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SUBJECT: AMITRAZ MITIGATION SCOPING DOCUMENT

Attached is the Amitraz Mitigation Scoping Document that spans a period of 12 years from the time of DPR's Exposure Assessment and Risk Characterization Documents in 1995 to the U.S. Environmental Protection Agency's final actions in 2007. All potential exposure scenarios - occupational, dietary, and residential - have been identified, associated risks quantified, and mitigation measures implemented. No additional mitigation is indicated at this time.

Two dog collar labels, Preventic Tick Collars for Dogs, 25" and ProMeris for dogs, do not contain the Proposition 65 warning.

California Environmental Protection Agency
Department of Pesticide Regulation
Worker Health and Safety Branch

HSM-09001

AMITRAZ
MITIGATION SCOPING DOCUMENT

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AMITRAZ MITIGATION SCOPING DOCUMENT

I. SUMMARY

The Amitraz Mitigation Scoping Document spans a period of 12 years during which time all applicable regulatory documents have been released. In 1995, the Department of Pesticide Regulation (DPR) released the Risk Characterization Document (RCD) and the Exposure Assessment Document (EAD), and the U.S. Environmental Protection Agency (U.S. EPA) released the Reregistration Eligibility Decision (RED). In 2006, the U.S. EPA released the Tolerance Reassessment Eligibility Decision (TRED) and in 2007, the Final Rule for amitraz tolerance levels.

Occupational, dietary, and residential post-application exposure scenarios have been identified, exposure dosages estimated, and risks quantified. Either required mitigation measures have been implemented or products have been canceled, reducing potential exposures and risks to levels considered protective of human health. Additional mitigation measures are not anticipated at this time, given available information.

Two amitraz-impregnated dog collars do not contain the California Proposition 65 warning on the labels. The U.S. EPA has required additional information on the use of cotton undelinted seed in foreign countries to support the amitraz import tolerance level, and toxicity studies and absorption chemistry data for the technical grade.

II. REGULATORY HISTORY/STATUS

Amitraz is a contact insecticide, miticide, and acaricide used to control white fly and spidermites on cotton; pear psylla on pears; ticks, mange mites and lice on livestock; and fleas and ticks on dogs. Applicable federal and state regulations are identified in Tables 1.A and 1.B.

Table 1.A. Federal Laws and Regulations Applicable to Amitraz

Laws	FIFRA Registration Type : **Section 3, Regular**	FIFRA Reregistration Eligibility Decision (RED) : **Issued March 1995**	FFDCA Tolerance Reassessment Eligibility Decision (TRED) : **Issued July 2006**	FQPA Susceptibility of Children : **Yes – Dermal & Incidental Oral**	FQPA Cumulative Risk : **Not Found For Tolerances**
Title 40 CFR	Part 170 Worker Protection Standard : **Established in the RED**		Part 180.287 Amitraz Tolerance Levels **Final Rule: September 19, 2007**		

FIFRA : Federal Insecticide, Fungicide, and Rodenticide Act, 1947 [Section 3(c)(5)(D) and Section 2(bb)]; Amended 1988 to require Reregistration of pesticides registered before 11/1/1984 [Section 4(g)(2)(A)].
FFDCA : Federal Food, Drug, and Cosmetic Act, 1938; Amended 1996 to require a safety determination of no harm from aggregate exposures [Section 408(b)(2)(A)(ii)].
FQPA : Food Quality Protection Act, 1996 [Section 408(b)(2)(C)(i) and (ii)].
CFR : Code of Federal Regulations

Table 1.B. California Regulations Applicable to Amitraz				
	Restricted Material	**Toxic Air Contaminant**	**Groundwater Protection List**	**Proposition 65 List**
Yes / No	No.	No.	No.	**Yes.**
Law	FAC Div 7, Ch 3, Art 1.5, Sec 14001	FAC Div 7, Ch 3, Art 1.5, Section 14021(b)	FAC Div 7, Ch 2, Art 15, Sec 13141	HSC Section 25249.5; Amitraz was added March 30, 1999
Regulation	3 CCR 6400	3 CCR 6860	3 CCR 6800	27 CCR 25000-27001
FAC : California Food and Agricultural Code HSC : Health and Safety Code CCR : California Code of Regulations				

III. SUMMARY of EXISTING DOCUMENTS

The health effect of concern for amitraz is neurotoxicity. Key findings of the four regulatory documents released between 1995 through 2007 are as follows:

1. *DPR's EAD, 1995 (Haskell, 1995.)*

   Occupational exposures were assessed for orchard blast operators, field crop operations (ground boom, aerial, and cotton scouts), pear harvesters, livestock treatment, and veterinarians (dog collar applications). Pear harvesters had the highest estimated dosages for daily, annual, and lifetime exposures.

