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M E M O R A N D U M

HSM-21001

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DATE: January 15, 2021

SUBJECT: REQUEST TO REPRIORITIZE ACTIVE INGREDIENTS THAT WERE PREVIOUSLY PRIORITIZED AND NOTICED FOR RISK ASSESSMENT INITIATION

INTRODUCTION

In accordance with the Food and Agricultural Code (FAC)[1], the Department of Pesticide Regulation (DPR) reviews the toxicology database of all registered pesticide active ingredients (AIs), assesses dietary risks associated with the use of pesticides, and strives to eliminate the use in California of any pesticide that endangers the agricultural or nonagricultural environment (Prichard 2008). To that end, AIs are evaluated and prioritized based on potential adverse health effects identified in studies of sufficient quality to allow risk characterization.

Prioritization of an AI for risk assessment begins with an evaluation by the Adverse Effects Advisory Panel (AEAP), comprised of staff from DPR and the Office of Environmental Health and Hazard Assessment (OEHHA). This panel meets periodically to group AIs into high-, moderate-, or low-priority categories based on criteria that include the Federal Insecticide, Fungicide and Rodenticide Act database (e.g., chronic toxicity, oncogenicity, reproductive toxicity, teratogenicity, genotoxicity) and exposure potentials indicated by label uses (DPR 2015).

The Risk Assessment Prioritization Work Group (RAPWG), comprised of staff from DPR, OEHHA, and the Air Resources Board, reviews and recommends ten AIs categorized by the AEAP (primarily those categorized as high-priority) for further examination. The RAPWG further ranks the ten AIs based on exposure potential, physical-chemical properties, and toxicity in order to determine the level of concern. The RAPWG meets as needed, in part to make recommendations for additional AIs to replace those that are removed when risk assessments are initiated (DPR 2015).

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[1] FAC Sections 13121-13130, 13134, and 12824.

Upon approval by its Chief Deputy Director, DPR proposes the list of AIs ranked by the RAPWG for risk assessment initiation, and begins a 45-day comment period. The ranked AIs are also presented at a meeting of DPR's Pesticide Registration and Evaluation Committee to provide committee members and the public an opportunity to make any comments. Following a review of all comments received, DPR decides which ranked AIs will enter the risk assessment process and issues a formal "Notice to Registrants" that the department is initiating the risk assessment process for registered pesticide products containing the selected AIs (DPR 2015).

During the risk assessment process, the Human Health Assessment Branch evaluates the AIs selected for risk assessment to determine the level of risk to human health associated with pesticide use and the likelihood of exposure. The risk assessment process culminates with the completion and publication of a risk characterization document.

The following AIs have already been prioritized, ranked, and noticed for risk assessment initiation by DPR: diazinon, esfenvalerate, lambda-cyhalothrin, paradichlorobenzene, and sulfur dioxide. However, risk assessments were never conducted. Thus, DPR management tasked the Worker Health and Safety (WHS) Branch with determining why the AIs had been prioritized for risk assessment in order to inform possible reprioritization in the future. Since several years have elapsed from the time initiations were noticed, WHS also evaluated current use, sales, and illness data associated with each AI. This memorandum summarizes WHS's review of the five AIs and provides recommendations moving forward.

Diazinon

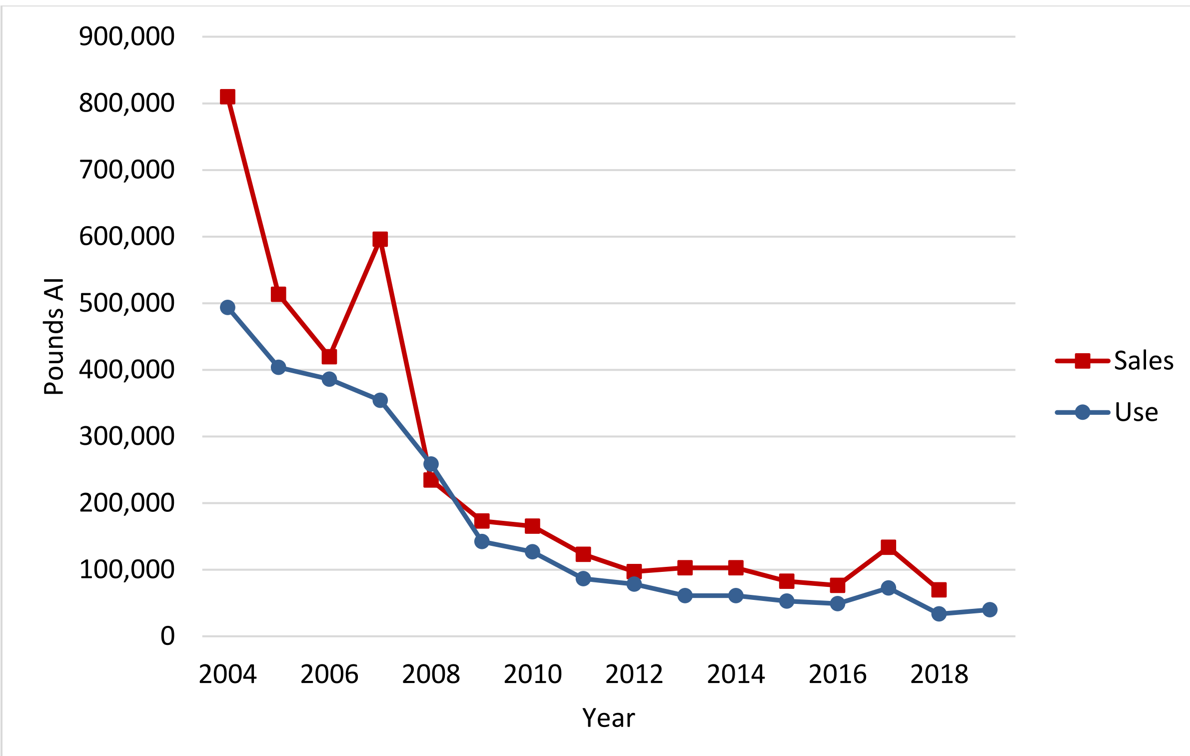
Diazinon is an organophosphate insecticide used in agricultural settings to control pests on tree fruits, vegetables, nuts, and other field crops. Currently, there are four registrants with eight active diazinon-containing products registered in California.

