INFORMATION *and* REPORT *concerning*

HEXAZINONE

submitted to the

PESTICIDE REGISTRATION EVALUATION COMMITTEE

pursuant to the

PESTICIDE CONTAMINATION PREVENTION ACT

by

E. I. du Pont de Nemours and Company
Wilmington, Delaware

April 9, 2011

INTRODUCTION

The following Information and Report Concerning Hexazinone is submitted by E. I. du Pont de Nemours and Company ("DuPont), in response to a November 1, 2010 Notice of Hexazinone Residue Detections in California Groundwater and Registrant Opportunity to Request a Hearing ("Notice") issued by the Department of Pesticide Regulation ("DPR" or "Department") pursuant to the Pesticide Contamination and Prevention Act ("PCPA"), Cal. Food & Agric. Code § 13149. (Attachment 1). DuPont filed a timely response and request for a hearing on November 23, 2010. (Attachment 2).

In preparation for the hearing, and pursuant to Section 13150 of the PCPA, DuPont is submitting this Information and Report Concerning Hexazinone ("Report"). The Report includes all of the information requested by the Department in the attached document entitled Information On the Registrant's Report and Documented Evidence. (Attachment 3). For ease of reference, we have followed the outline in Attachment 3 in providing this information.

SUMMARY

Hexazinone has been detected in some well water samples in the state of California. This is a threshold finding under the PCPA, which requires no further regulatory action if the material detected in groundwater, at the levels detected "has not polluted, and does not threaten to pollute, the groundwater of the state in any region within the state." Cal. Food & Agric. Code § 13150(a) (summarized in Attachment 3). The term "pollution," according to Section 13142(j) of the Code, "means the introduction into the groundwaters of the state of an active ingredient, other specified product, or degradation product of an active ingredient of a pesticide ***above a level, with an adequate margin of safety that does not cause adverse health effects.***" (Emphasis added.) DuPont demonstrates herein that the concentrations at which hexazinone has been detected does not exceed this level and that no further regulatory action is required to prevent pollution of groundwater in California by hexazinone.

The number of wells in which hexazinone was detected in any amount was small (26 out of 2300 wells), and the determination that hexazinone reached groundwater as a result of legal agricultural use was based on detections in 2 counties: 3 wells in one section in Fresno County, and 2 wells in adjacent sections in San Joaquin County. More importantly, the highest level at which hexazinone was detected was 0.274 parts per billion ("ppb").

The Health Advisory Level ("HAL") established for hexazinone by the United States Environmental Protection Agency ("US EPA") is 400 ppb. The level is based on a No Observable Adverse Effects Level ("NOAEL"), similarly established by US EPA, of 5.00 and 4.97 mg/kg/day in male and female dogs, respectively, and adjusted with an uncertainty factor of 100 to give a chronic reference dose (Chronic RfD) 0.05 milligrams per kilogram of body weight per day ("mg/kg/day"). The US EPA has set the health advisory level for hexazinone at 400 ppb using conservative presumptions that a person drinks 2 liters of water per day, weighs 70 kg, and should not receive over 20% of the RfD from drinking water.

It is therefore clear that the Health Advisory Level, a "level, with an adequate margin of safety, that does not cause adverse health effects," is at least 1000 times greater than the maximum concentration at which hexazinone was detected in any well. Thus, hexazinone "has not polluted, and does not threaten to pollute, the groundwater of the state in any region within the state."

Restricting the use of hexazinone, whether through cancellation or through requirements for mitigation, has the potential for causing significant economic impacts to California hay and forage producers. Hexazinone is the preferred herbicide for control of several weeds in alfalfa, particularly groundsel (*Senecio vulgaris)*, that are toxic to horses and cattle. Because the presence of even small amounts of groundsel poses a threat to livestock, groundsel-containing forage has a significant effect on the quality of alfalfa hay and the price that a grower will receive. According to Dr. Dan Putnam, the price penalty for hay containing toxic weeds may be at least a reduction to 50% of the price of hay that would otherwise be rated Fair (Putnam, April 7, 2011) and the Fair rating may bring less than 50% of the value of Supreme or Premium.

Mitigation options appear to be limited. In leaching Groundwater Protection Areas (GWPAs), managing irrigation by targeting 130% of the evapotranspiration would require sprinkler systems or drip irrigation, irrigation methods that are uneconomical in the case of alfalfa. For runoff GWPAs, draining irrigation water into a holding pond or recirculating irrigation water would be necessary to minimize the potential for transport of hexazinone to groundwater. Either option requires investments in land and equipment that will be difficult to implement for hay and forage operations, particularly in the case of alfalfa, where the value per acre is not high enough to justify either method.

The current labels (*e.g.*, Attachment 4) include a groundwater Environmental Hazard statement and directions for use that are intended to minimize the potential for hexazinone to leach to groundwater while maintaining efficacy and high quality hay. Applications to sandy, rocky or gravelly soil are prohibited, and the maximum application rate is restricted depending on the soil type and percentage organic matter. The labels already embody significant and sufficient user restrictions to prevent pollution of groundwater. These restrictions have been on the hexazinone label for many years and demonstrate an on-going commitment by DuPont to respond to EPA's evaluation of the leaching potential.

Because hexazinone has been detected in low concentrations in a very small percentage of wells sampled throughout the US (Attachment 5), the label instructions appear to be successful in minimizing the transport of hexazinone to groundwater. Similarly, the detection of hexazinone in low concentrations in a small number of wells in California demonstrates the success of the labeling and use instructions and does not appear to trigger further action under the PCPA. As a result, DuPont has not proposed mitigation measures, and requests that DPR continue registration of hexazinone without additional mitigation requirements or listing under Cal. Code Regs., *tit*.3, § 6800(a).

REPORT AND DOCUMENTED EVIDENCE

A. ACTIVE INGREDIENT

"Name of active ingredient."

The active ingredient detected in wells, according to the Notice, is hexazinone (CASRN 51235-04-2).

B. REGISTRANT(S)

"Name and address of registrant."

The name of the registrant for the products identified below is E.I. du Pont de Nemours and Company, also referred to as "DuPont." The company is located in Wilmington, Delaware.

C. CONTACT PERSON

The DuPont contact person with responsibility for this matter is Dr. Aldos C. Barefoot. Dr. Barefoot's contact information follows:

Dr. Aldos C. Barefoot
Research Fellow
STINE-HASKELL RESEARCH CENTER
1090 Elkton Rd.
Newark, DE 19714-0030
Phone: 302 451-5856
Fax: 302 351-6656
Email: aldos.c.barefoot@usa.dupont.com

D. HEXAZINONE REGISTRATIONS

"Name, EPA registration number, and label of each of your product(s) containing the detected active ingredient, other specified ingredient or associated degradation product, registered in California for agricultural use."

At the present time, DuPont holds 8 active registrations for pesticide products containing hexazinone. Information regarding these products follows.

1. **DuPont Hexazinone Technical** was registered on August 11, 1982 with DPR registration number 352-399-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. This is a

manufacturing use product. Health hazards associated with this product include skin, eye, and oral precautions. Environmental hazards involve application directly to water. The active ingredient is hexazinone at 98.7 percent; impurities make up the remaining 1.3 percent of the product.

2. **DuPont Velpar DF Herbicide** was registered on October 28, 1996 with DPR registration number 352-581-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a granular substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include skin, eye and oral precautions. Environmental hazards lists children/humans, drift, ground water and the application directly to water, and domestic animals and/or livestock. The active ingredient is hexazinone at 75 percent; inert ingredients make up the remaining 25 percent of the product.

3. **DuPont Velpar L Herbicide** was registered on July 31, 1985 with DPR registration number 352-392-ZA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a liquid concentrate, and the product has an agricultural use as a herbicide.. Health hazards associated with this product include skin, eye, and oral precautions. Environmental hazards lists children/humans, drift, ground water and the application directly to water, and domestic animals and/or livestock. The active ingredient is hexazinone at 25 percent; inert ingredients made up the remaining 75 percent of the product.

4. **DuPont Velpar Alfamax Gold Herbicide** was registered on August 25, 2009 with DPR registration number 352-666-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a granular substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include inhalation, skin, eye and oral precautions. Environmental hazards lists children/humans, threatened and endangered species, ground water and the application directly to water. The active ingredient is hexazinone at 23.1 percent; diuron at 55.4 percent; and, inert ingredients make up the remaining 21.5 percent of the product.

