities or pathological responses | 45178101 Frey, et al., 1998 | Acceptable |

No additional data regarding the reproduction effects of clomazone in mallards have been submitted.

C. Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below.

Mammalian Toxicity

| Species/ Study Duration | % ai | Test Type | Toxicity Value | Affected Endpoints | MRID No. |
|--|------|----------------------------------|--|--|----------|
| Laboratory rat (<i>Rattus norvegicus</i>) | 88 | acute oral | LD ₅₀ = 2077 mg/kg (male) LD ₅₀ = 1369 mg/kg (female) | | 00117121 |
| Laboratory rat (<i>Rattus norvegicus</i>) | 88 | 2-generation rat reproduction | NOAEL = 1000 ppm (50 mg/kg) | parental body weight gain, body weight during gestation, and food consumption | 00151108 |

An analysis of the results indicate that Clomazone is categorized practically non-toxic to small mammals on an acute oral basis.

D. Insect and other terrestrial invertebrates

A honey bee acute contact study using the TGAI is required for clomazone because its use may result in honey bee exposure. An earthworm toxicity study was also submitted and the results of these tests are tabulated below.

Nontarget Insect/Invertebrate Acute Contact Toxicity

| Species | % ai | LC50 | MRID No. Author/Year | Study Classification |
|--|------|--|------------------------------|---------------------------|
| Earth worm (<i>Eisenia foetida</i>) | 89.9 | 0.0057 mg/cm ² (48 hr. filter paper) 215 mg/kg (7 day soil) 156 mg/kg (14 day soil) | 41557503 Swigert, 1990 | Supplemental ^a |
| Honeybee (<i>Apis mellifera carnica</i> L.) | 89.5 | >85.29 ug a.i./bee (48 hr. LC50) >100 ug a.i./bee (48 hr. contact LD50) | 45178102 Nengel, S., 1998 | Acceptable |

^aStudy is scientifically sound but EPA/OPP does not have any guideline for this study.

Since the acute contact toxicity to honey bees is >100 ug a.i./bee, clomazone is considered practically non-toxic to honey bees.

II. Toxicity to Freshwater Aquatic Animals

A. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of Clomazone to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Freshwater Fish Acute Toxicity

| Species/ Flow-through or Static | % ai | 96-hour LC50 (ppm) (measured) | Toxicity Category | MRID No. Author/Year | Study Classification |
|--|------|-------------------------------------|-------------------|------------------------------------|-------------------------|
| Rainbow trout (<i>Oncorhynchus mykiss</i>) Flow-through | 88.8 | 19 | slightly toxic | Acc. No. 248475 Rhoderick, 1982 | Acceptable |
| Bluegill sunfish (<i>Lepomis macrochirus</i>) Flow-through | 88.8 | 34 | slightly toxic | Acc. No 248745 Rhoderick, 1982 | Acceptable |

Since the LC50 falls in the range of 10-100 ppm, Clomazone is categorized as slightly toxic to freshwater fish on an acute basis.

B. Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for clomazone because the end-use product may be applied directly to water or is expected to be transported to water from the intended use site and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. The preferred test species is rainbow trout. Results of this test are tabulated below.

Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

| Species/ Study Duration | % ai | NOAEC ¹ (ppm) | Endpoints Affected | MRID No. Author/Year | Study Classification |
|---|------|-----------------------------|--|-------------------------------|-------------------------|
| Rainbow trout (<i>Oncorhynchus mykiss</i>) | 95.6 | 2.29 | %Survival, mean length, average weight | Acc. No. 073830 Anon, 1985 | Ancillary |

EFED has never required the 72-4 guideline study. The registrant sent this study voluntarily without request. Since there are some deficiencies, the study is not considered acceptable. However, it does provide some useful data and is considered to be supplemental.

C. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of Clomazone to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Invertebrate Acute Toxicity

| Species/Static or Flow- through | % ai | 48-hour LC50/ EC50 (ppm) (measured/nominal) | Toxicity Category | MRID No. Author/Year | Study Classification |
|--|------|---|-------------------|---------------------------------|-------------------------|
| Waterflea (<i>Daphnia magna</i>) Static | 88.8 | 5.2 ppm | moderately toxic | Acc. No. 248475 Graney, 1982 | Acceptable |

Since the LC50/EC50 falls in the range of 1-10 ppm, Clomazone is categorized as moderately toxic to aquatic invertebrates on an acute basis.

D. Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for clomazone since the end-use product is expected to be transported to water from the intended use site. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Aquatic Invertebrate Life-Cycle Toxicity

| Species/Static Renewal or Flow-through | % ai | 21-day NOAEC | Endpoints Affected | MRID No. Author/Year | Study Classification |
|--|------|--------------|--------------------|-------------------------------|----------------------|
| Water flea <i>Daphnia magna</i> . Flow-through | 95.6 | 2.20 ppm | Reproduction | 073997, 073616 Anon., 1985 | Acceptable |

III. Toxicity to Estuarine and Marine Animals

A. Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for clomazone because the active ingredient is expected to reach the estuarine/marine environment since the

active ingredient is used in coastal counties where it is expected to reach estuarine/marine environment. The preferred test species is sheepshead minnow. Results of these tests are tabulated below.

| Estuarine/Marine Fish Acute Toxicity | | | | | |
|--|--------|-------------------------------|-------------------|-------------------------------|----------------------|
| Species/Static or Flow-through | % ai | 96-hour LC50 (ppm) (measured) | Toxicity Category | MRID No. Author/Year | Study Classification |
| Sheepshead minnow (<i>Cyprinodon variegatus</i>) | 92.94% | 40.6 | slightly toxic | Acc. No. 263081 Barrows, 1986 | Acceptable |

Since the LC50 falls in the range of 10 - 100 ppm, Clomazone is categorized slightly toxic to estuarine/marine fish on an acute basis.

B. Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for Clomazone because the active ingredient is expected to reach estuarine/marine environment because of its use in coastal counties. The preferred test species are mysid shrimp and Eastern oyster. Results of these tests are tabulated below.

| Estuarine/Marine Invertebrate Acute Toxicity | | | | | |
|--|-------|-------------------------------|-------------------|--------------------------------|----------------------|
| Species/Static or Flow-through | % ai. | 96-hour EC50 (ppm) (measured) | Toxicity Category | MRID No. Author/Year | Study Classification |
| Eastern oyster (shell deposition) (<i>Crassostrea virginica</i>) Flow-through | 95.4 | 5.3 ppm | moderately toxic | Acc. No. 260723 Carr, 1985 | Acceptable |
| Mysid Shrimp <i>Americamysis bahia</i> Flow-through | 92.94 | 0.566 ppm | highly toxic | Acc. No. 263080 Williams, 1986 | Acceptable |

Since the LC50/EC50 falls in the range of 0.1 - 10.0 ppm, clomazone is category ranges from moderately toxic to highly toxic to estuarine/marine invertebrates on an acute basis.

D. Estuarine and Marine Invertebrate, Chronic

An estuarine/marine invertebrate life-cycle toxicity test using the TGAI is required for clomazone because the end-use product is expected to be transported to the estuarine/marine environment from the intended use site, the mysid shrimp acute EC50 is less than 1 mg/L, and the EEC in water is equal to or greater than 0.01 of any acute EC50 value. The preferred test species is mysid shrimp. No study has been submitted.

IV. Toxicity to Plants

A. Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for clomazone because clomazone is used in non-residential outdoor use patterns and moves off the application site through volatilization (vapor pressure $>1.0 \times 10^{-5}$ mm Hg at 25°C) and endangered or threatened plant species may be associated with the application sites.

For seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (*Glycine max*), and the second is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (*Zea mays*).

Tier II tests measure the response of plants, relative to a control, and five or more test concentrations. Results of Tier II toxicity testing on the technical/TEP material are tabulated below.

| Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II) with Clomazone TGAI | | | | | |
|---|------|---|--------------------------------------|---------------------------|---------------------------|
| Species | % ai | EC25 (lbs ai/A) Endpoint Affected | EC05 (lbs ai/A) Endpoint Affected | MRID No. Author/Year | Study Classification |
| Monocot- Corn | 99.7 | 0.173 dry weight | 0.167 dry weight | 41557501, Chetram 1990 | Acceptable |
| Monocot- onion | | 0.014 fresh weight | 0.0062 fresh weight | | Acceptable |
| Monocot- ryegrass | | 0.063 dry weight | 0.0556 dry weight | | Acceptable |
| Monocot- oat | | 0.322 dry weight | 0.167 dry weight | | Acceptable |
| Dicot- cucumber | | 0.278 dry weight | 0.167 dry weight | | Acceptable |
| Dicot- Soybean | | > 1.500 | >1.500 | | Acceptable |
| Dicot- carrot | | 0.081 dry weight | < 0.081 dry weight | | Acceptable |
| Dicot-cabbage | | 0.170 fresh weight | 0.167 fresh weight | | Acceptable |
| Dicot- tomato | | 0.014 dry weight | <0.0062 dry weight | | Acceptable |
| Dicot- lettuce | 98.6 | 0.002 dry weight | 0.0019 dry weight | | 42165705, Chetram 1991 |