In 2007, the RAPWG prioritized diazinon for risk assessment due to its widespread use, toxicity profile, low no observed effects levels (NOELs), and demonstrated potential for exposure through ambient air (DPR 2007), as well as genotoxicity and reproduction studies (Patterson 2011). In 2008, DPR initiated the risk assessment process for registered pesticide products containing diazinon (Prichard 2008). In 2009, an air monitoring study, conducted in the Central Valley town of Parlier, found diazinon levels present in ambient air samples that exceeded the acute screening level (Wofford 2009).

Diazinon use peaked between 1993 and 1994 (1.41 million pounds and 1.36 million pounds, respectively) and has been in decline since that time. This decline is likely due to regulatory actions that were implemented by the United States Environmental Protection Agency and DPR, such as canceling residential uses and placing restrictions on agricultural uses (DPR 2007). Mitigation measures were also adopted to address surface water contamination concerns.

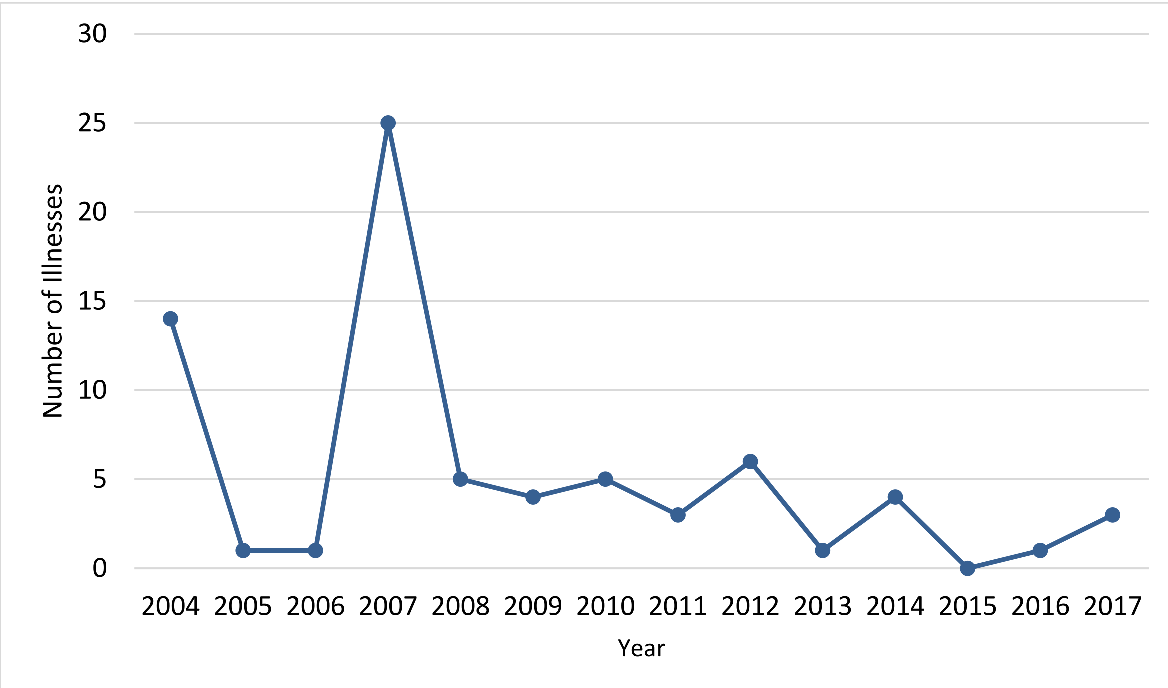
The reported total pounds sold annually have decreased from 809,813 pounds to 96,822 pounds between 2004 and 2012. There was an increase in reported sales in 2013 of 102,626 pounds but total pounds sold annually have continued to decrease from 102,783 pounds to 76,385 pounds between 2014 and 2016. In 2017, reported sales for diazinon increased again to 133,428 pounds, which was followed by a decrease to 69,707 in 2018, the most recent available data (Figure 1).

Figure 1. Diazinon use (2004-2019) and sales (2004-2018) (DPR 2020a, 2020b, 2020e)



According to the Pesticide Illness Surveillance Program (PISP) database, 73 reported illness cases were associated with diazinon between 2004 and 2017 (the most recent available data) (Figure 2). These reported illnesses were associated with both agricultural and non-agricultural uses, with 35 cases being classified as occupational and 38 cases classified as non-occupational. The most common routes of exposure were due to drift, odor, fumes, pesticide transfer (e.g., from contaminated hand/glove to eye), ingestion, and residue (DPR 2020c).