2. *DPR's RCD, 1995 (Frank, 1995)*

   Nine occupational commodity-worker activities were assessed: 1) pear orchard mixer/loader/applicators, 2) harvesters 3) cotton ground mixer/loaders/applicators, 4) aerial mixer/loaders, 5) pilots, 6) flaggers, 7) scouts, 8) cattle mixer/loader/applicators, and 9) swine mixer/loader/applicators. A seasonal average daily dose estimate was added for pear, cotton, and livestock uses. Pear harvesters had the highest seasonal exposure estimate. Job categories with margins of safety at levels of concern were: pear mixer/loader/applicators and harvesters; and cotton aerial mixer/loaders, pilots and flaggers. The RCD recommended mitigation to reduce exposures. Dietary margins of safety for potential acute exposure from consumption of pears were of concern for children aged one to six. The RCD recommended revised amitraz tolerance levels. Cancer risks estimates for occupational exposures including dietary were between 1 and 12 in 100,000; for dietary exposures only, cancer risk estimates were between 7 and 12 in 1,000,000.

3. *U.S. EPA's RED, 1995 (U.S. Environmental Protection Agency, 1995)*

   The U.S. EPA evaluated 11 occupational exposure scenarios of mixers, loaders, and applicators defined by the type of application equipment and procedures employed by handlers of amitraz on pears, cotton, and livestock. The margins of

safety were at levels of concern for pear handlers using wettable powder formulations mixed/loaded/applied from an open bag/open cab/air blast, and cotton handlers using liquid formulations mixed/loaded by open pour and applied by groundboom. Post-application exposures were greatest for workers entering treated pear orchards and cotton fields to perform tasks that required substantial dermal contact with treated foliage. Exposure estimates decreased after a lapse of 28 days before reentry. Excess carcinogenic risk estimates for handlers were estimated at 1 in 100,000. The U.S. EPA took a regulatory position for reregistration of amitraz requiring a closed mixing/loading system for pear and cotton applications; establishing personal protective equipment (PPE) for early entry workers; increasing the restricted entry interval to 28 days for applications on pears and to 48 hours on cotton; increasing the interval between successive applications on pears to 35 days; requiring mechanical flagging and harvesting for cotton; and revising tolerance levels. A regulatory alternative available to registrants is the request for voluntary cancellation of a product. By 2006, all registered uses of amitraz on cotton and pears were cancelled (U.S. Environmental Protection Agency, 2006b) (U.S. Environmental Protection Agency, 1997a) (U.S. Environmental Protection Agency, 1997b) (U.S. Environmental Protection Agency, 1998).

4. *Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Amitraz, 2006 (U.S. Environmental Protection Agency, 2006c)*

The TRED required U.S. EPA to consider aggregate risks from non-occupational sources of pesticide exposure, increased susceptibility to infants and toddlers, and cumulative effects of pesticides that share a common mechanism of toxicity. Aggregate risks were of concern for toddlers when acute dietary exposures were combined with the newly established residential post-application exposures. The revised human health risk assessment for the TRED assumed that the dog collar would be replaced continuously during the lifetime of a dog constituting a potential long-term exposure instead of the intermediate exposure assumed in the RED (U.S. Environmental Protection Agency, 2006a). Both dermal (petting) and incidental oral (hugging) routes of exposure had unacceptable margins of safety associated with the 3.8 gram amitraz-impregnated dog collar. The registrant requested voluntarily cancellation of the product (U.S. Environmental Protection Agency, 2007a) and developed two collars with lesser amounts of amitraz. For the purpose of tolerance reassessment, U.S. EPA did not find that amitraz shared a common mechanism of toxicity with other compounds. Revised tolerance levels for amitraz became effective in September 2007 (U.S. Environmental Protection Agency, 2007b).