5. **DuPont Velpar Alfamax Herbicide** was registered on May 17, 2006 with DPR registration number 352-665-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a granular substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include skin, eye, inhalation, and oral precautions. Environmental hazards involve groundwater and the application directly to water. The active ingredient is hexazinone at 35.3 percent; diuron at 42.4 percent; and, inert ingredients make up the remaining 22.3 percent of the product.

6. **DuPont Velpar Alfamax MP Herbicide** was registered on August 2, 2004 with DPR registration number 352-634-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its

formulation is a granular substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include skin, eye, inhalation, and oral precautions. Environmental hazards involve groundwater and the application directly to water. The active ingredient is hexazinone at 35.3 percent; diuron at 42.4 percent; and, inert ingredients make up the remaining 22.3 percent of the product.

7. **DuPont Velpar ULW Herbicide** was registered on July 12, 2004 with DPR registration number 352-450-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a granular substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include skin, eye, and oral precautions. Environmental hazards lists children/humans, drift, groundwater and the application directly to water. The active ingredient is hexazinone at 75 percent; inert ingredients make up the remaining 25 percent of the product.

8. **DuPont Westar Herbicide** was registered on May 6, 2005 with DPR registration number 352-626-AA, and remains active. This product has a DPR registration *Type A-Section 3 Regular Registration in the Category C-Chemical*. Its formulation is a dry flowable substance, and the product has an agricultural use as a herbicide. Health hazards associated with this product include skin, eye, and oral precautions. Environmental hazards lists children/humans, drift, groundwater and the application directly to water. The active ingredient is hexazinone at 68.6 percent; sulfometuron-methyl at 6.5 percent; and, inert ingredients make up the remaining 24.9 percent of the product.

In addition to the registrations detailed above, DuPont has held 7 other registrations for 7 other hexazinone pesticide products, which the Company has cancelled voluntarily over the years. Because those registrations are no longer active, we have provided only the names of the products and the registration numbers.

PRODUCT NAME	DPR REGISTRATION NUMBER
DuPont 25% Hexazinone Liquid	352-419-AA
DuPont 90% Hexazinone Composition	352-433-AA
DuPont Velpar Dry Flowable Weed Killer	352-388-AA
DuPont Velpar Herbicide	352-378-ZA
DuPont Velpar L Weed Killer	352-392-AA
DuPont Velpar Weed Killer	352-378-AA
DuPont Velpar Weed Killer *(for experimental use only)*	352-55104-EX

In addition to the registrations held by DuPont, DPR records show that there is one active registration for a hexazinone pesticide product held by one other company. The registration is listed below by product name, registration number and registrant.

PRODUCT NAME	REGISTRATION NUMBER	REGISTRANT
Velossa	5905-579-AA	Helena Chemical Company

E. DATE OF INITIAL REGISTRATION OF EACH PRODUCT IN CALIFORNIA

> *"Date of initial registration of each product in California, if known."*

The initial date of the registrations for all of DuPont's registrations appear in the table below:

PRODUCT NAME	REGISTRATION NUMBER	DATE OF REGISTRATION
DuPont Hexazinone Technical (MUP)	352-399-AA	August 11, 1982
DuPont Velpar DF Herbicide	352-581-AA	October 28, 1996
DuPont Velpar L Herbicide	352-392-ZA	July 31, 1985
DuPont Velpar Alfamax Gold Herbicide	352-666-AA	August 25, 2009
DuPont Velpar Alfamax Herbicide	352-665-AA	May 17, 2006
DuPont Velpar Alfamax MP Herbicide	352-634-AA	August 2, 2004
DuPont Velpar ULW Herbicide	352-450-AA	July 12, 2004
DuPont Westar Herbicide	352-626-AA	May 6, 2005
DuPont 25% Hexazinone Liquid	352-419-AA	February 10, 1984 inactive: June 7, 1994
DuPont 90% Hexazinone Composition	352-433-AA	February 10, 1984 inactive: December 31, 1995
DuPont Velpar Dry Flowable Weed Killer	352-388-AA	No registration date listed. inactive: November 10, 1981
DuPont Velpar Herbicide	352-378-ZA	July 31, 1985 inactive: December 31, 2002
DuPont Velpar L Weed Killer	352-392-AA	No registration dated listed. inactive: March 14, 1992
DuPont Velpar Weed Killer	352-378-AA	No registration date listed. inactive: December 31, 1990

PRODUCT NAME	REGISTRATION NUMBER	DATE OF REGISTRATION
DuPont Velpar Weed Killer (for experimental use only)	352-55104-EX)	No registration dated listed. inactive: November 9, 1982

F. EVIDENCE THAT MATERIAL DETECTED IN SOIL AND GROUNDWATER DOES NOT POLLUTE OR THREATEN TO POLLUTE GROUNDWATER

> *"Documented evidence that the material detected in soil does not threaten to pollute groundwater in any region of the state when used according terms under which it is registered; and that the material detected in groundwater has not polluted, and does not threaten to pollute, groundwater in any region of the state when used according to terms under which it is registered."*

1. *Statutory Standards for Determining When a Material Detected in Soil or Groundwater "Does Not Pollute or Threaten to Pollute Goundwater"*

The PCPA does not require that a pesticide product's registration be cancelled, or that the product be subjected to use restrictions or mitigation measures, simply because the pesticide has been detected in one or more wells. Such detection in monitoring wells initiates a process in which the pesticide product's registrant has an opportunity to demonstrate that notwithstanding such detection, the pesticide product in question "has not polluted, and does not threaten to pollute, the groundwater of the state . . ." Food & Agric. Code Section 13150(a)(2). "Pollution," in turn, is defined in Food & Agric. Code Section 13142(j) as "the introduction into the groundwater of the state of an active ingredient, other specified ingredient, or degradation product of an active ingredient of a pesticide above a level, with an adequate margin of safety, that does not cause adverse health effects."

In this case, DuPont can demonstrate convincingly that the trace levels of hexazinone that have been detected in a relatively few wells are so far below the levels at which any adverse health effects are conceivable that the subcommittee should find and recommend, and the Director should determine, that hexazinone does not pollute or threaten to pollute the groundwater of the state. *See* Food & Agric. Code Section 13150(b),(c)(1). Specifically, as demonstrated in detail in the following sections of this Report, the USEPA has established a lifetime "health advisory level" ("HAL") for hexazinone in drinking water of 400 micrograms per liter ("ug/l"). The HAL of 400 ug/l is the level at which humans will suffer no adverse effects assuming they are exposed at that level, in drinking water, over their entire lifetimes. The HAL already incorporates an "adequate margin of safety," as required by Food & Agric. Code Section 13142(j), in that it incorporates an "uncertainty factor" of 100 times the level at which hexazinone showed "no observed adverse effects" in test animals, and an additional five-fold uncertainty factor in that it assumes that human lifetime exposure to Hexazinone will be primarily by routes other than ingestion of drinking water (80%), and only allows 20% of exposure by ingestion of drinking water containing a maximum of 400 μg/l of hexazinone.

Considering the conservatism embodied in the hexazinone HAL, the Director should conclude that hexazinone does not pollute the groundwater of the state, with an adequate margin of safety, even if Hexazinone were currently being detected in drinking water wells at concentrations approaching the HAL. Given the adequate margin of safety. The facts are, however, that hexazinone has been detected at levels no higher than 0.274 ug/l – less than *one thousandth* of the HAL. There is more than a 1000-fold margin of safety against any "adverse health effects" to humans even assuming hexazinone were currently present in drinking water at the highest level detected in any well.

Clearly, the levels currently detected do not satisfy the statutory definition of "pollution." Equally clearly, given the half-life of hexazinone in the environment (154 days), there is no potential for the continued use of the chemical to "threaten to pollute" the groundwater because residues currently in the soil and groundwater will not accumulate over time to a level anywhere remotely near the adverse effects level, given the adequate margin of safety.

2. *Hexazinone Has Not Polluted Groundwater in Any Region of the State*

In November, 2010 DPR notified DuPont that hexazinone had been detected in groundwater as a result of legal agricultural use. This finding triggers a requirement that the registrant submit evidence supporting the continued registration, sale and use of hexazinone. The evidence must support the conclusion that "any active ingredient, other specified ingredient, or degradation product that has been found in groundwater has not polluted, and does not threaten to pollute the groundwater of the state in any region of the state in which the pesticide may be used according to the terms under which it is registered."

Hexazinone detections are generally infrequent, sporadic, and transitory. DPR reached its conclusion on the potential for hexazinone to migrate to groundwater as a result of legal agricultural use on the basis of detection of hexazinone in three wells in one section in Fresno County (10M17S19E36) and in two wells in adjacent sections in San Joaquin County (39M02S06E19, 39M02S06E30). Samples taken from wells in other adjacent sections did not reveal hexazinone (see Table 1, and Figures 1 and 2, below). Between 1996 and 2009, hexazinone was detected in an additional 21 wells that did not meet the requirements for the LAU determination. Figures 1 and 2 appear in the Appendix to this document.