Figure 2. Diazinon illnesses, 2004-2017 (DPR 2020c)



Esfenvalerate

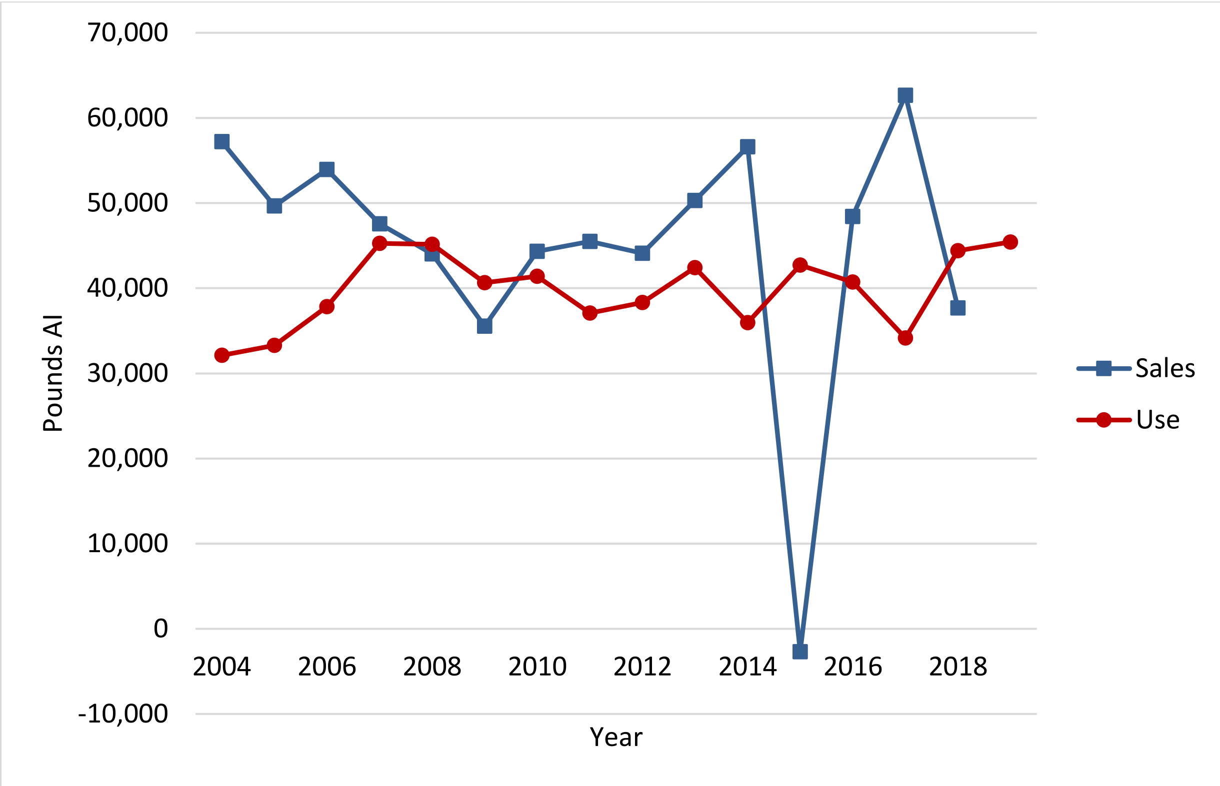
Esfenvalerate is a pyrethroid insecticide used to control pests on vegetable crops, fruit trees, nut crops, and lawns (Salomon 2008). It is used in agricultural, industrial, residential, and commercial settings. Currently, there are 27 registrants and 51 registered products containing esfenvalerate.

According to DPR's 2008 Scoping Document, there are potential exposure scenarios for occupational handlers (agricultural and commercial pesticide applicators), non-occupational residential handers, occupational/non-handlers (fieldworkers), and non-occupational/non-handlers (bystanders/residents) (Salomon 2008).

In 2011, esfenvalerate was identified as having potential adverse health effects in neurotoxicity studies (Patterson 2011). In 2012, DPR initiated the risk assessment process for registered pesticide products containing esfenvalerate (Prichard 2012).

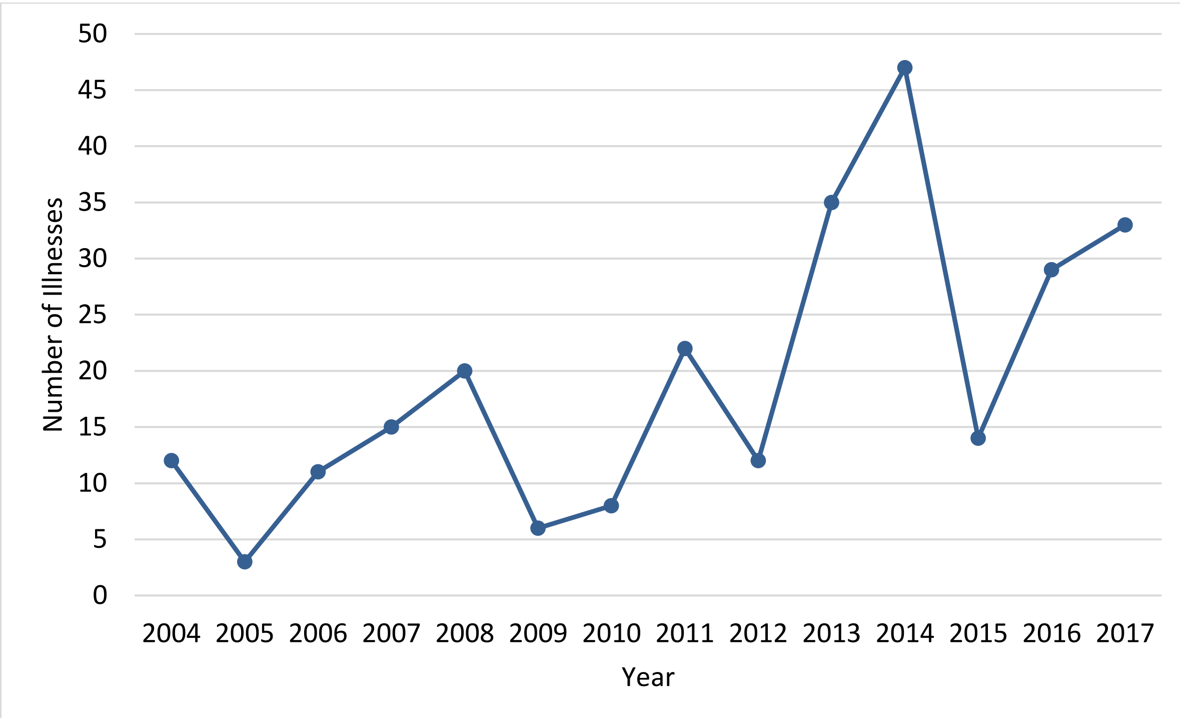
The reported total pounds sold annually decreased from 57,221 pounds to 35,522 pounds between 2004 and 2009, increased from 44,338 pounds to 62,672 pounds between 2010 and 2017, and decreased to 37,669 pounds in 2018. In 2015, negative 2,707 pounds of esfenvalerate were reported sold in California (Figure 3). Since specific details regarding pesticide purchases are not required to be tracked in California, it is difficult to determine the reason for a negative poundage. For instance, one scenario in which the total reported weight would reflect a negative amount is if a large purchase of a product was later returned within the same year. Furthermore, it is important to note that esfenvalerate has products that are registered in California for both residential use and agricultural use. The annual reported use may differ from the annual reported pounds sold because residential pesticide use is not required to be reported (Salomon 2008). Esfenvalerate use has generally increased between 2004 and 2019 (Figure 3).