For Tier II seedling emergence tests with Clomazone TGAI lettuce is the most sensitive dicot and onion is the most sensitive monocot.

| Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II) with Clomazone TEP (Command 3ME herbicide) | | | | | |
|--|------|--------------------------------------|--------------------------------------|-------------------------|----------------------|
| Species | % ai | EC25 (lbs ai/A) Endpoint Affected | NOEC (lbs ai/A) Endpoint Affected | MRID No. Author/Year | Study Classification |

Nontarget Terrestrial Plant Seedling Emergence Toxicity (Tier II) with Clomazone TEP (Command 3ME herbicide)

| Species | % ai | EC25 (lbs ai/A) Endpoint Affected | NOEC (lbs ai/A) Endpoint Affected | MRID No. Author/Year | Study Classification |
|-------------------|------|--------------------------------------|--------------------------------------|---------------------------|----------------------|
| Monocot- corn | | 0.76 shoot weight | 0.42 shoot weight | 45397701, Schwab, 2001 | Acceptable |
| Monocot- onion | | 0.19 shoot weight ¹ | 0.14 shoot weight | | Acceptable |
| Monocot- ryegrass | | 0.097 shoot weight | 0.046 shoot length | | Acceptable |
| Monocot- oat | | 0.12 shoot weight | 0.0154 shoot weight | | Acceptable |
| Dicot- cucumber | | 1.1 shoot length | 0.0154 shoot length | | Acceptable |
| Dicot- soybean | | >1.25 shoot length | 0.14 shoot length | | Acceptable |
| Dicot- carrot | | 0.23 shoot weight | 0.14 shoot weight | | Acceptable |
| Dicot-cabbage | | 0.36 shoot weight | 0.14 shoot weight | | Acceptable |
| Dicot- tomato | | 0.18 shoot weight | 0.14 shoot weight | | Acceptable |
| Dicot- lettuce | | 0.032 shoot length | 0.0051 shoot length | | Acceptable |

B. Aquatic Plants

Aquatic plant testing is required for clomazone because it has outdoor non-residential terrestrial uses that may move off-site by runoff (solubility >10 ppm in water) and by volatilization.

Aquatic Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs ai/A or less) and any pesticide showing a negative response equal to or greater than 50% in Tier I tests. The following species should be tested at Tier II: *Kirchneria subcapitata* (formerly *Selenastrum capricornutum*), *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Results of Tier II toxicity testing on the technical material are tabulated below.

Nontarget Aquatic Plant Toxicity (Tier II)

| Species | % ai | EC50 (ppm) / duration | MRID No. | Author/Year | Study Classification |
|---|------|--------------------------------|----------|-------------------|----------------------|
| Vascular Plants | | | | | |
| Duckweed (<i>Lemna gibba</i>) | 90 | 40 / 14 days NOAEC = 12 ppm | 44994803 | Kranzfelder, 1999 | Acceptable |
| Duckweed (<i>Lemna minor</i>) | 87.8 | 43.4 / 7 days | 44924902 | Bruns, 1998 | Supplemental |
| Nonvascular Plants | | | | | |
| Green algae (<i>Scenedesmus subspicatus</i>) | 30.8 | 0.8 / 3 days | 44924903 | Bogers, 1998 | Supplemental |
| Green algae (<i>Kirchneria subcapitata</i>) | 89.9 | 3.7 / 5 days | 41557502 | Suprenant, 1990 | Acceptable |
| Marine diatom (<i>Skeletonema costatum</i>) | 90 | 1.2 / 5 days | 44994802 | Kranzfelder, 1999 | Acceptable |
| Freshwater diatom (<i>Navicula pelliculosa</i>) | 90 | 0.159 / 5 days | 44994801 | Kranzfelder, 1999 | Acceptable |
| Blue-green algae (<i>Anabaena flos-aquae</i>) | 87.8 | 11.1 / 4 days | 44924901 | Bruns, 1998 | Acceptable |

The Tier II results indicate that freshwater diatom is the most sensitive nonvascular aquatic plant.