TABLE 1 HEXAZINONE USE AND MONITORING SUMMARY IN AND AROUND COMTRS10M17S19E36

	Reported Hexazinone Use (pounds)		Groundwater Monitoring Data			
Month and Year	Sum of 10M17S19E36	Sum of Adjacent COMTRS	COMTRS	WELL ID	Sample Date	Hexazinone (ppb)
Jan-90	18.9	218.6	10M17S19E36	23226	9/26/2007	0.247
Apr-90		13.5	10M17S19E36	23225	1/24/2008	0.127
Dec-90		52.9	10M17S19E36	23224	9/25/2007	0.081
Jan-91	41.5		10M17S19E36	4792	6/13/2001	0
Jan-92		159.4	10M17S19E36	4792	1/22/2008	0
Mar-92	12.0		10M17S19E25	23222	1/23/2008	0
Dec-92		70.0	10M17S19E26	23223	1/24/2008	0
Feb-93		13.0	10M17S19E35	4789	8/2/1994	0
Dec-93		35.0	10M17S19E35	4789	8/2/1994	0
Jan-94		90.6	10M17S19E35	4790	10/27/1997	0
Dec-94		40.7	10M17S19E35	4790	8/2/1994	0
Feb-95		36.0	10M17S19E35	4790	1/23/2008	0
Jan-96		27.0	10M17S19E35	4791	3/4/1993	0
Feb-97		6.4	10M17S19E35	4791	3/4/1993	0
Jan-98		55.5	10M17S20E31	4828	1/24/2008	0
Feb-98		52.5	10M17S20E31	23227	1/23/2008	0
Nov-98		37.0	16M18S19E01	23256	1/24/2008	0
Dec-98		11.7	16M18S19E01	23257	1/23/2008	0
Dec-99	17.6		16M18S20E06	23258	1/23/2008	0
Jan-00		87.1				
Dec-00	28.6	22.9				
Dec-01	29.4	37.7				
Jan-02		39.2				
Dec-02	28.6	31.0				
Jan-03		161.9				
Dec-03	21.0	34.4				
Jan-04		161.1				
Dec-04		61.5				
Jan-05	49.6	70.3				
Feb-05		2.6				
Dec-05	72.5	207.1				
Jan-06		77.0				
Feb-06		38.2				
Dec-06		160.3				
Jan-07		22.9				
Feb-07		119.4				
Dec-07	75.5	230.3				
Jan-08		30.0				
Dec-08		127.0				
Jan-09	17.0	22.0				
Dec-09		45.0				

The total number of samples with detectable residues is a very small percentage of the 3800 total samples analyzed in the groundwater monitoring program over 15 years (Attachment 5). The monitoring data shows that migration of hexazinone to groundwater is not widespread in areas where it is used, and that conditions leading to a pattern of detections that qualify for the LAU determination are confined to a few locations. As DPR noted (Nordmark and Quagliaroli, May, 2010), hexazinone is not consistently detected in areas where it is used, nor is it found in all wells that are sampled over time.

An analysis of each detection (Attachment 5) confirmed that hexazinone is not detected consistently in groundwater over the entire geographical area and that the detections are not consistent with the conclusion that further mitigation measures are required to minimize leaching.

Wells used for the LAU determination:

> Three wells in one section in Fresno County (10M17S19E36) showed hexazinone in concentrations ranging from 0.081 to 0.27 ppb (Table 1). A fourth well in the section showed no detectable hexazinone. Wells in the 8 sections surrounding 10M17S19E36 also showed no detectable hexazinone. (Figure 1).
>
> One well in San Joaquin County, section 39M02S06E19, and a well in an adjacent section ,39M02S06E30, showed hexazinone concentrations of 0.072 and 0.093 ppb, respectively, from sampling in 2009. Wells in several adjacent sections showed no detectable hexazinone (Figure 2). No hexazinone use was reported in either section from 2004-2009, although there was hexazinone use in several adjacent sections.

Wells with detectable concentrations and documented use, but did not meet requirements for the LAU determination:

> Detection of hexazinone was reported in one well in each of 9 sections. In several of the sections, there was no use of hexazinone in the year the detection was reported, and in several sections no use of hexazinone was reported for several years prior to the year in which the detection was reported.
>
> Detections in 6 wells were reported in sections with no reported use in the sections and no or very limited use in the adjacent sections.

DPR speculated on reasons for the inconsistent, sporadic detections, and highlighted the typical soils on which alfalfa is grown and the infrequent and wide geographically dispersed use. DPR did not consider the potential effect of the existing label instructions for minimizing the application rate on sandy soils with low organic matter; the prohibition against applications to gravelly, rocky soils, or sand; or the restriction of the maximum use rate to clays and loamy soils with high organic matter. The typical use patterns for hexazinone, the label instructions and use rate, and the typical soils on which alfalfa is grown all contribute to the very low observed frequency of detection and suggest that there is a very low probability that the number of hexazinone detections and the concentrations will increase significantly.

The maximum concentration of hexazinone reported (0.27 ug/l) is less than one-thousandth the US EPA Health Advisory Level (see section I, below). The HAL was established with a 100 X uncertainty factor; therefore the concentrations reported by DPR are far below any health effect level established with an adequate margin of exposure. Considering the results of monitoring data reported by DPR and the HAL, hexazinone has not polluted groundwater as pollution is defined by the Section 13142(j) of the Pesticide Contamination Prevention Act.

3. *Hexazinone Does Not Threaten to Pollute Groundwater*

Hexazinone has been registered for use on alfalfa in California for over 30 years, and use records show that total use in the state over the past 20 years has been consistent from year to year (Figure 3) with total use around 100,000 lbs/year. In alfalfa, total annual use has fluctuated in a range of 55,000 to 80,000 pounds over the same time period (Figure 4). The pattern reflects a product that has reached its market potential and additional uses are unlikely. Figures 3 and 4 appear in the Appendix to this document.

CDPR LEACHP TOOL MODELING

The California Department of Pesticide Regulation (DPR) uses probabilistic based modeling to determine the leaching potential of a pesticide (Troiano and Clayton, 2009). The CDPR LEACHP Tool focuses on a single vulnerable field, label rate applications, and a distribution of fate properties to assess leaching vulnerability. This probabilistic modeling approach produces a cumulative distribution for 1000 predicted well water concentrations. If the value at the 95th percentile is greater than or equal to 0.05 µg/L, then the active ingredient is determined to have a high potential to contaminate ground water. If the 95th percentile is less than 0.05 µg/L, the active ingredient is determined to have a low potential to be detected in ground water.

Determination of the leaching potential requires three steps:

- The model LEACHP is used to calculate pesticide concentration under two water application scenarios of 160% and 125% of the crop need. The distribution of the annual amount of pesticide leached below 3-meters is calculated from 1000 random combinations of sorption coefficients (Koc) and terrestrial field dissipation (TFD) half lives of the pesticide. SENSAN model is used to run 1000 LEACHP runs.

- Residues are aged according to an estimate for the amount of time it takes water to migrate from the 3-meter depth to drinking water wells.

- The estimated travel times to a well are assumed to be 10 and 13 years for the 160% and 125% irrigation water management treatments, respectively.

- The cumulative distribution for the predicted 1000 well water concentrations is constructed, and the 95th percentile concentration is compared to 0.05 µg/L, a concentration level that is typical of reporting limits in CDPR analytical methods.

To determine the leaching potential for hexazinone using the CDPR modeling tool, concentrations were simulated following one application of 1.5 lbs/acre on 15th January. All the chemical specific data were consistent with DPR guidance. Weather and soil data were unchanged from the standard DPR LEACHP input file. The well water concentrations were calculated at DPR recommended aging time of 10 and 13 years for 125% and 160% irrigation schemes, respectively. Using the standard aging times suggested in the tool documentation, all concentrations at all percentiles are below detectable levels (Table 2).

The well water concentrations were also calculated at aging times of 3, 4 and 5 years to represent wells immediately adjacent to treated fields, The 95th percentile concentrations values for 4 and 5 year aging times approach the maximum concentrations observed in the monitoring program, while those for the 3 year aging time exceed the observed maximum by about 4X. The modeling indicates that concentrations of hexazinone in wells adjacent to alfalfa fields will be far less than the Health Advisory Level.