Figure 3. Esfenvalerate use (2004-2019) and sales (2004-2018) (DPR 2020a, 2020b, 2020e)



Between 2004 and 2017, there were 267 reported illness cases associated with esfenvalerate (Figure 4). The reported illnesses were associated with both agricultural and non-agricultural uses, with 130 cases being classified as occupational and 137 cases classified as non-occupational. The most common routes of exposure were due to drift, spill or direct spray, and residue (DPR 2020c).

Figure 4. Esfenvalerate illnesses, 2004-2016 (DPR 2020c)



Lambda-Cyhalothrin

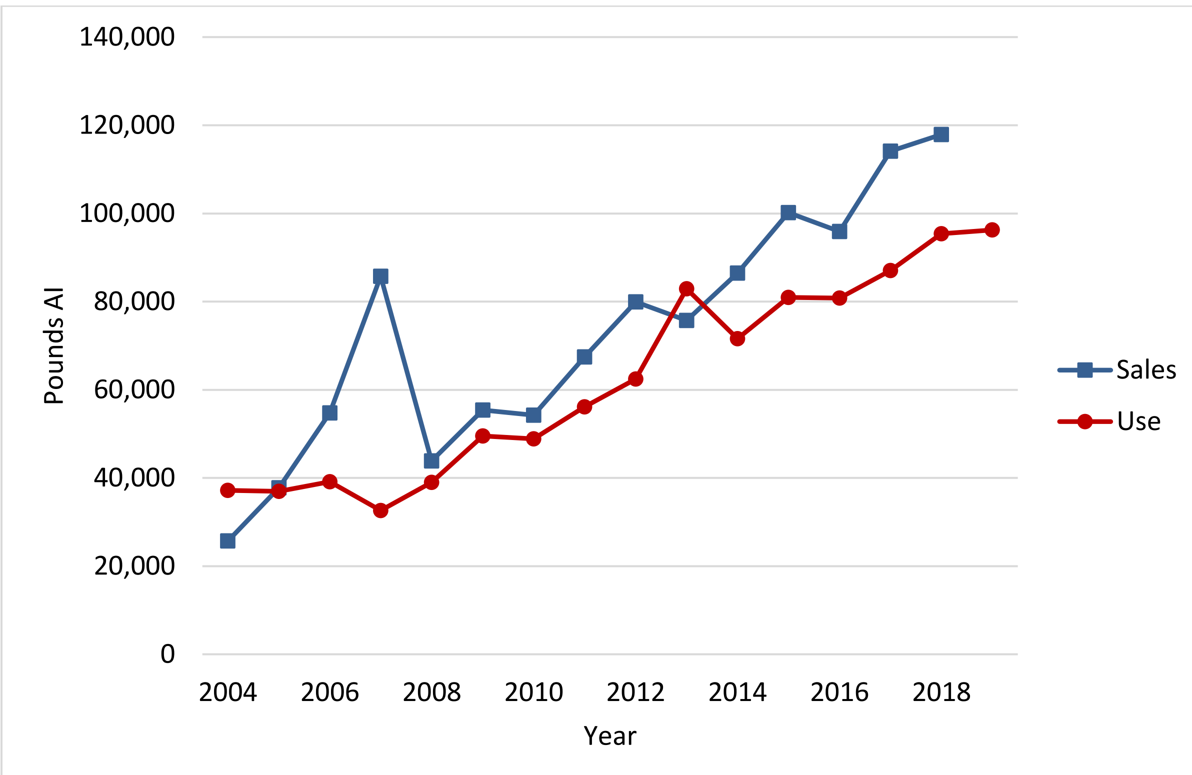
Lambda-cyhalothrin is a synthetic pyrethroid insecticide and miticide used to control various pests, such as aphids, adult Japanese beetles, grasshoppers, and butterfly larvae on a variety of agricultural sites (alfalfa, pistachio, lettuce, tomatoes, corn, cotton, and livestock) and non-agricultural sites, including in and around buildings and structures. Products containing lambda-cyhalothrin are typically applied using ground or aerial application equipment.

There are 35 registrants and 112 actively registered lambda-cyhalothrin products available in California. The product labels contain the "WARNING" signal word. The toxicity designations for lambda-cyhalothrin are Category II and III for the acute dermal toxicity and primary dermal irritation, respectively (DPR 2020d).

Lambda-cyhalothrin was prioritized for risk assessment initiation due to its relatively high NOEL for neurotoxicity in several animal species and studies, its carcinogenic potential (albeit equivocal), and its use in a variety of structural and residential settings (DPR 2007). In 2013, DPR initiated the risk assessment process for registered pesticide products containing lambda-cyhalothrin (Prichard 2013).

