



Department of Pesticide Regulation



Brian R. Leahy
Director

MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Dr. Marylou Verder-Carlos
Assistant Director
Pesticide Programs Division

HSM-15008

No. assigned after issuance of memo

FROM: Lisa Ross, Ph.D.
Environmental Program Manager II
Worker Health and Safety Branch
(916) 324-4116

[Original signed by L. Ross]

DATE: June 18, 2015

SUBJECT: COMPLETION OF METHYL ISOTHIOCYANATE (MITC) MITIGATION FOR RESIDENTS AND BYSTANDERS

The methyl isothiocyanate (MITC) mitigation memorandum (Zeiss 2015) describes the findings of the Worker Health and Safety Branch (WHS) in regards to the need for mitigation of MITC exposures for residents and bystanders.

In 2002, the Department of Pesticide Regulation (DPR) determined that resident and bystander acute exposure to MITC exceeded levels of concern (Helliker 2002, Gosselin 2002), resulting in declaration of MITC as a Toxic Air Contaminant in 2003. DPR has mitigated this risk via recommended permit conditions (Gorder and Edmiston 2010, Farnsworth 2015) that include the following measures designed to protect residents and bystanders:

- limits on size of application blocks and on application dosage per acre;
- restrictions on application timing;
- use of post-application water treatments;
- method-specific buffer zones; and
- monitoring of wind direction and sensory irritation both during and after the application.

In 2011 and 2012, the U.S. Environmental Protection Agency (U.S. EPA) added similar requirements to labeling of MITC-generating fumigant products (U.S. EPA 2014).

California air sampling during 2011 - 2013 showed MITC levels in ambient air were well below the exposure target value (Vidrio et al. 2013a, 2013b, 2014). During 2011 and 2012, only one incident involving a MITC-related illness to residents or bystanders was reported within California (DPR 2014).

Given the mitigation already put in place by both DPR and U.S. EPA, and its apparent effectiveness, WHS finds that there is no need for further mitigation action for MITC for residents and bystanders. Your approval of this conclusion is requested.

Attachment

cc: Linda O'Connell, Environmental Program Manager I
Kevin Solari, Senior Environmental Scientist (Supervisory)



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APPROVAL:

[Original signed by M. Verder-Carlos]

06/22/2015

Marylou Verder-Carlos, Assistant Director

Date

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Department of Pesticide Regulation



Brian R. Leahy
Director

MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Lisa Ross, Ph.D., Environmental Program Manager II
Chief, Worker Health and Safety Branch

Via: Linda O'Connell, Environmental Program Manager I
Worker Health and Safety Branch

FROM: Michael Zeiss, Senior Environmental Scientist (Specialist)
Worker Health and Safety Branch [Original signed by M. Zeiss]
(916) 323-2837

DATE: June 17, 2015

SUBJECT: MITIGATION OF METHYL ISOTHIOCYANATE (MITC) ACUTE EXPOSURE
TO RESIDENTS AND BYSTANDERS

Summary

This memorandum presents the facts that support a determination that no additional mitigation measures are needed for acute exposures of residents and bystanders to methyl isothiocyanate (MITC) from field soil fumigations. MITC is generated by the fumigant pesticides metam sodium, metam potassium (also known as potassium n-methyldithiocarbamate), and dazomet.

In 2002, DPR determined that resident and bystander acute exposure to MITC exceeded levels of concern (Helliker 2002, Gosselin 2002), resulting in declaration of MITC as a Toxic Air Contaminant in 2003. DPR has mitigated this risk via recommended permit conditions (Gorder and Edmiston 2010, Farnsworth 2015), which include the following measures designed to protect residents and bystanders:

- limits on size of application blocks, and on application dosage per acre;
- restrictions on application timing;
- use of post-application water treatments;
- method-specific buffer zones; and
- monitoring of wind direction and sensory irritation both during and after the application.

In 2011 and 2012, the U.S. Environmental Protection Agency (U.S. EPA) added similar requirements to labeling of MITC-generating fumigant products (U.S. EPA 2014).

California air sampling from 2011 to 2013 showed MITC levels in ambient air were well below the exposure target value (Vidrio et al. 2013a, 2013b, 2014). During 2011 and 2012, only one incident involving a MITC-related illness to residents or bystanders was reported within California (DPR 2014). This was due to an equipment malfunction that delayed the post-water application that should occur within 30 minutes of the completion of application. Given the mitigation already put in place by both DPR and U.S. EPA, and its apparent effectiveness, I conclude that no additional mitigation measures are needed for acute exposures of residents and bystanders to MITC from field soil fumigations.



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Scope of this memorandum

This memorandum addresses only the risks specified in DPR’s Risk Management Directive (Gosselin 2002), namely acute (short-term) off-site exposures to residents and bystanders from field soil fumigations with the MITC-generating fumigants metam sodium, metam potassium (also known as potassium N-methyldithiocarbamate), and dazomet.