TABLE 2: PROBABILISTIC MODELING OF LEACHING POTENTIAL
CDPR LEACHP MODELING

APPLICATION RATE	IRRIGATION AMOUNT	AGING TIME (YEARS)	LONGEST HALF-LIFE (DAYS)	CUMULATIVE PERCENTILE (µg/L)		
				50TH	90TH	95TH
1.5 lb/acre	125%	10	154	0.00	0.00	0.00
1.5 lb/acre	125%	5	154	0.01	0.03	0.03
1.5 lb/acre	125%	4	154	0.07	0.14	0.16
1.5 lb/acre	125%	3	154	0.38	0.73	0.80
1.5 lb/acre	160%	13	154	0.00	0.00	0.00
1.5 lb/acre	160%	5	154	0.03	0.04	0.05
1.5 lb/acre	160%	4	154	0.14	0.22	0.23
1.5 lb/acre	160%	3	154	0.74	1.14	1.21

WINPRZM MODELING

A recently developed PRZM based tool was also used to evaluate the spatial distribution of potential hexazinone leaching associated with actual applications. All applications for the period of 2000 to 2008 in the Bay-Delta Estuary, Sacramento and San Joaquin Watersheds (the primary use area) were evaluated using spatially assigned soils data, weather files, and the WinPRZM Pesticide Root Zone Model (PRZM-4.51) to simulate the pesticide leaching.

The PRZM model is a dynamic, compartmental model developed by the U.S. EPA for use in simulating water and chemical movement in unsaturated soil systems within and below the plant root zone (Carsel *et al*., 1998, Focus 2000a, FOCUS 2000b). The model simulates time-varying hydrologic behavior on a daily time step, including physical processes of runoff, infiltration, erosion, and evapotranspiration. The chemical transport component of PRZM calculates pesticide uptake by plants, surface runoff, erosion, decay, vertical movement, foliar loss, dispersion and retardation.

PRZM includes the ability to simulate pesticide metabolites and irrigation. Unlike the CDPR Monte Carlo methodology of variable degradation rates and sorption parameters, the simulations were conducted with a conservative set of inputs using the maximum field dissipation half-life (154 days) in the soil and the minimum sorption parameter (K_{oc} = 38 mL/g). Simulations were conducted for two year periods that include the year of application and a following year of weather and irrigation with results being presented for the combined water and mass amounts for the two year period associated with each simulated application year.

Irrigation was enabled in the model using US EPA standard scenario irrigation rates. In comparing simulated irrigation plus rainfall in relation to evapotranspiration, it is clear the adequate water was available for leaching with over 46% of the simulations having a greater than 125% of modeled evapotranspiration and over 5% having a greater than 160% of the modeled evapotranspiration. The irrigation routines of PRZM are driven by the simulated field capacity and irrigation events are automatically added based on the set threshold and irrigation rate parameters.

The maximum total leached below the soil core (315 cm) for each PLSS cell receiving a hexazinone application according to the PUR database was used as an input to the CDPR groundwater assessment methodology and used to determine estimated groundwater concentrations. As discussed previously, travel times of 13, 10, 5, 4, and 3 years were evaluated using the equation:

*Well water concentration (µg/L) = (M L *0.5 N) / D*

Table 3 provides a summary of well concentration for different travel times and percentiles relevant to the CDPR methodology (50^{th}, 90^{th} and 95^{th} percentile). Similar to CDPR modeling, a very low percentage of simulated areas were shown to have detectable levels of hexazinone and only when short travel times were considered. For travel times of 10 and 13 years, no detectable residues are expected. For travel time of 4 or 5 years, detectable residues are only expected in 1% of the areas. For travel times of 3 years about 5 percent of the areas are expected to have detectable residues. Maps of the predicted concentrations in each simulated section for different travel times (10, 5, 4, and 3 years) are presented in Attachment 5. To illustrate the modeling results, Figures 5 and 6 show a map of the maximum value from all years of simulations for 5 and 10-year travel times, respectively, from the application area to a groundwater well. Figures 5 and 6 appear in the Appendix to this document.

TABLE 3 RESULTS OF WINPRZM SPATIAL MODELING ASSESSMENT

AGING TIME (YEARS)	LONGEST HALF-LIFE (DAYS)	CUMULATIVE PERCENTILE (µg/L) OF ALL SIMULATIONS		
		50TH	90TH	95TH
13	154	0.000	0.000	0.000
10	154	0.000	0.000	0.000
5	154	0.000	0.000	0.003
4	154	0.000	0.000	0.015
3	154	0.000	0.002	**0.075**

Both modeling efforts indicate that hexazinone has a low probability of polluting groundwater within the context of the PCPA. Predictions of concentration are far less than the HAL. The CPDR Leaching model which was calibrated by comparison to monitoring clearly shows that the 95th percentile concentration in a vulnerable soil with high irrigation will be less than 0.05 ppb, the typical reporting limit for analytical methods used by DPR. By selecting the 95th percentile for comparison, DPR accepts that higher concentrations are likely in a small number of situations. The monitoring confirms that a small number of wells will contain detectable amounts of hexazinone, as predicted by the model. While detection of hexazinone in a small number of wells is expected, the spatial modeling indicates that few areas in California will be vulnerable to leaching in an amount sufficient to give detectable residues of hexazinone. The results of both models demonstrate that hexazinone does not threaten to pollute groundwater in California.

G. MITIGATION MEASURES

> *"The registrant may submit potential mitigation measures and rationale for their adoption, including proposed restriction or agricultural use modification for certain areas of the state or for the entire state."*

The physical and chemical properties and the environmental fate behavior of hexazinone indicate a potential for transport to groundwater that has led to requirements for a groundwater Environmental Hazard statement, directions for use that minimize the leaching potential, and a US EPA data requirement for a prospective groundwater study. The use pattern, intermittent use of hexazinone, restrictions on applications to soils that are vulnerable to leaching, and the usual practices for releasing irrigation water combine to minimize the potential for hexazinone to be detected in groundwater. The low frequency of detections and the low concentrations detected demonstrate the successful management of hexazinone by growers and by DuPont.

Because it does not appear that hexazinone triggers requirements for mitigation above the current labeled directions for use, DuPont has not proposed any changes in the label or changes in regulatory oversight required for hexazinone. Demonstrating the effects of mitigation measures would require an extensive monitoring program to detect a significant change in the number of detections, since the sporadic nature of detections would lead to considerable uncertainty in the trend analysis.

As part of the DPR groundwater protection program, mitigation measures that have been approved for use in permitted applications of agricultural products on the Groundwater Protection List (Cal. Code Regs., tit. 3, § 6800(a)) have been published. While several of the approved methods could be appropriate for hexazinone, there is no need to burden growers who use hexazinone when the concentrations observed are much, much less than the levels that have been established by US EPA for exposure to hexazinone in drinking water. Hexazinone concentrations already meet the standard for acceptable groundwater quality required by PCPA. Therefore, DuPont proposes to continue its efforts to provide information to applicators through label instructions and technical bulletins, and is committed to working with DPR to insure that label instructions continue to achieve the intended result of minimizing incidents of transport of hexazinone to groundwater.

H. ECONOMIC HARDSHIP

> *"The registrant may submit evidence that agricultural use modification or cancellation of the product(s) will cause severe economic hardship on the state's agricultural industry. Such evidence should show why the registrant's product is the preferred material for use and also the additional costs to growers if agricultural use modifications are made or alternative products are used."*

DuPont requested information from Dr. Mick Canevari on the use of hexazinone for weed control in alfalfa and a comparison to alternative herbicide treatments. Dr. Canevari's comments may be found in Attachment 6. A portion of his comments were extracted and are reproduced here.

Hexazinone is the preferred option for control of toxic weeks in alfalfa hay. There are over one million acres of alfalfa in California grown in three major regions. The largest is the Sacramento and San Joaquin valleys at 66%, the remainder split between low desert and high elevation mountain counties. Weed free alfalfa is an important step to produce high quality hay; it improves harvest efficiency by speeding the drying and baling time, expands marketing opportunities and commands a higher price. The presence of poisonous weeds will reduce the value or in many cases make it an unmarketable commodity. Weeds such as Common Groundsel *Senecio vulgaris*, Coast Fiddleneck *Amsinckia intermedia*, and Poison hemlock *Conium maculatum* can cause serious health issues or even death to cattle and horses. The incentive to produce high quality weed-free alfalfa is substantial to achieve profitability and avoid liability associated with the presence of poisonous weeds in hay.