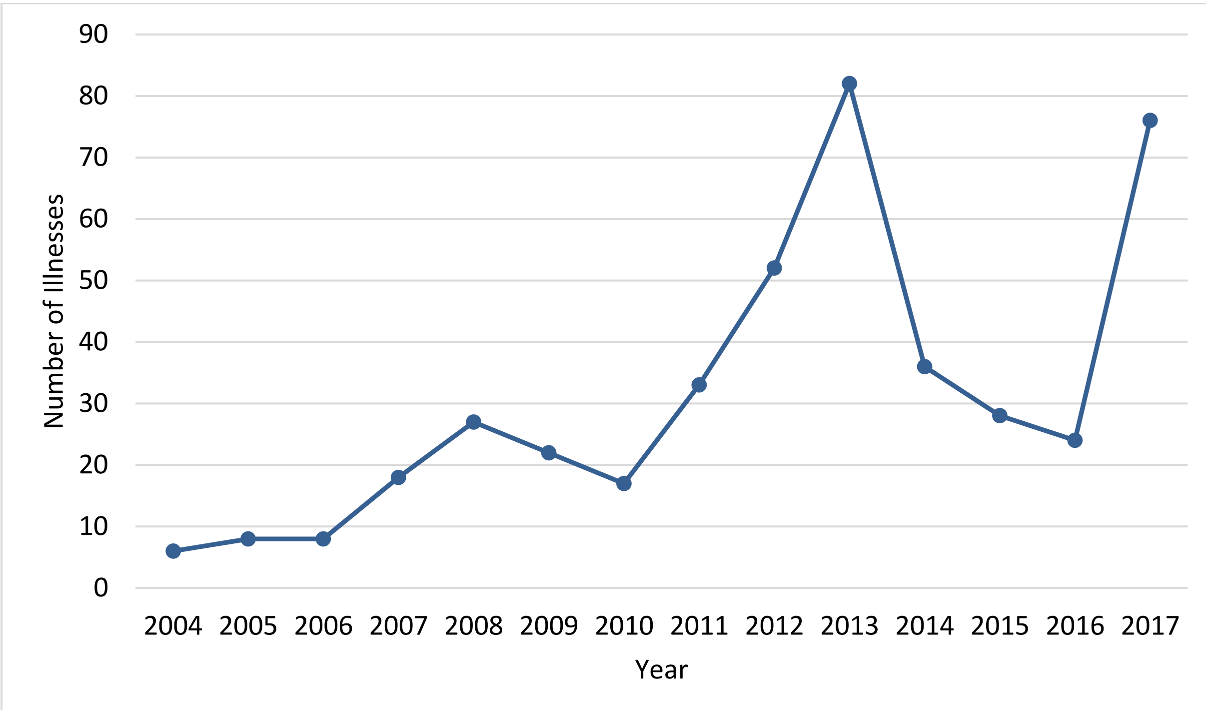
From 2004 to 2019, the annual use of lambda-cyhalothrin has generally increased. Annual sales of lambda-cyhalothrin have also generally increased from 2004 to 2018 (Figure 5).

Figure 5. Lambda-cyhalothrin use (2004-2019) and sales (2004-2018) (DPR 2020a, 2020b, 2020e)



According to PISP data, 437 lambda-cyhalothrin illnesses were reported from 2004 to 2017. The lowest number of illnesses (6) was observed in 2004 and the highest number of illnesses (82) was observed in 2013 (Figure 6). There were 222 occupational, 213 non-occupational, and 2 unknown illnesses observed between 2004 and 2017. The most common routes of exposure were due to drift, residue, and spill or direct spray (DPR 2020c).

Figure 6. Lambda-cyhalothrin illnesses, 2004-2017 (DPR 2020c)



Paradichlorobenzene

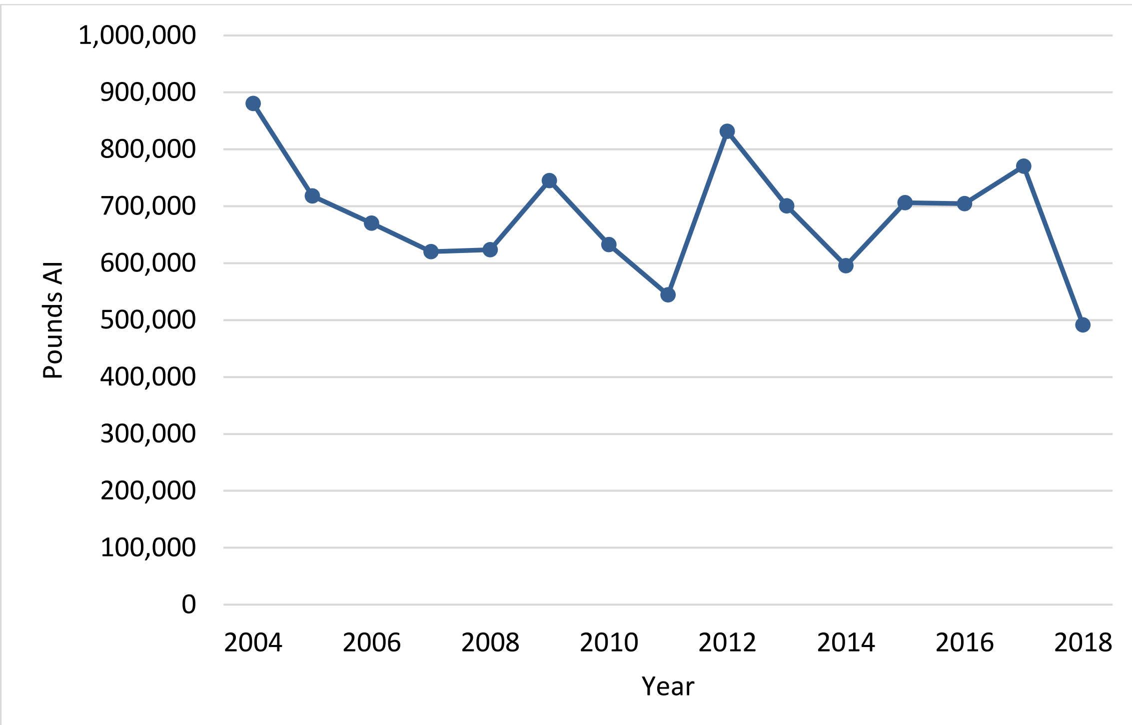
Paradichlorobenzene is a non-food and non-agricultural use fumigant pesticide, used to control insects and mold and to deodorize spaces (Kelly 2009). Paradichlorobenzene is commonly used in residential and commercial spaces as an indoor pesticide, often in the form of mothballs placed inside closets and drawers. Paradichlorobenzene is considered moderately toxic (Category III) via oral ingestion and for dermal irritation, and low toxicity via inhalation routes (Category IV). It is also listed as a toxic air contaminant in California.

