**Hillsborough County Paladin Investigation, 2014**
**Florida Department of Health**

## Background

In August and September 2013, the Florida Department of Health (DOH) received complaints of health effects following a strong chemical odor in Hillsborough County. Based on reported use in the area, the Florida Department of Agriculture and Consumer Services (DACS) informed DOH that the odor was likely due to a newly approved soil fumigant which contains dimethyl disulfide (DMDS) as the active ingredient. DMDS has a sulfurous odor similar to sulfur compounds added to gas and propane products to warn people of a leak. Since the odor threshold for DMDS is much lower than levels potentially affecting human health, unpleasant odors may occur in and around areas of application.

Two fumigation products containing DMDS, Paladin® (98.8% DMDS) and Paladin® EC (93.8% DMDS) (hereinafter referred to as Paladin), were registered in Florida in 2011 and approved by the Environmental Protection Agency (EPA) and DACS for use in controlling pre-emergent weeds, soil-borne plant pathogens, and nematodes in soils used to grow vegetables, cucurbits, strawberries, blueberries, field-grown ornamentals, and forest nursery stock. Paladin is used as an alternative to methyl bromide (MeBr), a more toxic soil fumigant. Paladin is a toxicity category II (indicates moderate toxicity) product whereas MeBr is a category I (indicates high toxicity) product. Prior to planting, Paladin can be either injected beneath the soil surface with specialized application equipment or applied to the soil surface through a drip irrigation line. All treated areas must be covered with a plastic tarp to retain the fumigant in the soil to improve efficacy and mitigate odor concerns. Starting in 2014, the product label for Paladin required the use of Totally Impermeable Film (TIF).

Paladin was first commercially used in Florida in 2012, but the product was not applied to a significant amount of acreage until 2013. In 2013, DACS received several complaints from Hillsborough County residents of a strong garlic-like odor. All complaints were made by local residents living in households close to the application areas. DOH received the first reports of symptomatic individuals following exposure to the Paladin odor on September 5, 2013 and received a total of six reports of illness during the 2013 application season. Reported symptoms included eye irritation, stuffy nose, exacerbation of pre-existing respiratory conditions, and chest pain. Information was shared with the DOH in Hillsborough County for follow-up and investigation. DOH in Hillsborough County conducted interviews and obtained available medical records. Following the investigation of these six reports, it was determined that none of these individuals met the case classification for acute pesticide-related illness and injury. The Chemical Disease Surveillance Program's (CDSP's) Pesticide Poisoning Investigator (PPI) traveled to Hillsborough County to meet with partners and visit surrounding health care centers in an attempt to identify additional individuals presenting with signs and symptoms possibly related to the Paladin application. The PPI was able to identify three Hispanic females with signs and symptoms following exposure to the odor. Symptoms included dizziness, fatigue, headache, nausea, and stomach cramps. All three met the DOH case classification for a suspect case.

In 2014, Paladin application began in Hillsborough County during the second week of August and continued until September 6th. The first complaint of an illness was reported to the CDSP on August 28th. Information was shared with the DOH in Hillsborough County for investigation

and follow-up. DOH received a few more complaints of illness potentially associated with Paladin leading up to a community event that took place on September 22nd. This community meeting was conducted in Hillsborough County to address concerns related to the Paladin application and was hosted by DACS and included representatives from the Environmental Protection Commission (EPC) of Hillsborough County, DOH, as well as DACS. This event was attended by almost 100 citizens from the local community. Many individuals provided their contact information to DOH for follow-up regarding health concerns potentially related to the Paladin application.

DOH initiated a larger investigation in late September to better understand the health effects potentially related to the application of Paladin, identify potential risk factors, and determine the extent of the impact on the public's health following exposure to Paladin.

**Methods**

Acute pesticide-related illness and injury is listed as a notifiable disease in the State of Florida under Statute 381.0031, Rule 64D-3, *Florida Administrative Code* (*F.A.C.)*. Health care providers, laboratories, and other public health personnel are required to report the occurrence of notifiable diseases as defined in the rule.