Common groundsel is a pyrolizidine alkaloid PA (toxicant) containing plant that is commonly found in alfalfa and winter forages. Groundsel is especially a problem in alfalfa hay because it is toxic to animals in either dry hay or silage. Poisoning occurs in situations where animals cannot separate out the toxic plants while they feed--when they are mixed with the forage in a pasture, or when they are fed in hay or silage. The toxicant causes a liver disease that is chronic and progressive, resulting in death usually months after feeding, with few or no symptoms until 2 or 3 days before death. A lethal amount for cattle or horses is 5-7 percent of their body weight of groundsel or approximately 50 pounds. With lesser amounts consumed, the liver loses function, but no symptoms may be apparent until the animal is stressed by pregnancy, a new feed, a different toxin, etc. Sheep and goats have rumen bacteria that detoxify the alkaloids, so they are able to consume twice their body weight of groundsel without liver damage.

Ensiling pyrolizidine alkaloid producing plants does not decrease toxicity to a safe level for feeding. PA containing plant material is not recommended as feed for cattle or horses.

Common groundsel is prevalent and widespread in the central valley and low desert alfalfa regions of California and Arizona. It germinates and grows during the winter months when alfalfa is dormant. Groundsel produces abundant seeds, which spread by floating on the wind with their parachutes of hairs. One groundsel plant can produce as many as one million seeds in a season. Groundsel is a hardy plant that germinates over a wide range of temperatures beginning in Oct through March with moisture. Plants can survive cold temperatures and drought then flower and set seeds early in the spring. February to March is the primary period of bloom, though plants flower throughout the growing season.

An increased effort for field research to document groundsel control measures has followed the increase of infestations reported and livestock poisoning. Herbicide applications or grazing by sheep are the usual methods used to control poisonous weeds in alfalfa. Several research trials were conducted in 2009-2010 in San Joaquin County and the Sacramento valley evaluating herbicide programs for control. Herbicides active on groundsel generally perform best at early germination periods when plants are small and a combination of a post and pre emergent herbicide are possible. Velpar®, Chateau® and Gramoxone®, are the key alfalfa herbicides that have shown various levels of effectiveness in controlling groundsel. Velpar®, pre and post emergent, consistently shows the best long term control when rainfall and sunny days occur following application.

Figures 7 and 8 show herbicide performance from early and mid season application timings for controlling groundsel in an established alfalfa field in San Joaquin County during 2009-2010. The trial was conducted by Mick Canevari, UCCE advisor in San Joaquin County. Figures 7 and 8 appear in the Appendix to this document.

Economic impacts of toxic weeds on the value of alfalfa hay were reported by D. Putnam, UC Davis agronomist ("Comments Pertaining to the Need for Control of Winter

Weeds in California Alfalfa Fields." April 5, 2011). For convenience to the reader, Dr. Putnam's comments on economic impacts are reproduced below.

> "**Economic Impacts.** Forage quality normally accounts for an average of $48 per ton of hay, or 50% of the value of the crop in California markets (Table 1). Differences due to quality are largest in low-price years, and least in high-price years. Forage quality in California markets is a complex determination based upon lab analyses (such as Crude Protein and Fiber), condition of hay (e.g. moldiness), and presence of weeds. The definitions of Supreme and Premium quality hays ***require*** that the alfalfa hay be free of weeds. 'Good' hay may contain some other forage crops, such as forage grasses, or a few weeds, but cannot contain poisonous or noxious weeds. 'Fair' hay is often used for weedy hay, but alfalfa with groundsel is most categorized below 'fair' or 'utility' grade, sometimes called 'low' quality.
>
> Marketers of hay will tell you that the presence of significant groundsel or other poisonous or harmful weeds in an otherwise high quality (Supreme or Premium) hay is sufficient to know the price at least to the 'Fair' quality, and more frequently to the 'utility' grade. Thus the penalty for significant groundsel weed infestation in alfalfa is likely to be a minimum of 50% of the value of the crop."

TABLE 4: ECONOMIC IMPACTS AS PRICE DIFFERENCES

PRICE. *Price Differences based upon quality. California markets (USDA – Market News Reports).*					
Year	*Supreme*	*Premium*	*Good*	*Fair*	*Top-Bottom*
1999	$129	$114	$91	$69	$60
2000	$127	$111	$93	$77	$50
2001	$147	$137	$124	$111	$37
2002	$142	$125	$107	$89	$52
2003	$130	$116	$97	$78	$52
2004	$148	$135	$119	$101	$47
2005	$179	$166	$146	$125	$54
2006	$165	$149	$130	$104	$62
2007	$186	$175	$166	$156	$31
2008	$238	$229	$218	$206	$32
2009	$140	$131	$113	$95	$45
2010	$164	$150	$134	$110	$54
Average	**$158**	**$145**	**$128**	**$110**	**$48**
Source: USDA-Market News Summary					

Source: D. Putnam, "Comments Pertaining to the Need for Control of Winter Weeds in California Alfalfa Fields," April 5, 2011.

I. SAFE LEVELS IN SOIL AND GROUNDWATER

"The registrant may recommend a level of the material in the soil or groundwater that does not significantly diminish the safety margin for adverse health effects."

Hexazinone is registered in the Unites States as a food-use pesticide. As such, an extensive toxicology database has been established for the compound. The full battery of data includes acute toxicity, mutagenicity, developmental toxicity, reproductive toxicity and long-term toxicity studies, which have been developed by DuPont in order to obtain and maintain the federal and state registrations.

U.S. EPA has reviewed the toxicity data for hexazinone multiple times. The agency reviewed the entire data base in the course of re-registration as required under the Federal Insecticide, Fungicide and Rodenticide Act, resulting in the *Reregistration Eligibility Decision (RED) Hexazinone* (U.S. EPA, 1994). The agency conducted a second review in 2002, resulting in *The Revised Toxicology Chapter for the TRED for Hexazinone* (U.S. EPA, 2002a). Based on this, the agency also published a *Tolerance Reassessment Eligibility Decision* (U.S. EPA, 2002b). A summary of the U.S. EPA's review of health effects data for hexazinone is provided in the Appendix to this document. In addition, the California Department of Pesticide Regulation has reviewed all of the data, as required for California registration under the California Food & Agricultural Code.

To select endpoints for the human health risk assessments, various exposure routes and durations are considered. For a drinking water risk assessment, the oral route is the most relevant. Long-term exposure scenarios can be used, since there could be the potential exposure to the compound for a lifetime. Hence, chronic or long-term mammalian toxicity studies can be used to determine the acceptable level of long-term human exposure. The long-term toxicity of hexazinone has been tested in three species, rats, mice and dogs. The dog was found to be the most sensitive species and the 1-year dog study was selected by the U.S. EPA for the chronic reference dose[1] ("Chronic RfD"), which is an estimate of a level to which humans could be exposed daily for a lifetime without an appreciable risk of adverse health effects.

According to U.S. EPA (2002), the NOAEL for hexazinone in dogs is 200 ppm in the diet (equivalent to 5.00 and 4.97 mg/kg body weight/day in males and females, respectively). This was based on findings of thinness in one male and hepatotoxicity as evidenced by changes in clinical chemistry parameters and microscopic changes at $\geq$ 1500 ppm hexazinone in the diet (equivalent to 41.24 and 37.57 mg/kg body

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[1] Defined by U.S. EPA as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived . . . from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used; generally used in U.S. EPA's noncancer health assessments." (http://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do).

weight/day in males and females, respectively). DPR also agreed that 200 ppm was the NOAEL for this dog study (California EPA, 2000).

For risk assessment purposes, the NOAEL of 5.00 mg/kg body weight/day was converted into a chronic reference dose by reducing the NOAEL by an uncertainty factor of 100. The purpose of the uncertainty factor is to account for potential interspecies variability between animals and humans, and assumes humans are more sensitive than dogs (although the opposite could be true). In addition, uncertainty factors are used to account for potential intraspecies variability within the human population, in case one group of individuals is more sensitive than the other. Thus, the chronic reference dose (Chronic RfD) established for hexazinone by the U.S. EPA is 0.05 mg/kg/day.

U.S. EPA adds extra adjustment factors to lower the reference dose when there are uncertainties in the data, in order to build additional conservatism into the risk assessment. No extra adjustment factors were added to the hexazinone reference doses (U.S. EPA, 2002c), because the database was considered sufficient and there were no special concerns for infants and children.

