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Director

MEMORANDUM

Jared Blumenfeld  
Secretary for  
Environmental Protection

TO: Nan Singhasemanon  
Assistant Director  
Pesticide Programs Division

**HSM-20002**

FROM: Susan McCarthy, M.S. *(original signed by S. McCarthy)*  
Environmental Program Manager II  
Chief, Worker Health and Safety Branch  
(916) 324-4116

DATE: September 30, 2020

SUBJECT: COMPLETION OF AMITRAZ MITIGATION FOR AGRICULTURAL USE  
EXPOSURES

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The amitraz agricultural use exposure mitigation completion memorandum (Schaffner 2020) describes the findings of the Worker Health and Safety (WHS) Branch with regard to the need for mitigation of agricultural use exposures for amitraz.

In 1995, the United States Environmental Protection Agency (U.S. EPA) issued a Reregistration Eligibility Decision (RED) and the Department of Pesticide Regulation (DPR) completed a risk characterization document (RCD) for amitraz (U.S. EPA 1995, Frank 1995). Both the RED and RCD found all potential human health exposure scenarios of concern to be acceptable, with the exception of pear and cotton handler and post-application exposures.

By 2006, all registered uses of amitraz on pears and cotton were cancelled. By 2010 there was no reported agricultural use. However, in 2013, impregnated strips for beehives were registered and remain the sole registered agricultural use for amitraz. In 2017, 14 total pounds of amitraz were applied, primarily to treat beehives (DPR 2020).

In 2014, DPR evaluated agricultural use exposures for handlers placing impregnated strips in beehives, which had not specifically been addressed in the original RCD, and determined that these exposures were not of concern (Reeve 2014). U.S. EPA's 2018 draft human health risk assessment for amitraz also determined that exposures resulting from placing impregnated strips in beehives were not of concern (U.S. EPA 2018).

Given that all agricultural use products except impregnated strips have been cancelled, the remaining use on beehives has no exposure concerns, and reported use of amitraz is very low, WHS finds that no further mitigation measures are needed for agricultural use products containing amitraz. Your approval of this conclusion is requested.

Attachment

cc: Shelley DuTeaux, Chief, Human Health Assessment Branch  
Eric Kwok, Senior Toxicologist, Human Health Assessment Branch

Nan Singhasemanon  
September 30, 2020  
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Svetlana Koshlukova, Senior Toxicologist, Human Health Assessment Branch  
Kevin Solari, Environmental Program Manager I, WHS Branch  
Ann Schaffner, Senior Environmental Scientist (Supervisory)

APPROVAL: *(original signed by N. Singhasemanon)* *October 19, 2020*  
Nan Singhasemanon, Assistant Director Date

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## MEMORANDUM

TO: Susan McCarthy  
Environmental Program Manager II  
Chief, Worker Health and Safety Branch

VIA: Kevin Solari *(original signed by K. Solari)*  
Environmental Program Manager I  
Worker Health and Safety Branch

FROM: Ann Schaffner *(original signed by A. Schaffner)*  
Senior Environmental Scientist (Supervisory)  
Worker Health and Safety Branch  
(916) 445-0111

DATE: September 24, 2020

SUBJECT: COMPLETION OF AMITRAZ MITIGATION FOR AGRICULTURAL USE  
EXPOSURES

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### Summary

This memorandum presents the recommendation that no additional mitigation measures are needed for agricultural use-related exposures to the insecticide/acaricide amitraz. In 1995, the United States Environmental Protection Agency's (U.S. EPA) Reregistration Eligibility Decision (RED) evaluated 11 agricultural use exposure scenarios, while the Department of Pesticide Regulation's (DPR) Amitraz Risk Characterization Document (RCD) evaluated 9 agricultural use scenarios. Both U.S. EPA and DPR identified several occupational exposures on pears and cotton that exceeded levels of concern (U.S. EPA 1995, Frank 1995). In 2014, DPR evaluated agricultural use exposures for handlers placing beehive treatment strips, which were not specifically addressed in the original RCD, and determined that these exposures were not of concern (Reeve 2014). U.S. EPA's draft human health risk assessment for amitraz also determined that exposures resulting from placing impregnated strips in beehives were not of concern (U.S. EPA 2018). The recommendation that no additional mitigation measures are needed for agricultural use products containing amitraz is based on the following:

- 1) By 2006, all registered uses of amitraz on cotton and pears were cancelled (U.S. EPA 1997a, U.S. EPA 1997b, U.S. EPA 1998, U.S. EPA 2006b).
- 2) Use of amitraz is low and has been in steady decline since 1995. By 2010, there was no reported agricultural use. In 2013, impregnated strips for beehives were registered and remain the sole registered agricultural use for amitraz. In 2017, 14 total pounds of amitraz were applied, primarily to treat beehives (DPR 2020a).
- 3) Based on Pesticide Illness Surveillance Program (PISP) data from 1992 to 2017 (the last year for which data are available), there have been no reports of worker illnesses due to exposure to amitraz since 1997 (DPR 2020d).

- 4) There were no amitraz residues detected on agricultural commodities from 1990 to 2018 (DPR 2020c).

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## **Scope**

This mitigation completion memorandum addresses agricultural exposures due to agricultural uses of amitraz specified in U.S. EPA’s registration evaluations, DPR’s RCD, and agricultural exposures to handlers of impregnated strips for beehives evaluated in a 2014 supplemental amitraz exposure memorandum (Reeve 2014). In addition to the agricultural handler scenario, the 2014 memorandum evaluated four non-agricultural scenarios that were not specifically addressed in the 1995 Amitraz RCD. These scenarios included post-application exposures to adults and children from spot-on and pet collar products (Reeve 2014). This mitigation completion memorandum does not address the non-agricultural exposures.

## **Amitraz Classification and Use**

Amitraz is a contact insecticide, miticide, and acaricide classified in the amidine chemical group. Amitraz was first registered as a technical grade pesticide in the U.S. in 1975 (U.S. EPA 1995). According to acute toxicity studies, amitraz shows slight oral and inhalation toxicity and moderate dermal toxicity. Amitraz is not categorized as a dermal or eye irritant, nor is it a dermal sensitizer (U.S. EPA 2006a). Amitraz is classified as a Group C "possible" human carcinogen (U.S. EPA 1995).

Historically, amitraz was used in agricultural settings to control white flies and spidermites on cotton; pear psylla on pears; ticks, mange mites, and lice on livestock; and fleas and ticks on dogs (Kelly 2009). Amitraz is currently used agriculturally to control varroa mites on honeybees and in beehives (impregnated strips for application between beehive comb frames) and has non-agricultural uses controlling fleas and ticks on dogs (impregnated collars).

## **Regulatory History**

### ***1995 RCD***

DPR's Amitraz RCD evaluated nine agricultural scenarios: pear orchard mixer/loader/applicators; pear harvesters; cotton ground mixer/loader/applicators; cotton flaggers and field checkers; cotton aerial mixer/loaders; pilots; cattle mixer/loader/applicators; and swine mixer/loader/applicators. Scenarios with margins of safety (MOSs) for acute exposure that exceeded levels of concern were pear mixer/loader/applicators and harvesters, cotton aerial mixer/loaders, pilots, and flaggers. Acute MOSs were based on No Observable Effect Levels (NOELs) from human data, thus MOSs of at least 10 were considered protective of human health. However, MOSs for seasonal, annual, and lifetime exposures were based on NOELs from non-human mammalian data, so an additional safety factor of 10 was used (i.e., MOS of 100). For seasonal and annual exposures, only the MOS for pear harvesters exceeded levels of concern. Dietary MOSs for potential acute exposure from consumption of pears were of concern for children, ages 1 to 6. Cancer risks estimates for occupational and dietary exposures were between 1 and 12 in 100,000. For dietary exposures only, cancer risk estimates were between 7 and 12 in 1,000,000 (Frank 1995).