Appendix B: Non-target plant incidents

Non-target Plant Incidents in 1986

Wisconsin Department of Agriculture, Trade, and Consumer Protection submitted eight incidents and FMC submitted one incident involving non-target plant incident from the use of clomazone 4EC formulation on soybeans using a broadcast spray application. One of the incidents involved wind-borne soil contaminated with clomazone after application. Other incidents were a result of volatilization that occurred shortly after rain, fog, or high humidity. The non-target plants that were damaged were up to one mile away from the application site. The species and type of nontarget plants that were found to be very sensitive to clomazone are ornamentals, poplars, wild cherry, willow, tomato, barley, alfalfa, plums, and box elders. Damage also occurred on dairy pastures, wooded lot, residential areas, ash trees, red oaks, and black locusts. Much of the vegetation cited did not green back during the season. The tomatoes and strawberries were replanted, barley and alfalfa fields died, and plum and willow trees defoliated.

Another incident occurred in Ohio as a result of soybeans being sprayed with the 4EC formulation during minimal wind in accordance with the label. Two to three days after application, rainfall came followed by wind. The whitening of the plants was very apparent 10 days after application. The annual flowers died. Following another rain, maples, grapes, clematis and Jerusalem artichokes showed damage. About two months after application, damage was still apparent to raspberry bushes, sorrel, teasel, and willow trees. Following another rain, ferns, radishes, and nontarget plants in a wood 1200 feet from the application site showed damage. Damage to locust, cottonwood, and other deciduous trees, as well as sorrel and brambles can be seen 600 yards (1800 feet) away. Some of these plant species recovered later.

The Minnesota Department of Agriculture submitted nine incidents of nontarget plants damage from the use of 4EC clomazone formulation on soybeans using broadcast spray application. Of the nine incidents, one incident occurred after light frost and eight occurred after a rainfall. The sensitive species that did not recover within the season are plum, willow, tomatoes, raspberries, roses, gardens, vegetables, oak tree, box elder and honey locust. Other species that were affected are barley, alfalfa, oats, lettuce, radish, apple, maple, ash, peas, cherry, plum, cottonwood and wild cherry. The incidents occurred up to 0.7 miles away from the application sites (soybean).

The Michigan Department of Agriculture submitted five incidents and the Ohio Department of Agriculture submitted one incident of non-target plant damage from the use of 4EC clomazone on soybeans. Of the six incidents, one may be attributed to spray drift and five were attributed to volatilization. According to the state inspectors, some of the volatilization sites exhibit injury to the nontarget plants in a pattern that could not be attributed to drift or runoff. The nontarget plants at the volatilization sites seem to have injury shortly after a rainfall. The nontarget plants that were damaged are oats, tomatoes, raspberries, fruit trees, ornamentals, pastures, poison ivy, and trees (dogwood, basswood, honey locust, ash, shagbark hickory, wild cherry, maple, Austrian pine, and willow). Tomato, raspberries and Austrian pine are known to have died. We have no data on whether the other species survived. Extensive defoliation of trees was observed at some sites. The damages were reported up to 0.75 mile away from the application site. Some sites reported visible damage at least 1.5 months after application but no follow-up was reported to determine if the damages were season-long or any more mortalities observed.

Non-target Plant Incidents in 1992

FMC reported one nontarget plant incident from the use of the EC formulation in each of these states:

Iowa, Alabama, Kentucky, and Ohio.

Nontarget Plant Incidents for 1993

In 1993 there were a large number of non-target plant incidents from the use of clomazone EC formulation on cotton and soybean. Surveys were done to determine the extent of the incidents and the problem. FMC was asked to provide data from the 800 phone number calls on clomazone. The following is a summary of the minimal number of non-target plant and ecological incidents from the phone summary and state surveys that were reported to FMC:

- Alabama - 8 complaints on pecan damage
- Arkansas - 96 complaints on vegetable, strawberries, cauliflower, peach, plum, apple, rose, trees, cherries, berries, milo and wheat, oak, gardens, redbud trees, walnuts, azaleas, ferns, flowers.
- Louisiana - 10 complaints on peanuts and pecans
- Missouri - 34 complaints on corn, pecans, dogwood, tomato, radish
- Mississippi - 8 complaints on rose, gardens, pecans
- Ohio - several plants in one complaint
- Tennessee - 166 complaints on trees, shrubs, nut trees, cherry trees, pecans, oak trees, corn, pasture, gardens, apple, vegetables, blackberry, rose, fruit trees, peach, and a fish kill from runoff.
- Texas - 8 complaints on nontarget plants.
- North Carolina - 2 complaints on nontarget plants.