DRINKING WATER RISK ASSESSMENT FOR HEXAZINONE

Based on the chronic reference dose established for hexazinone, drinking water limits were calculated by the U.S. EPA's Office of Water. Various Health Advisory Levels are set by the U.S. EPA, but the most conservative value for hexazinone is the Life-time Health Advisory (HAL). Before the HAL is set, a Drinking Water Equivalent Level is calculated. The Drinking Water Equivalent Level is a lifetime exposure concentration protective of adverse, non-cancer health effects which assumes that all the exposure to a substance is from drinking water. The HAL, on the other hand, only allows for 20% of the exposure to the chemical to come from drinking water. For food use pesticides such as hexazinone, part of the permissible exposure comes from residues in the consumption of edible commodities. For dietary exposure, EPA concluded that for all commodities, the chronic risk estimates of exposure are below the U.S. EPA's level of concern for the U.S. population and all population subgroups. Source: U.S. EPA, 2002, Memorandum dated May 15, 2002, Memorandum entitled Subject: Hexazinone Acute and Chronic Dietary Exposure Assessments for the TRED).

The Drinking Water Equivalent Level (DWEL) can be calculated with the following equation.

DWEL = Chronic RfD x (mass of a reference person) / water consumed per day

U.S. EPA assumes a reference person of 70 kg and consumption of 2 liters of water/day for a lifetime. Thus, for hexazinone the calculation is:

DWEL = 0.05 mg/kg/day x 70 kg person / 2 L

= 1.75 mg/L, which the U.S. EPA rounded up to 2 mg/L

Because the HAL allows only 20% of the exposure to the compound to come from drinking water, to derive the Health Advisory Life-time the DWEL is further lowered by multiplying it by a factor of 0.2. Thus, the Health Advisory Life-time was calculated as:

Life-time Health Advisory = 2 mg/L x 0.2

= 0.4 mg/L (*i.e.* 400 ppb or 400 μg/L)

The maximum level of hexazinone detected in well water in the state of California was 0.274 ppb with a median concentration of 0.093 ppb. Given the extremely wide margin between the low level of potential exposure to hexazinone via well water and the adequately conservative Health Advisory Life-time established by the U.S. EPA, one can be reasonably certain that no harm will occur, based on comparison to the concentrations reported in monitoring wells.