DOH carries out a public health investigation for all reports of illness or injury potentially associated with exposure to pesticides. Investigations include surveillance, interviews, medical record reviews, review of supporting documentation (e.g., DACS investigation reports), and determination of case status. Interviews were conducted among individuals reporting health effects potentially associated with the Paladin application using a standard questionnaire designed to obtain demographic, exposure, and health effect information. Medical records were requested for all individuals interviewed who reported seeking medical care and provided information about the health care facility they visited. DOH reviewed available records for additional information about symptoms, diagnoses, treatment, and testing. DACS investigation reports were reviewed for information about the pesticides used, dates and locations of application, violations, and environmental sampling.

The final step during the investigation was to review all available information for each interviewed individual and determine their case classification and severity. The goal of this step was to determine if reported health effects were consistent with what would be expected following exposure to Paladin and, if so, to classify them based on the amount of evidence available. The Safety Data Sheets (SDS) for Paladin and ASHTA Gold™ (99% Chloropicrin, a chemical used along with Paladin) were used to identify the potential health effects. In determining the associated health effects, symptoms were also included if they were related to but not specifically mentioned as listed health effects. For example, if the SDS stated respiratory tract irritation, associated effects (e.g., cough) were classified as related. The odor of DMDS may result in nausea, headache, or dizziness. DMDS may cause irritation of the upper respiratory tract, eyes, and skin. Upper respiratory tract irritation may result in sneezing, coughing, sore throat, dyspnea, chest tightness, and a feeling of suffocation. Inhalation of chloropicrin may result in sore throat, coughing, labored breathing, dizziness, nausea, vomiting, bluish skin, and faintness. Chloropicrin is a powerful lachrymator.

DOH has adopted guidelines from the National Institute of Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR) program to classify cases. A brief description of the DOH case classification can be found in Table 1 and a more detailed explanation can be found at http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-

surveillance/_documents/cd-pesticide.pdf. A case was classified as confirmed, probable, or suspect based on information regarding their exposure, health effects, and the causal relationship between reported symptoms and the specific pesticide exposure. Severity of illness was determined using the same guidelines and was based on the reported symptoms, number of days hospitalized, and/or the number of days absent from work or normal activities. Information obtained from interviews and medical records were entered into the CDSP database, classified, and reviewed.

Information used to summarize the investigation in this report include age, gender, race, ethnicity, presence of pre-existing conditions, medical care, health effects, case classification, and severity of illness. Race was categorized as American Indian or Alaskan native, Asian or Pacific Islander, black, white, mixed race, other, or unknown. Ethnicity was categorized as Hispanic, non-Hispanic, or unknown. Pre-existing conditions included asthma, allergies, and multiple chemical sensitivity and were categorized as clinician reported, exposed individual reported, or pre-existing condition not present. Medical care received included a visit to a physician's office or medical care clinic, emergency department, or admission to a hospital for inpatient care. Health effects were grouped into broader organ systems (e.g., respiratory) and also categorized as clinician reported, exposed individual reported, or health effect not present. According to the case classification provided in Table 1, all individuals interviewed were categorized as confirmed, probable, suspect, unlikely, insufficient information available, or unrelated. Severity of illness was categorized as death, high severity, moderate severity, or low severity. More information about guidelines for classifying cases and severity can be found on the NIOSH website at http://www.cdc.gov/niosh/topics/pesticides/case.html.

Locations of the application sites and residential addresses for all interviewed individuals that indicated home exposure were mapped using Google Earth. Distance from the residence to the closest border of an application site was calculated. Data were analyzed to determine average distance from the application site and proportion of individuals within 0.25 miles, 0.5 miles, or 1 mile of an application site.

Descriptive statistics were carried out using data from all interviewed individuals. Results are presented as means or proportions. All analyses were carried out using SAS software version 9.3 (SAS Institute Inc., Cary, NC).