The total number of the above complaints that FMC provided to the EPA from phone call-ins is at least 333. The above survey revealed that pecan was a common sensitive species in the southern states that reported plant species. Most of the clomazone application at the time was not incorporated on cotton. Data on the average daily wind speed for Mississippi every day in May was <10 mph. For average wind speed in the Missouri boot heel region from May 1 to 23, 16 days of those days were \leq 10 mph and seven of the days were >10 mph. During some visits to the Missouri incident sites, observations were made of the distances from the incident sites to the application sites. These observations are:

- 0 feet to 150 feet = 72 incidents
- 150 feet to 500 feet = 25 incidents
- 501 feet to 1050 feet = 12 incidents
- 1050 feet to 1500 feet = 10 incidents

The buffer zones of 1000 feet and 1500 feet were added in 1989. Although there were several instances in which the cotton sites of application did not adhere to the buffer zones on the label, there were many incidents in which the buffer zones were adhered to. For those sites where nontarget plant incidents occurred, most of the applications were made when the wind speed was less than 10 mph as required on the label.

A survey of state activities concerning Command was conducted by EPA regions 4, 6, and, 7. There were 569 complaints on nontarget vegetative damage.

The spring of 1993 was wet with late applications being made. Some aerial applications were made in Mississippi and Alabama under section 24C. There was some failure to incorporate clomazone due to the wet ground. At the time of the incidents, some of the soil surfaces became dry from some windy conditions several days after most of the applications were made. Clomazone contaminated soil particles

were blown to sensitive plants where injury occurred. In addition, volatilization also occurred causing clomazone to be transported to nontarget sensitive plants. A small minority of the complaints stems from spray drift.

Missouri State officials indicate that the blowing of sandy loam soil after application contributed to the movement of clomazone in the boot heel region. Mississippi State officials indicate that volatility was the primary cause in their state. Tennessee State officials saw damage to nontarget plants up to 2 miles from the site of application. Although FMC's literatures on Command say that the whitening of the plants "lasts only 14 to 30 days," the state and EPA regional officials indicate that the whitening on many of the nontarget plants was much longer than 30 days. Observations by the State and EPA regional officials observed widespread mortalities of nontarget plants at several incident sites.

Tennessee State officials made some recommendations to the EPA to mitigate the movement of command off the application site. They are

1. Prohibit the 2nd or lay-by application of clomazone.
2. Clomazone is to be restricted use.
3. Cut the rates of application of clomazone by ½.
4. Application of clomazone should be at the maximum boom height of 24 inches, the maximum pressure of 30 psi, and wind <10 mph.
5. There is to be a setback of 1500 feet from desirable plants and residences.

To illustrate the damage to nontarget crops, one incident involving 2,000 30-year-old pecan trees in Tennessee occurred. In these incidents, the pecan trees were exposed in 1992 and were weakened with the pecans aborting in the development. In 1993, several of the trees died and others aborted the fruit and defoliated. Although the label has requested a 1500-foot buffer from desirable vegetation, the application was made 1800 feet from the pecan groves and every tree in the 2-mile across a pecan orchard was affected by the off-application site movement of clomazone. Apparently, the clomazone volatilizes and moves into the orchard and re volatilize again after rainfall. Nontarget plants in the woods ¾ mile from the application site were bleached white. Although the FMC brochure says that the whitening "lasts only 14 to 30 days," the pecans were white when observed by state officials four months later. Another incident occurred again in 1994.

In June 1993, there was a clomazone incident in New Hampshire. An organic commercial vegetable grower's vegetables bleached white by movement off the site of clomazone from a pumpkin field that was broadcast applied. Application was made on a calm day and 300 feet (less than 1,500 feet buffer) from the organic vegetables and without the required drift reducing additive.

Nontarget Plant Incidents in 1996

FMC reported one nontarget plant incident in Colorado from exposure to clomazone 4EC.

Louisiana Department of Agriculture submitted one nontarget plant incident from exposure to the EC formulation.

Nontarget Plant Incidents in 1997

Prior to 1997, FMC has registered a new formulation of clomazone, 3ME which is a micro encapsulated formulation. The 3ME was supposed to cut down on the amount of volatility of clomazone. The first registration of this product was for soybeans with broadcast application.