APPENDIX

FIGURE 1 WELLS IN FRESNO COUNTY WITH HEXAZINONE DETECTION

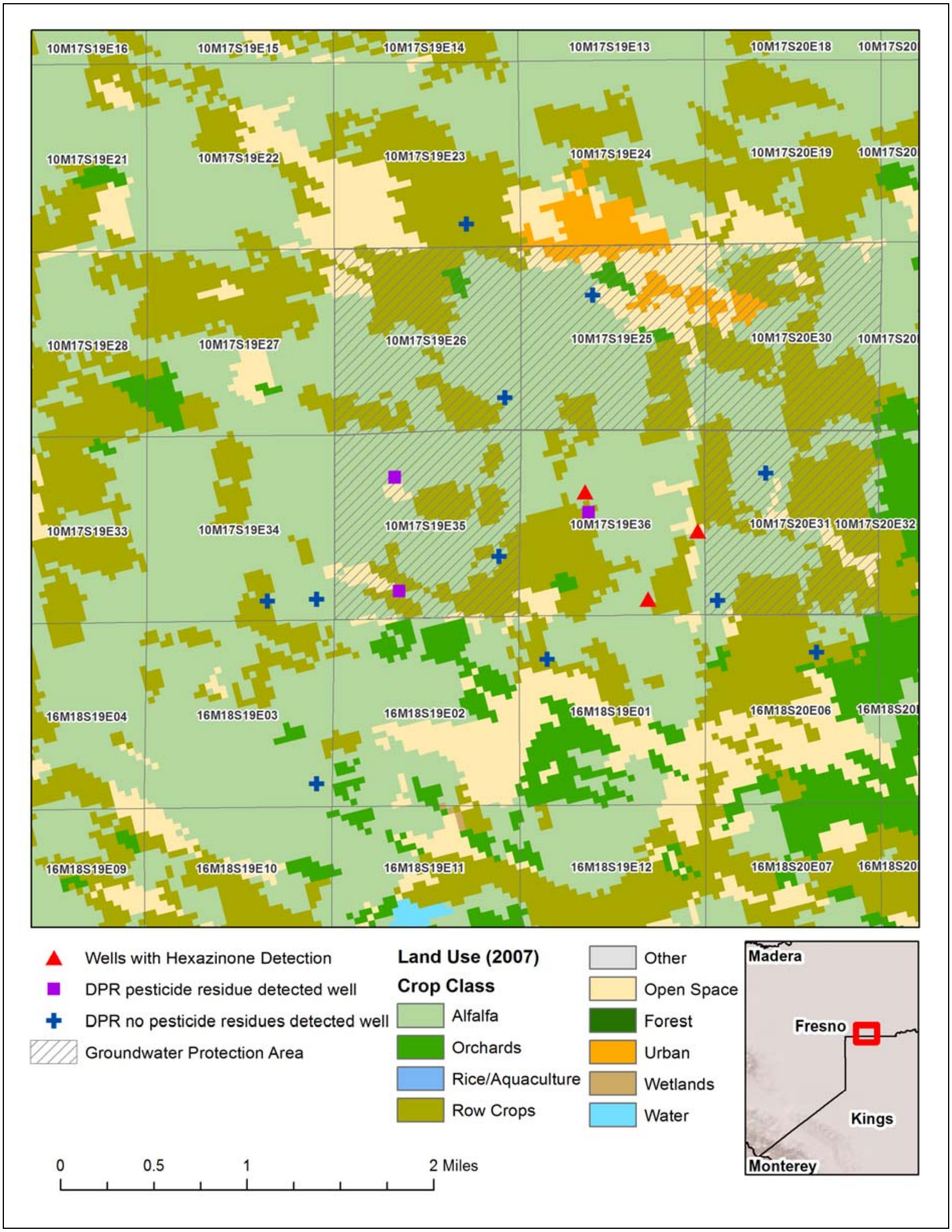


FIGURE 2 WELLS IN SAN JOAQUIN WITH HEXAZINONE DETECTION

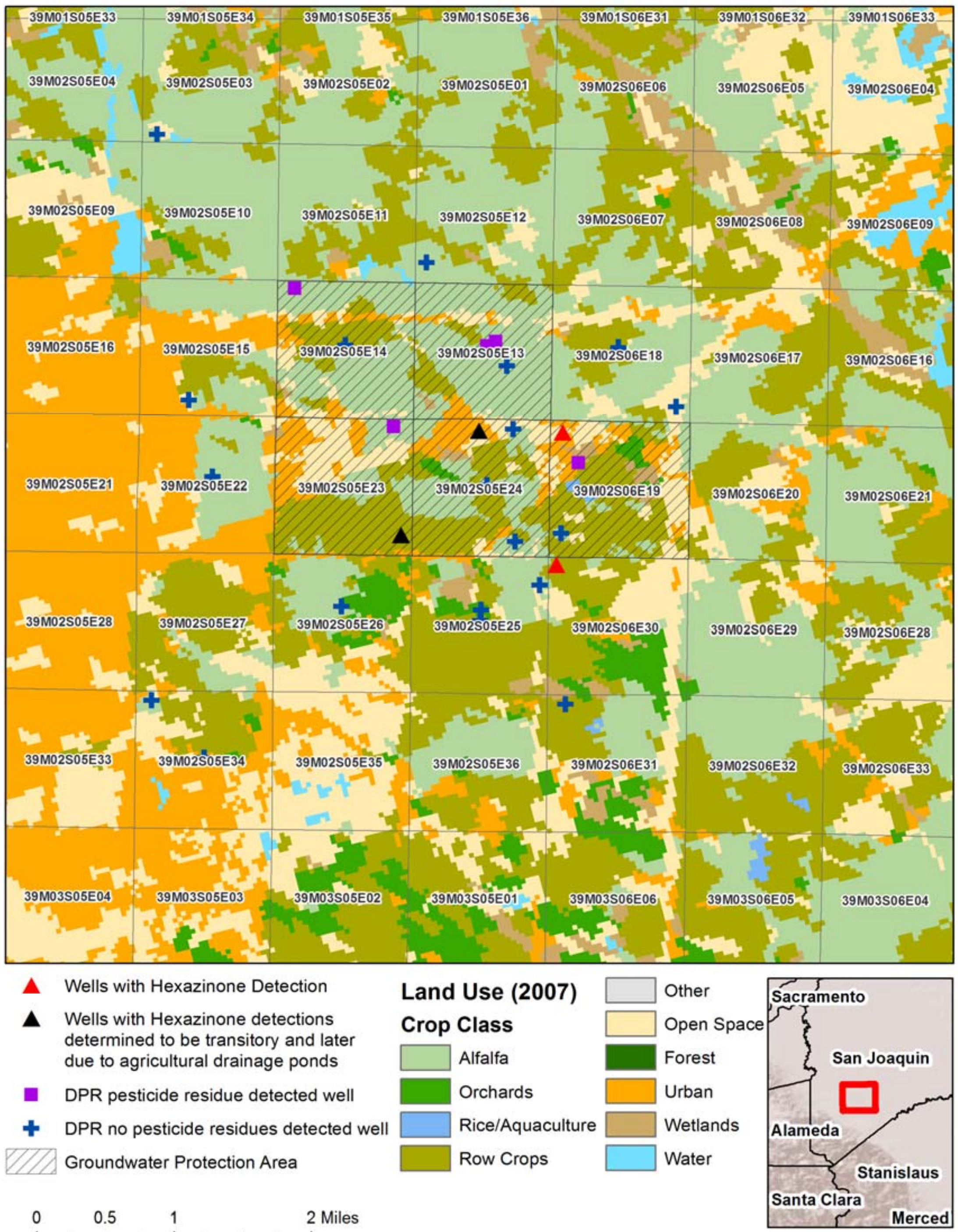


FIGURE 3 TOTAL HEXAZINONE USE IN CALIFORNIA

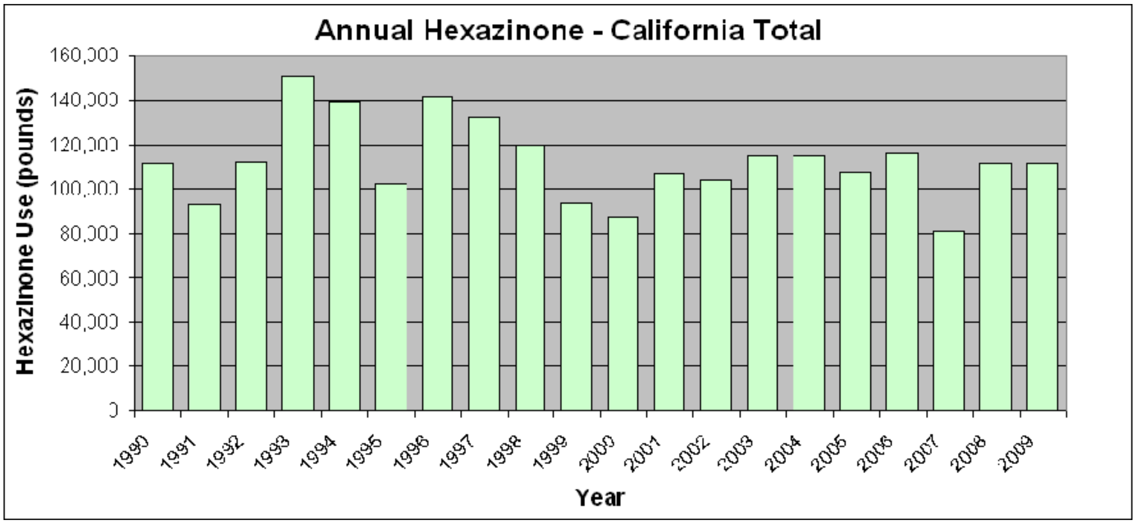


FIGURE 4 TOTAL HEXAZINONE USE ON ALFALFA IN CALIFORNIA

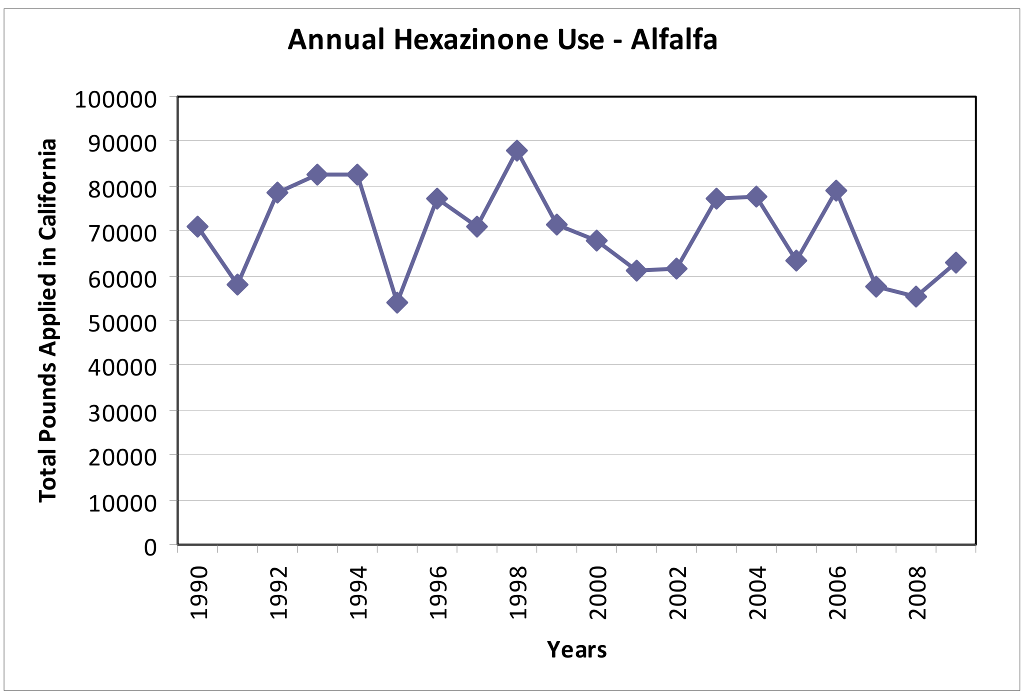


FIGURE 5 DISTRIBUTION OF HEXAZINONE CONCENTRATIONS IN GROUNDWATER - WIN PRZM MODELING , 5 YEAR TRAVEL TIME