**Table 1. Matrix for case classification - Florida acute pesticide-related illness and injury cases**

| Classification Criteria* | Classification Category | | | | |
|---|---|---|---|---|---|
| | Confirmed | Probable | | Suspect | |
| | | | | Possible | Suspicious |
| **Exposure** | 1 | 1 | 2 | 2 | 1 or 2 |
| **Health effects** | 1 | 2 | 1 | 2 | 1 or 2 |
| **Causal relationship** | 1 | 1 | 1 | 1 | 2 |

*Cases are placed in a classification category based on scores received on available evidence for exposure, health effects, and causal relationship.
Scores relating to criteria for exposure: 1=clinical, laboratory, or environmental evidence for exposure; 2=evidence of exposure based solely on written or oral report.
Scores relating to criteria for health effects: 1=two or more new post exposure signs or laboratory findings reported by a licensed health care professional; 2=two or more post exposure symptoms reported by the patient.
Scores relating to criteria for a causal relationship: 1=the observed health effects are consistent with known toxicology of the pesticide; 2=insufficient toxicological information available to determine if there is a causal relationship between the pesticide exposure and the health effects.

**Unlikely**: Evidence of exposure-health effect relationship is not present: a temporal relationship does not exist or the constellation of health effects are not consistent based on the known toxicology.
**Insufficient information available**: Insufficient data available about the exposure or the health effects (e.g., having only one new post-exposure abnormal sign/symptom).
**Unrelated**: Illness determined to be unrelated to pesticide exposure based on no history of pesticide exposure or evidence of non-pesticide causal agent.

Source: Florida Department of Health. Surveillance case definitions for selected reportable diseases in Florida, January 2011. Case definition for pesticide-related illness and injury cases. Available at http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/_documents/cd-pesticide.pdf.

## Results

Following the community event on September 22nd, DOH received complaints of health effects from exposure to the Paladin odor from 40 households (some were also referred to DOH by DACS). Among the 33 households contacted, DOH interviewed 66 individuals complaining of health effects related to the Paladin application (the other 7 households were unable to be reached after several attempts to make contact or declined to be interviewed). Just over half (51.5%) of the households contacted had more than one individual complaining of health effects related to Paladin (one household had 10 people complaining of health effects). Thirty-one individuals stated that they visited a health care facility following exposure to Paladin. We received medical records for 16 individuals willing to provide provider information.

Of the 66 individuals interviewed, 43 (65.2%) matched the case classification for a suspect case of pesticide-related illness and injury. Thirty-eight cases (88.4%) were classified with a low severity of illness and five cases (11.6%) were classified with a moderate severity. The remaining 23 individuals interviewed were determined not to be a case; 11 were considered as unrelated/unlikely and 12 had insufficient information available for classification purposes. None of the individuals interviewed were classified as a confirmed or probable case.

Just over half of the cases were female (53.5%); almost all were non-Hispanic White. Average age was 48 years, ranging from 3 to 71 years. Eleven cases had a pre-existing condition of asthma (n=4), allergies (n=5), both asthma and allergies (n=1), or chemical sensitivity (n=1). The most common symptoms reported by cases included eye pain and irritation, cough, dyspnea, sore throat, nausea, vomiting, dizziness, headache, weakness, and fatigue (Table 2).