### ***1995 RED***

The U.S. EPA RED for amitraz evaluated 11 occupational exposure scenarios for mixers, loaders, and applicators defined by the application equipment and procedures used by handlers to treat pears, cotton, and livestock. Scenarios with MOSs exceeding levels of concern were 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 ground boom. 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. Excess carcinogenic risk estimates for handlers were estimated at 1 in 100,000. Based on the evaluated exposure scenarios, U.S. EPA took a regulatory position for reregistration of amitraz requiring closed mixing/loading systems for pear and cotton applications; personal protective equipment for early entry workers; an increase in the restricted entry interval to 28 days for applications on pears and 48 hours on cotton; an increase in the interval between successive applications on pears to 35 days; mechanical flagging and harvesting for cotton; and revised tolerance levels (U.S. EPA 1995).

### ***2006 Tolerance Reassessment Progress and Risk Management Decision (TRED)***

U.S. EPA's TRED determined that acute dietary risk estimates for the general U.S. population and youth (>13 years old) and adult population subgroups exceeded the level of concern. However, the acute dietary risk estimates for these subgroups were below the level of concern when hops, the primary contributor to the risk, were excluded (U.S. EPA 2006a). Based on dietary risks to youth and adults, the tolerance for hops was revoked (U.S. EPA 2006c, 2007).

By 2006, all registered uses of amitraz in beehives were canceled, along with the voluntary cancellation of amitraz use on cotton and pears. Because of continued use on animal commodities in the U.S., tolerances for cattle and swine were retained. Thus, amitraz tolerances for canceled uses were revoked and tolerances for remaining uses were revised; these tolerance actions became effective in September 2007 (U.S. EPA 2007). In the TRED, Arysta Life Sciences requested to retain an import tolerance for cotton, undelinted seed (U.S. EPA 2006c). However, in July 2011, Arysta notified U.S. EPA that it no longer wanted to support the tolerance. Therefore, in November 2015, U.S. EPA revoked the tolerance for amitraz on cotton, undelinted seed, which became effective May 2016 (U.S. EPA 2015). Following a Cancer Assessment Review Committee re-evaluation of amitraz, it was classified as a non-quantifiable “Suggestive Evidence of Carcinogenicity” (U.S. EPA 2006c).

### ***2018 Draft Human Health Risk Assessment***

In September 2018, U.S. EPA released a draft human health risk assessment for amitraz. The risk assessment determined that occupational and residential dermal and inhalational exposures resulting from the application of impregnated strips in beehives was negligible (U.S. EPA 2018).

### **Current Regulatory Status**

All registered uses of amitraz in agricultural settings were canceled by 2006. However, in May 2013, the amitraz product, Apivar (87243-1-AA), was registered for use on beehives in California. Apivar, manufactured by Veto-Pharma S.A., is a hanging strip impregnated with amitraz that is placed in beehives to control varroa mites. In March 2014, U.S. EPA established a permanent tolerance to support amitraz use in honey at 0.2 parts per million (ppm) and honeycomb at 9 ppm (U.S. EPA 2013). The U.S. EPA draft human health risk assessment recommended that amitraz residue tolerances in honey to be reduced to 0.1 ppm (U.S. EPA 2018).