DPR identified paradichlorobenzene as having potential adverse health effects in studies of sufficient quality to allow risk characterization (Prichard 2007). Thus, DPR initiated a risk assessment for paradichlorobenzene due to possible adverse effects identified in oncogenicity, reproduction, and genotoxicity studies (Patterson 2011).

According to DPR's 2009 Scoping Document, there are no occupational handler, aggregate, or cumulative exposure risks for paradichlorbenzene since it is a non-food pesticide. However, there are potential non-occupational (residential) exposure risks via household applications (Kelly 2009).

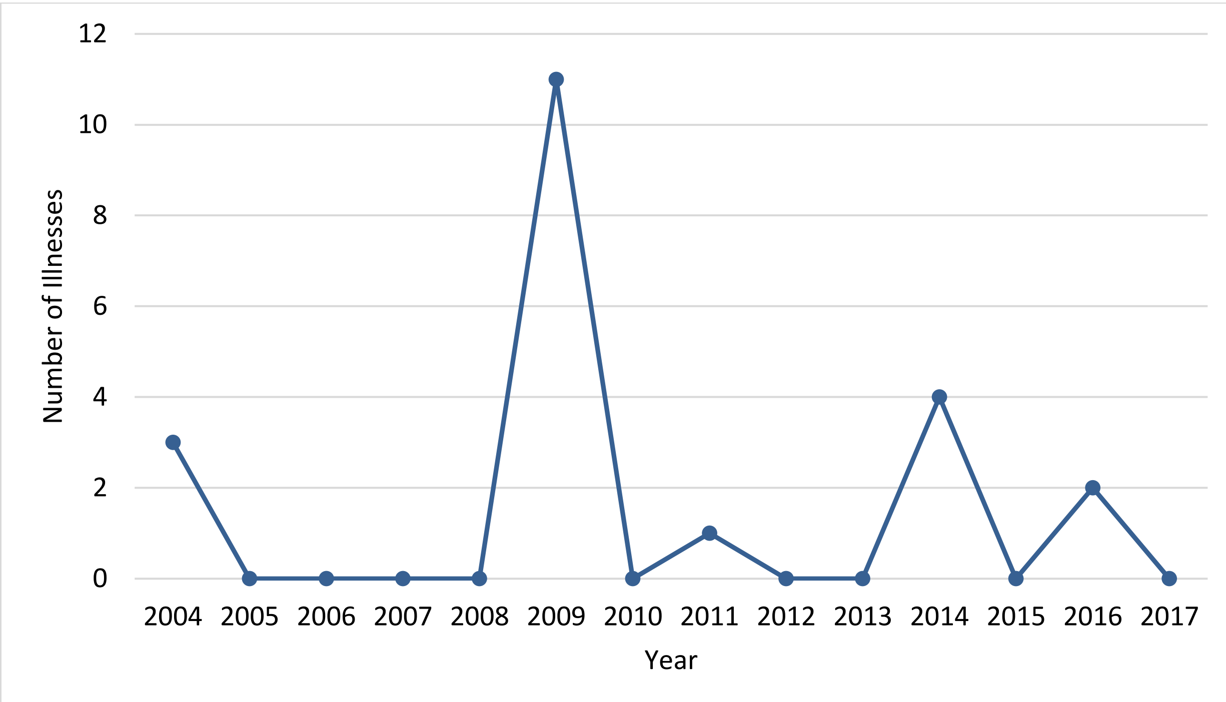
Currently, there are five registrants and 27 active paradichlorbeneze-containing products registered in California. The total pounds of paradichlorobenzene sold annually decreased from 880,715 pounds to 544,277 pounds between 2004 and 2011, but has increased from 595,605 pounds to 770,278 pounds between 2014 and 2017. This was followed by a decrease to 491,453 in 2018 (Figure 7). Since residential pesticide use is not required to be reported in California, the total pounds of paradichlorobenzene used by year are not available.

Figure 7. Paradichlorobenzene sales, 2004-2018 (DPR 2020b)



According to PISP data, there were 21 reported illnesses (all non-agricultural and non-occupational) associated with paradichlorobenzene between 2004 and 2017 (Figure 8). The most common routes of exposure were due to drift (includes spray, mist, fumes, or odor carried by air from the target site and relates to mix/load and application activities only), followed by ingestion and residue (DPR 2020c).

Figure 8. Paradichlorobenzene illnesses, 2004-2017 (DPR 2020c)



Sulfur Dioxide

Sulfur dioxide (SO_2) is a toxic gas with a smell similar to that of burnt matches. Large amounts of SO_2 are formed in the combustion of sulfur-containing fuels. SO_2 is introduced into the atmosphere through volcanic eruptions, burning biomass, and anthropogenic sources. In the atmosphere, it can combine with water vapor to form sulfuric acid. SO_2 is used in wineries as a sanitizer to control mold in wine containers (barrels and tanks) and corks, and as a non-sanitizer, antioxidant, and preservative to inhibit the growth of wild yeast during the fermentation process, and to prevent oxidation in the winemaking process.