In early November, a 45 year old female who was interviewed during the investigation died. All documents (i.e., medical records, case report form, death certificate) related to this individual were reviewed by a DOH physician. The cause of death was officially attributed to pulmonary embolus (PE). The deceased had a number of risk factors for PE, including chronic obstructive pulmonary disease (COPD) and morbid obesity. DMDS is documented to act as an airway irritant; thus could be a source of some morbidity to an individual with COPD. Medical records for this individual did not make reference to DMDS, Paladin, chloropicrin, or sulfide allergies, but did make reference to recent pneumonia, sleep apnea, and difficulty maintaining blood oxygen levels. This individual did not make reference to a strong odor during the DOH interview and there was no mention of an odor in the medical records. Therefore, given the patient's chronic health problems; the absence of evidence for high pesticide exposure; and a cause of death not known to be related to Paladin, chloropicrin, or sulfide exposure, DOH concluded that Paladin exposure was unlikely to be the cause of death. This individual was classified as having insufficient information due to lack of exposure history (reporting a strong Paladin odor) and inability to attribute health effects to Paladin exposure based on known toxicological information.

Fifty-seven individuals (36 cases and 21 non-cases) from 28 households indicated that their exposure was at or near their home (the other 9 individuals indicated that exposure was at a location other than their home). Mapping data revealed that the average distance of a household from an application site was 1.75 miles (range from 0.03 to 7.34). Four households (14.3%) were within 0.25 miles of an application site, four (14.3%) were between 0.25 and 0.5 miles, five (17.9%) were between 0.5 and 1 mile, and the remaining fifteen (53.6%) were greater than 1 mile away.

The average distance from an application site was 0.74 miles among individuals classified as a suspect case (n=36) and 2.84 miles among individuals not classified as a case (n=21) (difference was statistically significant). Individuals classified as a case were more likely to live within 0.25 miles and less likely to live more than 1 mile away from an application site compared to individuals not classified as a case (p=0.001).

DACS conducted seven investigations in August through October 2014 following complaints from citizens of a strong odor; however, only four investigations involved application of Paladin. After completing their investigations, DACS reported that a technical violation involving the application of Paladin was identified during one of the investigations, but that it was unlikely to have precipitated the reported odor.

**Table 2. Characteristics of acute pesticide-related illness and injury cases following Paladin application in Hillsborough County – Florida, 2014 (n=43)** [¶]

| Characteristics | Number | Percent |
|---|---|---|
| **Age group (years)*** | | |
| <20 | 6 | 14.3 |
| 20-44 | 6 | 14.3 |
| 45-64 | 24 | 57.1 |
| ≥65 | 6 | 14.3 |
| **Gender** | | |
| Female | 23 | 53.5 |
| Male | 20 | 46.5 |
| **Race** | | |
| American Indian | 1 | 2.3 |
| Black | 2 | 4.7 |
| White | 40 | 93.0 |
| **Ethnicity** | | |
| Hispanic | 0 | 0.0 |
| Non-Hispanic | 43 | 100.0 |
| **Health effects**[†] **(Individual Reported)** | | |
| Neurological | 35 | 81.4 |
| Headache | 28 | 65.1 |
| Weakness | 12 | 27.9 |
| Dizziness | 11 | 25.6 |
| Respiratory | 30 | 69.8 |
| Sore throat | 10 | 23.3 |
| Dyspnea | 9 | 20.9 |
| Cough | 8 | 18.6 |
| Ocular | 20 | 46.5 |
| Eye pain | 19 | 44.2 |
| Gastrointestinal | 15 | 34.9 |
| Nausea | 12 | 27.9 |
| Vomiting | 7 | 16.3 |
| Cardiac | 6 | 14.0 |
| Chest pain | 4 | 9.3 |
| Fatigue | 10 | 23.3 |
| **Medical care** | | |
| Physician's office only | 15 | 34.9 |
| Hospital | 3 | 7.0 |
| None | 25 | 58.1 |
| **Case classification**[¶] | | |
| Confirmed | 0 | 0.0 |
| Probable | 0 | 0.0 |
| Suspect - Possible | 32 | 74.4 |
| Suspect - Suspicious | 11 | 25.6 |
| **Severity of illness** | | |
| Low | 38 | 88.4 |
| Moderate | 5 | 11.6 |
| High | 0 | 0.0 |

[¶]23 symptomatic individuals were not classified as a case. They were classified as unrelated/unlikely (n=11) or insufficient information (n=12).
*One individual with unknown age.
[†]The number and percentage of individuals reporting health effects totals greater than 43 due to multiple health effects reported by some individuals. Ocular (pain, irritation, lacrimation, blurred vision); Respiratory (throat irritation, dyspnea, coughing, wheezing); Gastrointestinal (nausea, vomiting, abdominal pain); Neurological (headache, dizziness, fatigue, sweating); Cardiac (chest pain, high BP, irregular heart beat).