IV. PESTICIDE USE and SALES

Predominant uses of amitraz in California were on cotton to control white fly and spidermites, and on pears to control pear psylla. The year of highest reported use occurred in 1995 with 368,480 pounds applied to cotton and 8,155 pounds to pears (Department of Pesticide Regulation, 2008b). In 1995, cotton applications occurred in the following counties: Colusa, Fresno, Imperial, Kern, Kings, Madera, Merced, Riverside, San Bernardino, and Tulare. Livestock are not considered an agricultural commodity in California for the purpose of pesticide reporting. Consequently, data on use of amitraz on livestock is not known. Amitraz contributed less than 0.01% of total annual pounds of pesticides sold for the period 1993 to 2006.

Table 2. Amitraz Use and Sales Data in California, 1993 - 2006

Year	Site	Pounds Amitraz Used (a)	Pounds Amitraz Sold (b)	Total Pounds Pesticides Sold	% Amitraz Sold
1993	Cotton	78	None		Not
	Pear	9,723	Reported	661,930,865	Available
1994	Cotton	348,894	None		Not
	Pear	4,143	Reported		Available
	Outdoor Plants	10		624,879,618	
1995	Cotton	368,480	None Reported		Not
	Pear	8,155			Available
	Other	306		542,698,646	
1996	Cotton	261,761			
	Pear	7,632	57,556	639,302,185	0.009
1997	Cotton	66,664			
	Pears	644	90,228	645,084,329	0.01
1998	Cotton	12,836			
	Pears	705			
	Sugarbeet	22	14,302	617,049,796	0.002
1999	Almond	8			
	Beehives	8			
	Cotton	7,538			
	Pears	4	10,872	707,150,778	0.002
2000	Cotton	8,032			
	Pears	56	5,028	601,034,019	0.001
2001	Cotton	263	5,952	563,154,095	0.001
2002	Cotton	141			
	Pears	12	266	598,160,626	0.000
2003	Cotton	115	198	661,488,765	0.000
2004	0	0	172	667,103,789	0.000
2005	0	0	184	611,368,382	0.000
2006	Rights of Way	12	312	742,761,450	0.000

(a) Department of Pesticide Regulation, Summary of Pesticide Use Report Data, accessed March 4, 2008 www.cdpr.ca.gov/docs/pur/purmain.htm.
(b) Department of Pesticide Regulation, Report of Pesticides Sold in California, Mill Assessment Branch, accessed March 4, 2008 www.cdpr.ca.gov/docs/mill/nopdsold.htm.

V. FORMULATION and USES

In 2006, Mitac W Insecticide for use on livestock was voluntarily cancelled and in December 2008, the registrant did not renew the product for use in California. Six products are currently registered for use in California (Table 3).

Table 3. Amitraz Products Registered in California as of January 2009					
	Product and % Active Ingredient (AI)	**Registrant and U.S. EPA Number**	**Signal Word**	**Use**	**Date DPR Accepted Label**
1	Taktic Emulsifiable Concentrate Miticide/Insecticide, 12.5% AI	Intervet Inc. 54382-3-ZA	Danger	On beef and dairy cattle and swine to control ticks, mange mites & lice	11/21/2005
2	Preventic Tick Collars For Dogs 25", 9 % or 2.5 grams AI	Virbac, Inc. 2382-104-AA	Caution	On dogs to kill ticks	3/23/2000
3	Preventic Tick Collar For Dogs 18", 9% or 1.8 grams AI	Virbac, Inc. 2382-104-ZC	Caution	On dogs to kill ticks	6/25/2007
4	ZEMA Tick Detach For Dogs 25", 9 % or 2.5 grams AI	Virbac, Inc. 2382-104-ZB	Caution	On dogs to kill ticks	9/12/2003
5	ZEMA Tick Detach 18" 9 % or 1.8 grams AI	Virbac , Inc. 2382-104-ZD	Caution	On dogs to kill ticks	6/25/2007
6	ProMeris for Dogs Sizes XS, S, M, L, XL, 14.34% AI	Fort Dodge Animal Health 80490-2-AA	Caution	Single spot application for control of fleas & ticks on dogs aged 8 weeks and older	8/17/2007

VI. LABEL REQUIREMENTS

As a product for use on livestock, Taktic Emulsifiable Concentrate would normally be outside the Worker Protection Standard. However, the RED specified baseline PPE.