SO_2 is moderately toxic (Category III) via acute inhalation; toxicity via other routes of exposure has not been determined. SO_2 is corrosive, causes skin and eye damage, and can be fatal if vapors or sulfur dust are inhaled (DPR 2020d).

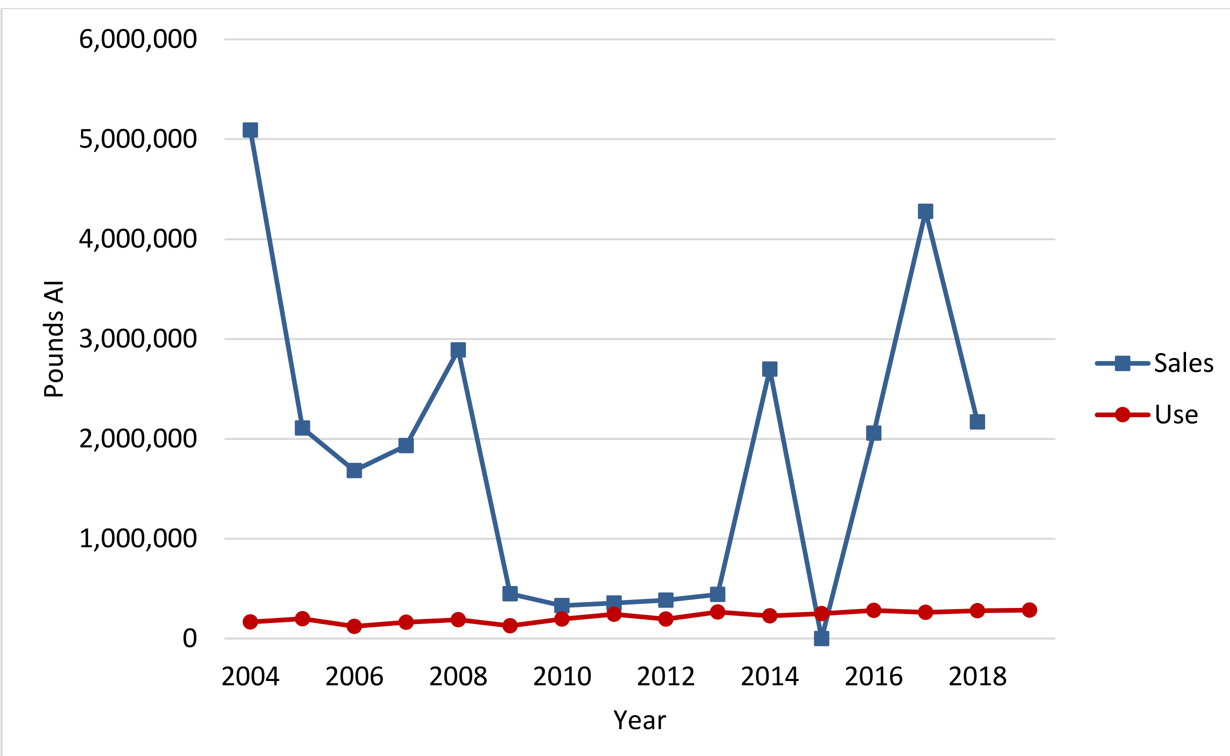
SO_2 was prioritized for risk assessment initiation because of its potential for inhalation exposure and for causing adverse respiratory effects in people. Because the pesticidal uses of SO_2 are insignificant contributors to the overall sulfur dioxide ambient air pollution, a risk assessment of SO_2 would only address its pesticidal use and the risks directly attributable to this use (DPR

2007). In 2014, DPR initiated the risk assessment process for registered pesticide products containing SO_2 (Prichard 2014).

There are two actively registered products in California: Air Gas Sulfur Dioxide and The Fruit Doctor. These products are pressurized gas, liquid, spray, and fogger formulations. Despite the Category III toxicity designation, both products are federally restricted materials and contain the signal word, "POISON/DANGER." The products are registered for postharvest grapes, wineries, wine cellars, figs, commercial transport facilities, and wood treatments. They can be applied via fumigation equipment to control bacteria, mold, microbes, and fungi.

The annual use of SO_2 has steadily increased, ranging from 122,213 to 284,493 pounds with the lowest and the highest use in 2006 and 2019, respectively (Figure 9). Annual sales of SO_2 were lowest from 2010 to 2013 (329,342 to 442,513 pounds) and highest (5,099,047 pounds) in 2004 (Figure 9).

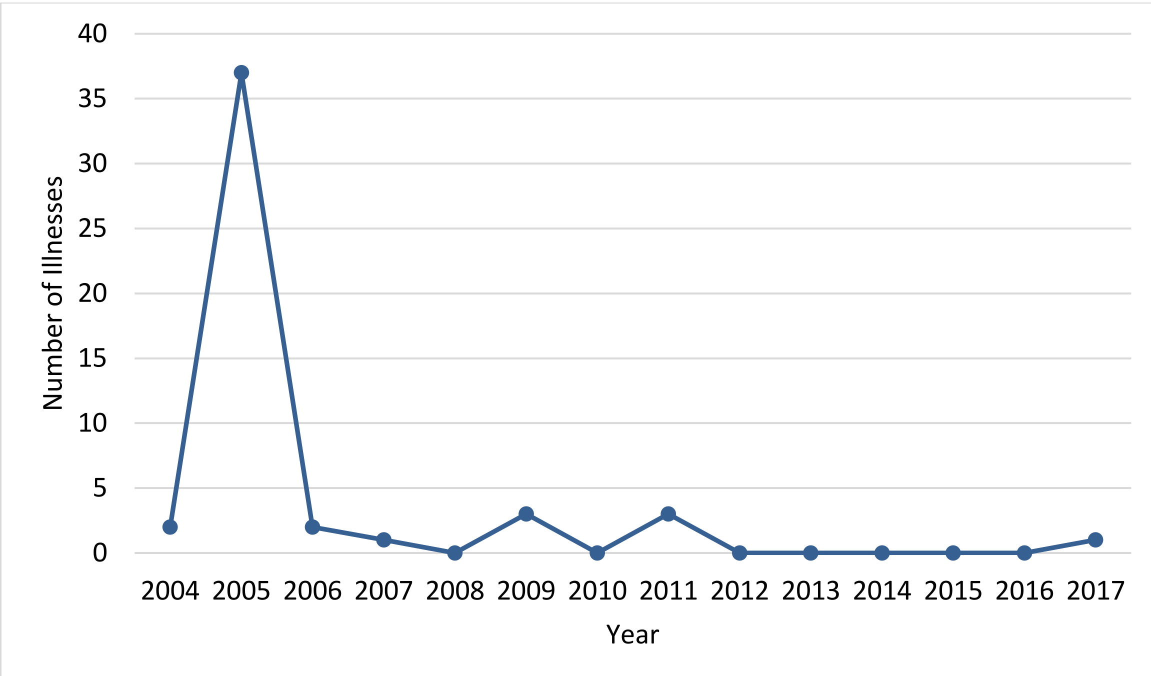
Figure 9. SO_2 use (2004-2019) and sales (2004-2018) (DPR 2020a, 2020b, 2020e)