## Discussion

A public health investigation of complaints of health effects from Hillsborough County, Florida residents following Paladin applications on surrounding farms did not identify any confirmed or probable cases of pesticide illness or injury. Of 66 interviewed individuals, 43 were classified as suspect cases and 23 as non-cases. The majority of cases were classified with a low severity of illness. The most frequent self-reported health effects included eye pain and irritation, sore throat, cough, dyspnea, nausea, vomiting, dizziness, chest pain, and fatigue. Sixty percent of individuals with a reported exposure at or near their home lived within 1 mile of an application site.

DMDS has a sulfurous odor similar to that of garlic and decaying fish with an odor threshold of approximately 7 ppb, which is much less than the health-based level considered by the EPA to be safe (55 ppb).[1] This means that the odor, possibly a strong odor, may be present at levels not considered toxic. Detecting an odor does not mean that harmful amounts of DMDS are being inhaled. Under certain environmental conditions, unpleasant odors may occur in and around use areas for short periods of time, despite buffer zones to protect bystanders. DMDS products generally have a low to moderate toxicity; however, because they are used to control a wide range of pests, large quantities are applied to agricultural fields, making them potentially hazardous. It is unlikely that people in areas near treated agricultural fields will experience adverse toxicological effects when products are used according to the stringent requirements of EPA product labels. In some individuals, the odor of DMDS may cause nausea, headache, and dizziness. Often, symptoms will fade when the odor goes away. Therefore, it is possible that some of the health effects reported by residents in the area surrounding application sites may have resulted from the odor, not necessarily from the toxic effects of DMDS. The manufacturer of Paladin performed over 500 air monitoring readings in Hillsborough County in August and September of 2014. They measured Paladin concentrations between 0-1 ppb at the edges of the farm fields.[2] DOH does not have additional information about these test results (e.g., timing of collection).

Concerns about ground water contamination from DMDS were raised during the community event that took place in Hillsborough County on September 22nd. Ground water contamination was also a concern voiced during many of the interviews. Evaluations by EPA and Florida DACS found that testing of area ground and surface water would be unnecessary. The risks of DMDS to water are reduced by DMDS' tendency to partition to air rather than soil or water, and its short persistence in the environment.

Of the 66 individuals interviewed, 43 were classified as suspect cases while the remaining 23 were classified as unlikely, unrelated, or did not have enough information to make a determination. It is important to understand what is meant by a "suspect" case before interpreting the results found in this report. A suspect case classification was given, instead of confirmed or probable, because laboratory, clinical, or environmental evidence indicating a Paladin exposure was not available and health effects characteristic of a Paladin exposure were not reported by a licensed health care professional. In addition, health effects characteristic of a Paladin exposure are very broad and could be indicative of a number of other conditions (e.g., upper respiratory tract infection). All suspect cases were further classified as "possible" or "suspicious" (see Table 1 for details). To receive a "possible" classification, evidence of exposure is based solely upon written or verbal report (e.g., a strong odor reported by the case or a witness), not from laboratory or clinical evidence (e.g., results from air, soil, or biological samples); evidence of adverse health effects is based on the individual's report, not by a licensed health care professional; and evidence for the causal relationship is based on whether the reported health effects are consistent with the known toxicology of Paladin. A "suspicious"

classification is assigned when there is not enough toxicological information available to determine the causal relationship between Paladin and the individual's reported health effect(s). For example, when a health effect has been shown to be associated with other sulfur products, but not shown to be associated with Paladin (i.e., listed in the Safety Data Sheet).