This memorandum does not address minor, non-agricultural applications of those fumigants, such as treatments of sewer pipes or utility poles. The reason is, “these applications are made in controlled settings and the off-site exposure to the public is expected to be minor.” (Andrews 2007, page 1).

Further, this memorandum does not address the following risks from field soil fumigations, for the reasons stated in the Risk Management Directive (Gosselin 2002) and summarized below:

- **Seasonal off-site and ambient exposures to residents and bystanders:** “Since the risk from acute (short-term) off-site exposures to residents and bystanders poses the most concern, it will take priority over managing seasonal exposures. Once we implement the mitigation strategy for acute off-site exposures, we will initiate the process of developing mitigation measures for seasonal off-site and ambient exposures.” (Gosselin 2002, page 1).
- **Annual and lifetime exposures to residents and bystanders:** “were not addressed in the [Risk Management Directive] and will be considered in the future.” (Gosselin 2002, page 1).
- **Occupational exposures:** “In regard to occupational exposures . . . we will forgo activity on risk mitigation until completion of the comprehensive risk characterization document. Upon completion of these documents we will determine which occupational exposures require risk mitigation through another risk management directive.” (Gosselin 2002, page 1).

Reported use and sales in California

Taken as a group, MITC-generating fumigants are among the pesticides with highest quantity of use in California. In 2013, the most recent year for which statistics are available, total reported use of all MITC-generating fumigants was more than 14 million pounds of active ingredient statewide (Figure 1). Sulfur, mineral oil, and petroleum oil were the only pesticides with higher reported use (DPR 2015).

Figure 1. Reported use of MITC-generating fumigants statewide (all use sites combined).

Source of data: DPR's California Pesticide Information Portal (Cal-PIP) database
<http://calpip.cdpr.ca.gov/main.cfm>
Query run on April 28, 2015 by Larry Wilhoit.