According to PISP data, 49 SO_2 illnesses were reported from 2004 to 2017. The number of illnesses was lowest (1) in 2007 and 2017, and the number of illnesses was highest (37) in 2005. There were no illness incidences in 2008 or 2010, or from 2012 to 2016 (Figure 10). There were

6 occupational and 43 non-occupational illnesses observed between 2004 and 2017. The most common route of exposure was due to drift (DPR 2020c).

Figure 10. SO_2 illnesses, 2004-2017 (DPR, 2020c)



CONCLUSION

Although diazinon, esfenvalerate, lambda-cyhalothrin, paradichlorobenzene, and sulfur dioxide were prioritized, ranked, and noticed for risk assessment initiation based on identified potential adverse health effects and exposure concerns, risk assessments were never conducted. Given that there is no indication that respective human health concerns for these AIs have been addressed and that they continue to be used and sold in California, WHS recommends that these five AIs be reprioritized for risk assessment.

Your approval of this recommendation is requested.

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APPROVAL

(original signed by N. Singhasemanon) *January 29, 2021*
Nan Singhasemanon, Assistant Director Date

REFERENCES

Department of Pesticide Regulation. 2020a. Summary of Pesticide Use Report Data 2004-2017. California Pesticide Information Portal (CalPIP), Pesticide Use Report Database, indexed by Chemical. California Environmental Protection Agency, Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/pur/purmain.htm.

Department of Pesticide Regulation. 2020b. Reports of Pesticides Sold in California 2004-2018. Pesticides Sold in California. California Environmental Protection Agency, Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/mill/nopdsold.htm.

Department of Pesticide Regulation. 2020c. Summary of Pesticide Illness Data 2004-2017. California Pesticide Illness Query (CalPIQ). California Environmental Protection Agency, Department of Pesticide Regulation. https://apps.cdpr.ca.gov/calpiq/.

Department of Pesticide Regulation. 2020d. Product Label Database Search. California Environmental Protection Agency, Department of Pesticide Regulation. http://www.cdpr.ca.gov/docs/label/labelque.htm.

Department of Pesticide Regulation. 2020e. Pesticide Use Reporting Data 2018-2019. https://www.cdpr.ca.gov/docs/pur/purmain.htm. Data supplied by Kimberly Steinmann November 20, 2020.

Department of Pesticide Regulation. 2015. Process for Human Health Risk Assessment Prioritization and Initiation. December 21, 2015. California Environmental Protection Agency, Department of Pesticide Regulation.

Department of Pesticide Regulation. 2007. Final Notice on Active Ingredients Prioritized for Risk Assessment Initiation Memorandum. A memorandum from DPR to interested parties, dated September 17, 2007. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch.

Kelly, Lillian J. 2009. Para-dichlorobenzene Initial Scoping Document. California Environmental Protection Agency, Department of Pesticide Regulation, Worker Health and Safety Branch. HSM-09006.

Patterson, Gary. 2011. Prioritization and Status of Active Ingredients for Risk Characterization: Report #52. Environmental Protection Agency, Department of Pesticide Regulation, Medical Toxicology Branch.

Prichard, Ann. 2018. Final Decision Concerning Reevaluation of Diazinon Pesticides. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2018-05.

Prichard, Ann. 2014. Notice to Pesticide Registrants Regarding Initiation of Risk Assessment Process for the Active Ingredient Sulfur Dioxide. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2014-02.

Prichard, Ann. 2013. Notice to Pesticide Registrants Regarding Initiation of Risk Assessment Process for the Active Ingredient Lambda-cyhalothrin. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2013-01.

Prichard, Ann. 2012. Notice to Pesticide Registrants Regarding Initiation of Risk Assessment Process for the Active Ingredient Esfenvalerate. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2012-11.

Prichard, Ann. 2008. Notice to Pesticide Registrants Regarding Initiation of Risk Assessment Process for the Active Ingredient Diazinon. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2008-8.

Prichard, Ann. 2007. Notice to Pesticide Registrants Regarding Initiation of Risk Assessment Process for the Active Ingredient Paradichlorobenzene. California Environmental Protection Agency, Department of Pesticide Regulation, Pesticide Registration Branch. California Notice 2007-3.

Salomon, Maria. 2008. Exposure Scoping Document for Esfenvalerate Memorandum. California Environmental Protection Agency, Department of Pesticide Regulation, Worker Health & Safety Branch. HSM-08009.

Wofford, Pam et al. 2009. Pesticide Air Monitoring in Parlier, CA Report. California Environmental Protection Agency, Department of Pesticide Regulation, Environmental Monitoring Branch.