### ***Proposition 65***

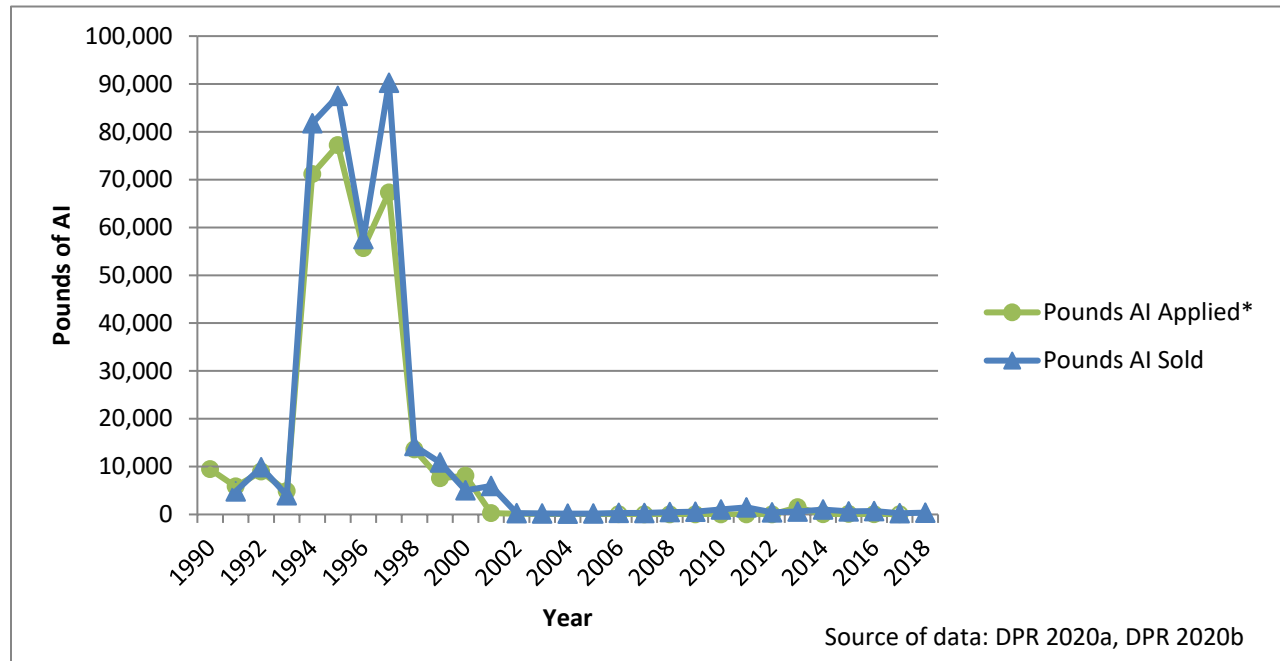
Amitraz was included on the Office of Environmental Health Hazard Assessment (OEHHA) Proposition 65 list in 1999 (OEHHA 1999). In September 2012, OEHHA listed amitraz in the first priority group of chemicals for which a maximum allowable dose level would be developed (OEHHA 2012).

### **Use and Sales in California**

From 1990 to 2010, amitraz was used primarily on pears, cotton, and livestock. Reported use was highest in 1995 (77,000 pounds of amitraz were applied) followed by a steady decline (Figure 1). From 2010 to 2012, there were no reported uses of amitraz. Then in 2013, amitraz use increased to 1,486 pounds; use was almost entirely on beehives, (DPR 2020a). Since then, use

decreased significantly to only 14 pounds in 2017. From 1991 to 2018, reported amitraz sales within California showed a similar decline (DPR 2020b, Figure 1).

**Figure 1. Reported Amitraz Use and Sales in California, 1990 – 2018\***



\*Amitraz use data is from 1990 – 2017 (the last year for which data are available).

### **Residue data**

Each week, DPR’s Food Safety Residue Program collects samples of harvested fruits and vegetables throughout the channels of trade and analyzes the produce samples for pesticide residues. According to the Food Safety Residue Program database, from 1990 to 2017, there were no residue detections for amitraz (DPR 2020c). In 1990, amitraz appeared in the database because a specific screen was requested to analyze for the presence of the pesticide; the screen was negative for amitraz (DPR 2014).

### **Illness data**

Between 1992 and 2017 (the most recent data available), the PISP database reported seven amitraz-related illness cases. Five of the seven cases occurred between 1992 and 1997; these were all due to agricultural use. In 1994, there was a “possible” exposure incident in which a homeowner was exposed to drift from an aerial application. In 1995, there were two “possible” exposure incidents in which two crew members developed rashes while weeding a cotton field.

In 1997, one “definite” exposure incident occurred when an applicator splashed pesticide in his eye after opening an amitraz container for the mixer/loader, and one “possible” exposure occurred when an irrigator developed a body rash consistent with dermal exposure to pesticide residue while irrigating a cotton field that had been treated 13 days earlier. (DPR 2020d).

Between 1998 and 2015 and in 2017, there were no reported illness cases. However, in 2016, there were two non-agricultural use incidents. One “definite” exposure incident occurred when a woman fell ill after inadvertently drinking a flea treatment instead of a similarly packaged laxative, both of which had been recently purchased in Mexico. One “probable” exposure occurred when a woman complained of symptoms after spraying an insecticide (possibly purchased in Mexico) in her home without ventilation and staying inside all day (DPR 2020d).

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