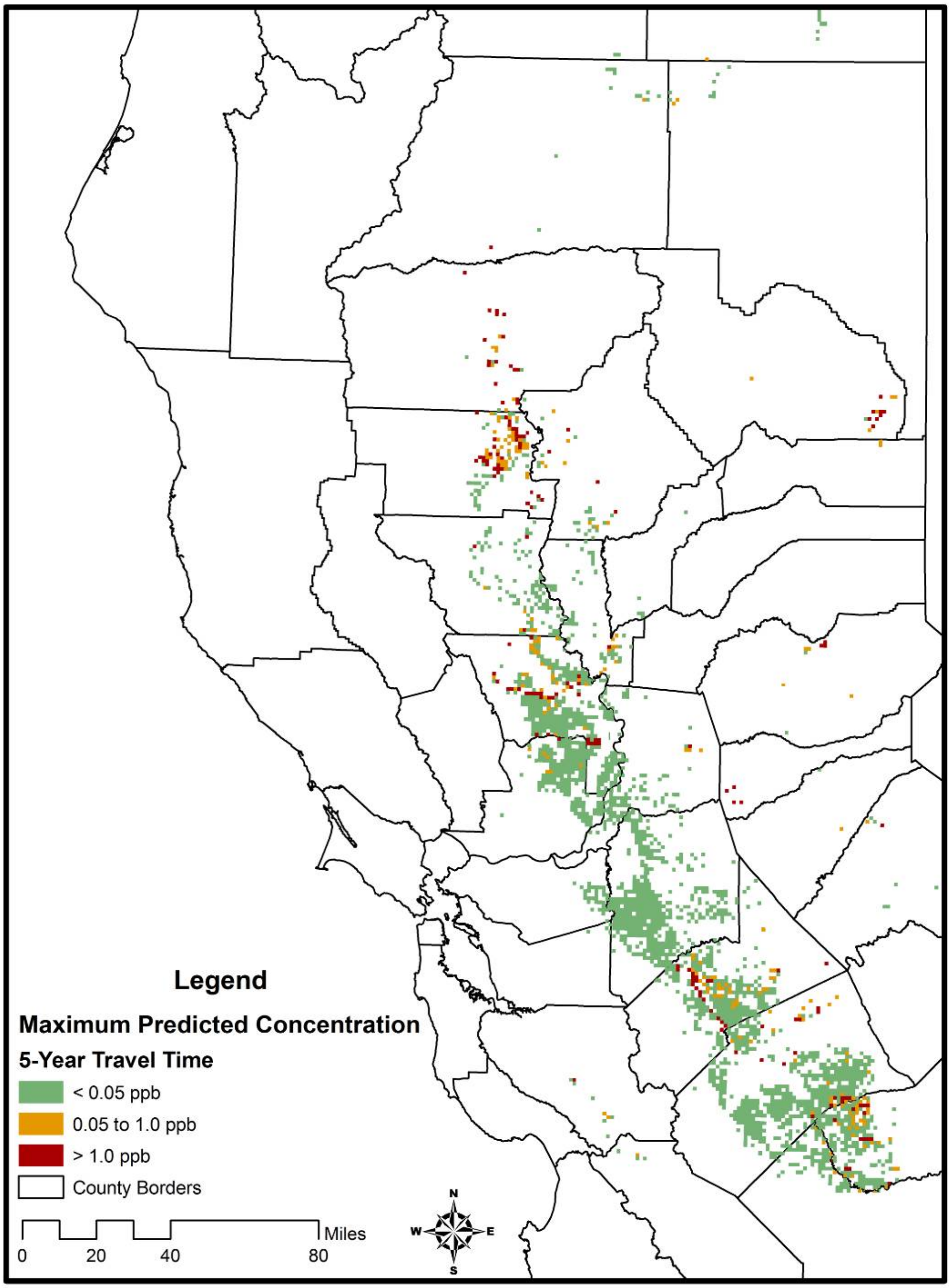


FIGURE 6 DISTRIBUTION OF HEXAZINONE CONCENTRATIONS IN GROUNDWATER - WIN PRZM MODELING , 10 YEAR TRAVEL TIME

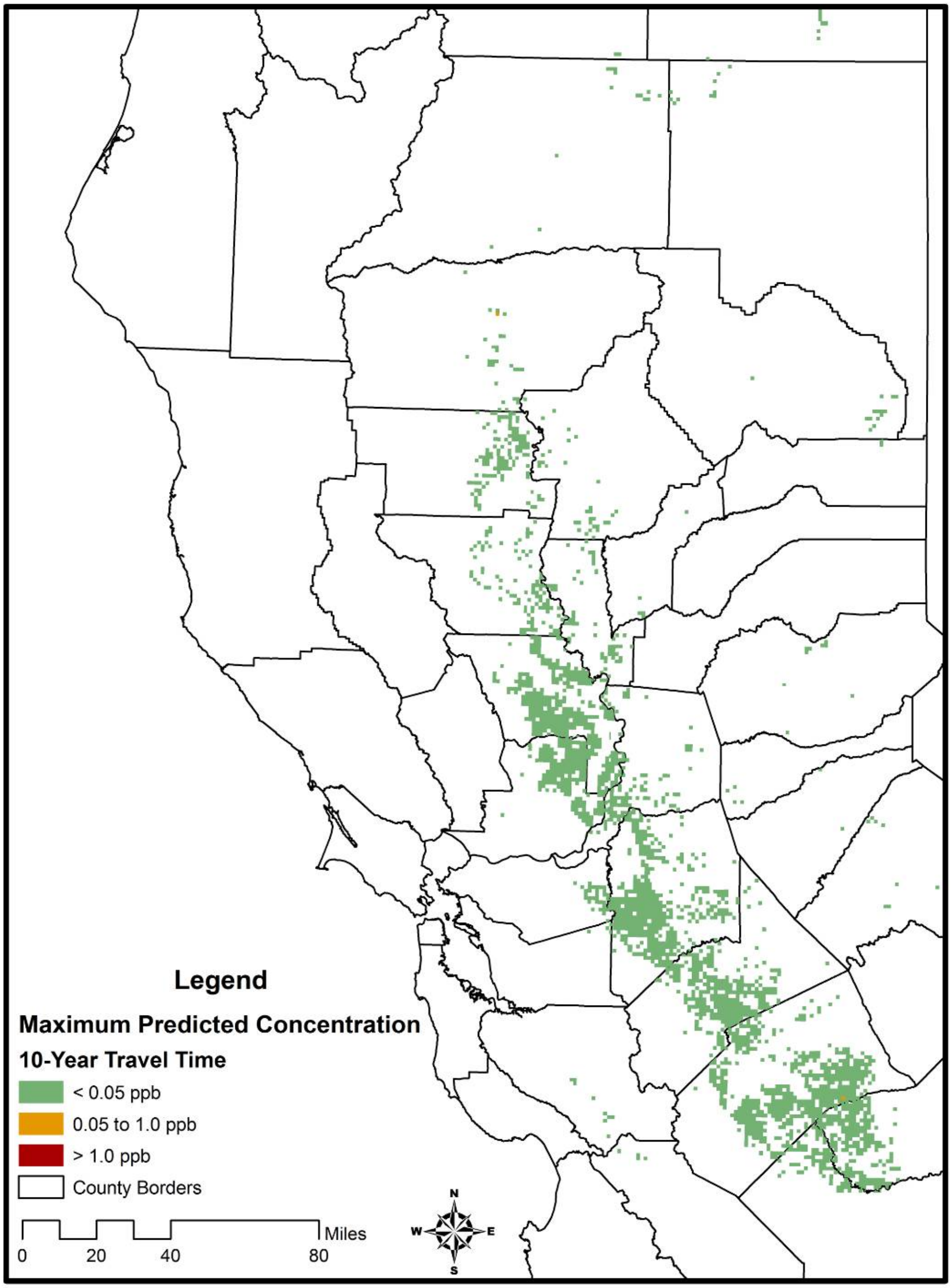


FIGURE 7 EARLY SEASON GROUNDSEL CONTROL IN ALFALFA

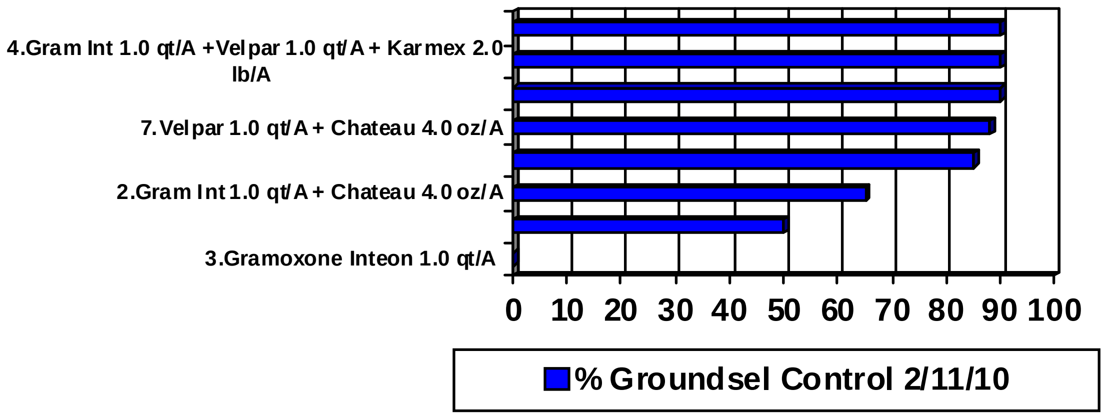
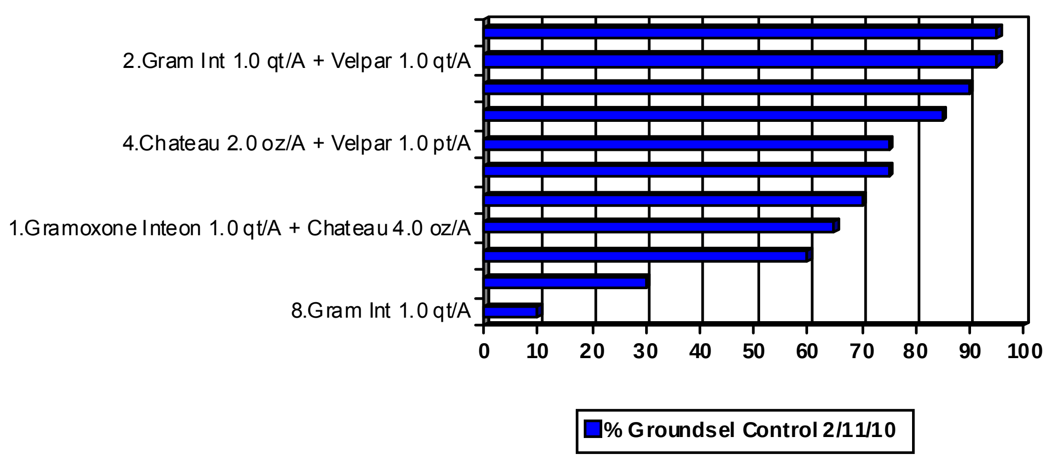


FIGURE 8 MID SEASON GROUNDSEL CONTROL IN ALFALFA



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