Table 4. Amitraz Label Statements For Products Registered in California as of December 2008						
Label Statement	**Taktic EC** Made in Canada	**Preventic 25"** Made in France	**Preventic 18"** Made in France	**ZEMA 25"** Made in France	**ZEMA 18"** Made in France	**ProMeris for dogs** Made in Italy
First Aid & Hot Line	Yes.	No.	Yes.	First Aid	Yes.	Yes.
PPE – Applicators & Handlers	Chemical-resistant **:** • apron or coveralls over long-sleeved shirt & long pants; • footwear plus socks; • gloves; • headgear for overhead exposure. Goggles or face shield & chemical-resistant apron when cleaning equipment, mixing/loading.	None Established	None Established	None Established	None Established	None Established
User Safety	Written In Spanish: "If unable to read English, do not use until fully explained"					
Storage & Disposal	Yes.	Disposal	Yes.	Yes.	Yes.	Yes.
Available only from licensed veterinarian	No.	**Yes.**	**Yes.**	No. Note to Veterinarian	No. Note to Veterinarian	**Yes.**
Proposition 65 Notice	Yes.	Absent	Yes.	Yes.	Yes.	Absent

VII. EXPOSURE SCENARIOS

Occupational, dietary, and residential post-application exposure scenarios were identified for pesticide handlers, the general U.S. population, and infants and toddlers, respectively. Exposure dosages were estimated, risks quantified, and either mitigation measures were implemented or

products were cancelled. Additional exposure scenarios are not anticipated at this time, given available information. The U.S. EPA has required additional information on the use of cotton undelinted seed in foreign countries to support the import tolerance level, and toxicity studies and absorption chemistry data on the technical grade.

VIII. PESTICIDE ILLNESS REPORTS

The only illnesses reported to DPR associated with use of amitraz for the period 1994 through 2006 occurred with applications to cotton. Of five reported illnesses, one occurred in 1997 when an applicator left the enclosed cab and opened an amitraz container for the mixer/loader without wearing protective eye goggles as required. Four others occurred between 1994 and 2006 with amitraz listed as one of several pesticides associated with the incident (Department of Pesticide Regulation, 2008a).

A literature search identified 17 articles on amitraz poisonings, all from other countries and primarily from Turkey (Table 5). Increased use of amitraz in agriculture and veterinary medicine in Turkey in the 1990s was noted in the articles.

Table 5. Amitraz Poisonings in Other Countries 1996 - 2006

	Country, City	Number of Cases (Period Covered)	Age (months / years)	Route; Number of Suicides	Reference
1	France	4	15 mos–82 yrs	Oral; 3 suicide	(Kennel *et al.*, 1996)
2	Belgium	1	45 yrs	Oral	(Jorens *et al.*, 1997)
3	China	1	33	Oral; suicide	(Leung *et al.*, 1999)
4	Turkey, Diyarbakir	11	2.5–6 yrs	Oral	(Yaramis *et al.*, 2000)
5	Turkey, Izmir	10	4–34 yrs	Oral; 2 suicide	(Ulukaya *et al.*, 2001)
6	Turkey, Samsun	2	35-80 yrs	Oral; 1 suicide	(Doganay *et al.*, 2002)
7	Turkey, Konya	14 (1994-2001)	2-5 yrs	12 Oral; 2 Dermal	(Atabek *et al.*, 2002)
8	Turkey, Konya	24	2-6 yrs	23 Oral; 1 Dermal	(Aydin *et al.*, 2002)
9	Turkey, Trabzon	43 (1993-2000)	10 mos–13 yrs	29 Oral; 14 Dermal	(Kalyoncu *et al.*, 2002)
10	Turkey	9 (1995-2002)	10 mos–8yrs	Oral; 1 suicide	(Yilmaz and Yildizdas, 2003)
11	Turkey, Van	8 (1996-2002)	1-4 yrs	Oral	(Caksen *et al.*, 2003)
12	Turkey, Izmir	7 (1999-2001)	2-6 yrs	6 Oral; 1 Dermal	(AAgin *et al.*, 2004)
13	Israel	1	54 yrs	Oral	(Elinav *et al.*, 2005)
14	Turkey, Sivas	1	22 yrs	Intravenous; suicide	(Gursoy *et al.*, 2005)
15	Turkey, Erzurum	1	36 yrs	Oral	(Aslan *et al.*, 2005)
16	Turkey, Kayseri	23 (1995-2004)	16-78 yrs	21 Oral; 7 suicide 1 Dermal; 1 Dermal and/or inhalation; 1 died from pulmonary embolus	(Avsarogullari *et al.*, 2006)
17	Turkey, Sivas	45 (1997-2004)	4-97 yrs	Oral; 15 suicide	(Demirel *et al.*, 2006)

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