DOH reached out to DACS and the manufacturer to find out if Paladin was being used in other states and, if so, were they receiving odor and health effect complaints. Paladin was registered for use in 26 states, with Florida reported as using the largest volume. The manufacturer reported that they have not received complaints in other states from the distributors, consumers, or state agricultural agencies. DOH also reached out to other states who conduct pesticide-related illness and injury surveillance to find out if they received any complaints of health effects related to Paladin. There were no cases related to Paladin reported in Michigan, Louisiana, North Carolina, Washington, and Texas. In addition to the greater amount of Paladin used in Florida (especially in Hillsborough County) as compared to other States, differences in topography, climate, and practices could have contributed to the complaints in Hillsborough County.

In addition, the CDSP's PPI visited the area where the complaints originated to see if he could identify any farmworkers that may have experienced health effects from the Paladin application. The PPI visited surrounding clinics and farmworker communities in December 2014 to inquire about pesticide exposure to farmworkers from August and September, but was unable to identify any additional cases of pesticide-related illness or injury following exposure to Paladin. The CDSP also reviewed DOH's syndromic surveillance system to identify emergency department visits or Florida Poison Information Center Network (FPICN) exposure calls potentially related to Paladin. Exposure calls to FPICN related to Paladin received follow up, but none of the calls identified any cases that DOH was not already aware of. There were no work-related Paladin exposures reported to DOH. Three people reported health effects following a Paladin application in Miami-Dade County. The DOH in Miami-Dade County conducted an investigation and determined that they did not meet the case classification for pesticide-related illness or injury. There were no other Paladin exposure complaints reported in Florida.

The findings in this report are subject to some limitations. Acute illnesses related to Paladin might be underreported. Typically, symptoms might only last a few hours and can resolve without medical treatment; people might never associate symptoms with exposure or the odor. In addition, individuals who do not seek medical care or advice from FPICN are not identified by DOH surveillance systems; although, most cases from this investigation were identified from the community event. Symptoms of acute Paladin exposure are nonspecific and not pathognomonic, and diagnostic tests are not available to measure blood or urine levels of the active ingredient, DMDS; therefore diagnosis by a physician is difficult. It is also possible that some cases of acute pesticide-related illness or injury might have been excluded because insufficient information was provided to meet the case classification. On the other hand, some health complaints temporally related to the Paladin applications might be coincidental and not caused by Paladin. Therefore, false-positives might have been included as cases.

Some recommendations for individuals that may be exposed to pesticides, including Paladin, in the future would be to move to fresh air; seek medical attention from a physician or hospital emergency department; call the FPICN at 1-800-222-1222; and/or report health effects to the local health department or the Florida Department of Health, Bureau of Epidemiology pesticide hotline at 1-800-606-5810.

To our knowledge, this is the first report of a public health investigation into the health effects potentially associated with application of DMDS, specifically Paladin. Paladin is being applied to farms as a soil fumigant in other parts of the state and country. Findings from this investigation will help inform activities and preparations taken by DOH for future applications of Paladin. DOH will continue to work with partners (e.g., DACS, EPA, EPC) prior to the 2015 application season to exchange information and prepare for anticipated public concerns and potentially related health effects. DOH plans to perform outreach activities to local health care providers to inform them of past issues associated with application of Paladin, identification of individuals with health effects that may be related to Paladin, and reporting to DOH for public health investigation. DOH will target public health surveillance activities during Paladin applications in Hillsborough and other Counties.

References:


1. Frequently Asked Questions about Dimethyl Disulfide. Available at http://www.freshfromflorida.com/content/download/3302/20733/DMDS_QnA_3-20-2013.pdf
2. Paladin in Florida by Arkema. Questions related to Paladin® soil fumigant. Available at http://www.arkema-americas.com/en/social-responsibility/community-outreach/paladin-in-florida/