In 1997, several incidents of clomazone damage to nontarget plants occurred with the 3ME formulation. The following incidents were reported for 1997:

Indiana State Chemist's office submitted 11 cases to EPA region five regarding nontarget plant injury from clomazone 3ME. Of the submitted cases, about a quarter of the cases were applied when the wind speed was >10 mph and the application site did not use the 1000 or 1500 foot buffer zones. There was a corn field that suffered damage from the application site ½ mile away and hickory trees that were defoliated 1½ mile away from exposure to clomazone. In one case, the nontarget plants that were damaged from clomazone were 300 feet away from the edge of the field in the opposite side of the field where wind would have carried the clomazone if drift had occurred.

Wisconsin Department of Agriculture submitted 49 cases of clomazone damage to nontarget plants in which nine cases involve the 4EC formulation and 40 involve the 3ME formulation. The data from these cases indicate that the nine 4EC formulation cases were all incorporated and the 40 cases of 3ME were all not incorporated. The set back buffers for the labels in Wisconsin call for 300 feet from desirable plants and 1200 feet to residences, commercial fruit and greenhouses. It appears that most of the violations were a result of not enforcing the buffer zones of 300 feet or 1200 feet. One label from Illinois firm did not have any set back buffer zones. Of the 49 cases, only two are known to have wind speeds at the time of application of >10 mph. The nontarget species that were impacted beside garden, trees, bushes, and ornamental are alfalfa, raspberries, apple, ash, maple, mulberry, oats, clover, locust, radishes, greenhouse plants, birch, corn, strawberries, tomatoes, peppers, basswood, hazelnut, cherry, plums, and linden. Damage was also as diverse as to organic field contamination, and as widespread as to 1700 acres of trees, oats and alfalfa and to 1,000 newly planted trees. Adverse impacts to nontarget plants were seen as far as 1/4 mile away. Many of the fields were reported to have clomazone damage on all sides of the field and not on one side as would be expected in a spray drift scenario. It appears that the incorporated 4EC formulation did not move beyond the 300 feet.

Minnesota Department of Agriculture submitted 17 complaints of clomazone 3ME impacts on nontarget plants. The data submitted is sketchy but the amount of time between application and symptoms appearing ranges from three days up to 2½ weeks.

Iowa Department of Agriculture submitted 15 complaints of clomazone 3ME used on soybeans in 1997. Only one case had the wind been >10 mph at time of application. The nontarget species affected are linden tree, choke cherry, oat, willow, alfalfa, pear, radish, tomato, strawberry, dogwood, corn, rhubarb, filbert, potato, beet, sweet corn, hickory tree, spinach, peony, raspberry, grape, ash, and birch. An organic farm was also adversely impacted. Nontarget plants were adversely impacted from up to 2 miles away from the site of application. The appearance of symptoms on the nontarget vegetation ranges from three days to three weeks after the application of clomazone.

During a June 30, 1997 telephone conference calls between the States of WI, MN, MI, IA, IN, and IL; the EPA regions and EPA/OPP; the States have indicated that FMC is slowly over time amending the label to reduce the set back distances from residential and desirable vegetation. The States have said that the reduction in the set back distances is unwarranted.

Wisconsin also indicated in the correspondence to EPA "that the damage done by 3ME appears to be more severe and longer lasting than the 4EC. Trees are turning white a month after the initial investigation."

The incidents that FMC submits from 1986 to 1997 appear to only reflect the court cases and not any other incidents except for the phone survey that was conducted at the request of EPA. Therefore it is reasonable to assume that there are much more incidents happening than are reported under 6(a)(2).

Recent Clomazone Incidents (2000 - 2004) from Arkansas

| Year | Number of Total Complaints | Number Confirmed | Number of Ground Applications | Number of Aerial Applications |
|------|----------------------------|------------------|-------------------------------|-------------------------------|
| 2000 | 28 | 12 | 12 | 0 |
| 2001 | 15 | 8 | 6 | 2 |
| 2002 | 12 | 8 | 4 | 2 |
| 2003 | 15 | 12 | 6 | 4 |
| 2004 | 14 | 7 | 2 | 4 |

Of the total number of incidents confirmed for the five-year period, only one complaint was not regarding a home garden or landscape plants. The complaints were submitted to Jim Breithaupt, EFED from Arkansas State Plant Board, Pesticide Division.