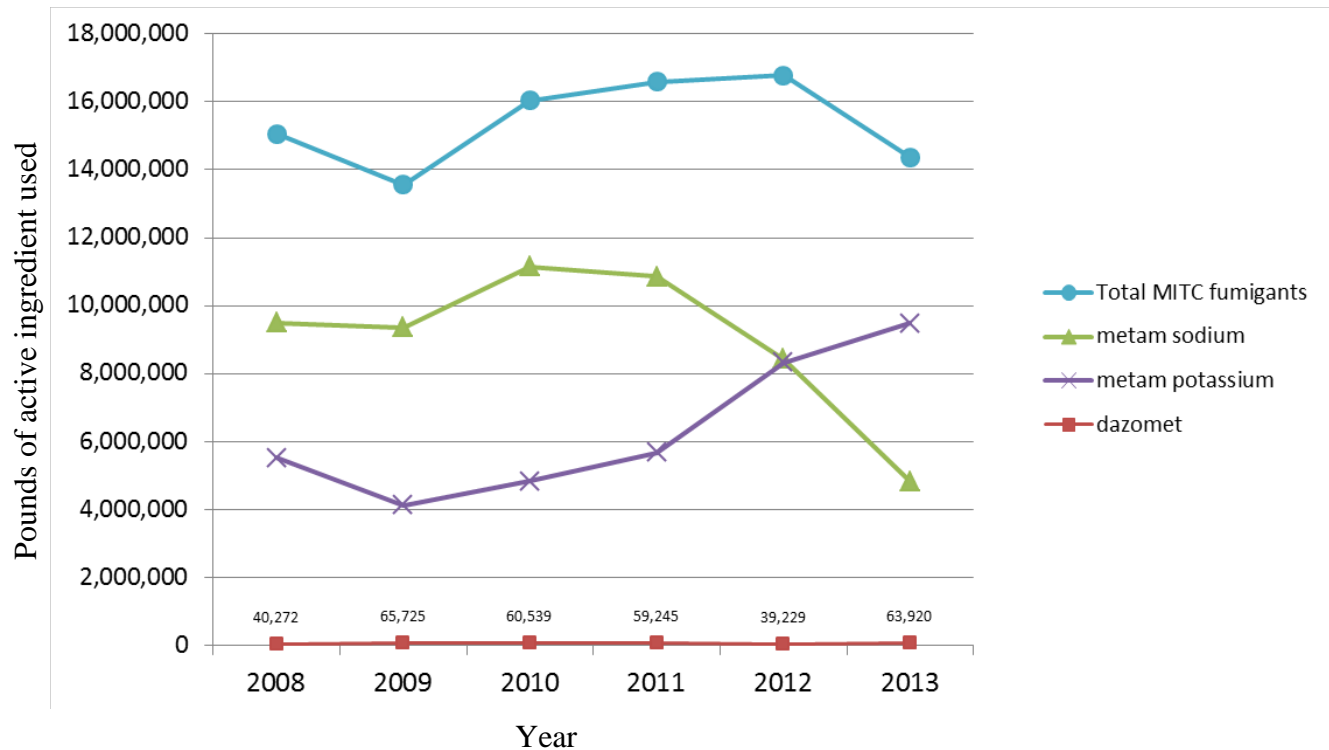
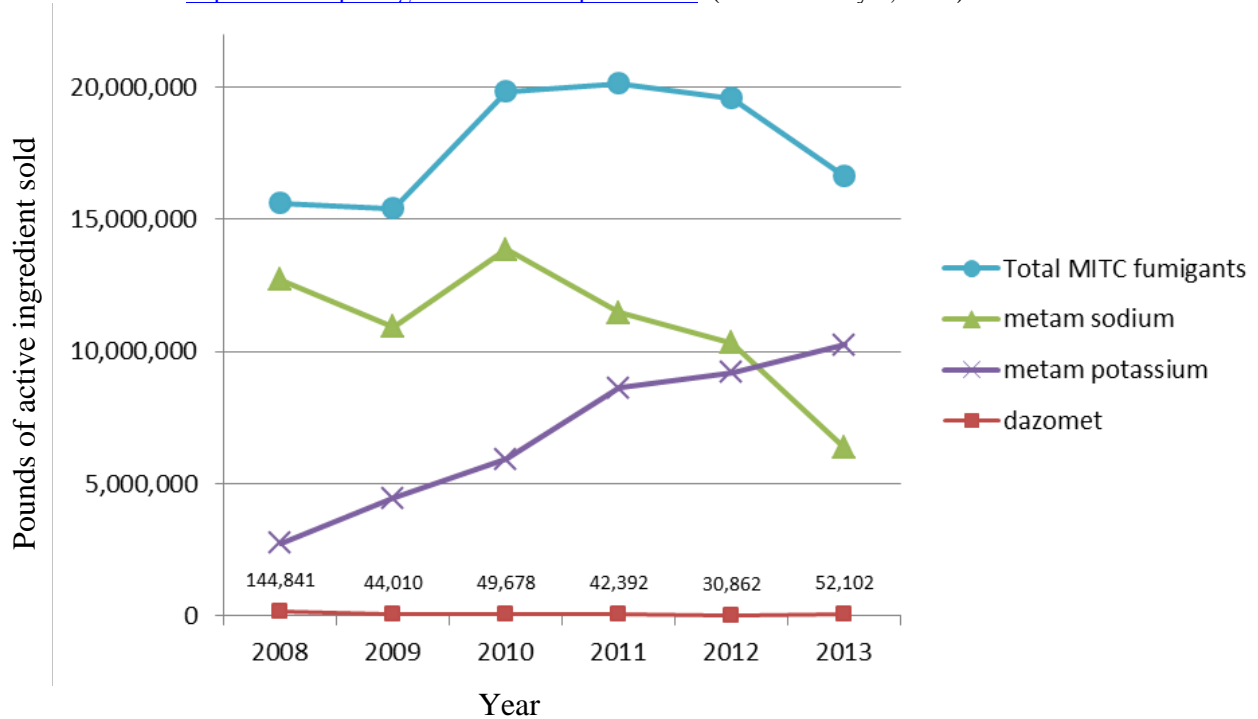


Figure 2. Reported sales of MITC-generating fumigants statewide.

Source of data: DPR's Reports of Pesticide Sold in California
<http://www.cdpr.ca.gov/docs/mill/nopdsold.htm> (accessed May 1, 2015)



Recent regulatory history and future plans

2002 Risk Management Directive

DPR's Risk Management Directive (RMD), "determined that the use of metam-sodium and other MITC-generating pesticides results in unacceptable acute and seasonal exposures" (Gosselin 2002, page 1). The RMD established acute exposure as the priority for mitigation. Further, the RMD set the exposure target value - - that is, the maximum exposure that would be considered acceptable when evaluating subsequent mitigation - - at 220 parts per billion (ppb) MITC averaged over an eight-hour period. The RMD states that this value was identified in the risk assessment as the no-observable-effects level (NOEL) for the endpoint of reversible eye irritation, indicated by an increase in the rate of eye blink.

The RMD concluded, "Our goal is to ensure the use of metam-sodium and other MITC - generating products does not result in noticeable eye or respiratory effects. To meet this goal, we will develop and provide restricted-material permit guidance to county agricultural commissioners, and may adopt or amend regulations." (Gosellin 2002, page 3).

2003 declaration as Toxic Air Contaminants

California Food and Agricultural Code section 14022 requires DPR to determine whether pesticides “emitted into the ambient air of California” are Toxic Air Contaminants (TAC) requiring additional mitigation measures to reduce exposure via inhalation. In order for DPR to designate a pesticide as a TAC, the pesticide must have measured concentrations in the ambient air greater than one-tenth of the air concentration that has been determined to be health protective (California Code of Regulations, title 3, section 6864).

In 2002, DPR proposed to designate MITC and pesticides that generate MITC as TACs (Helliker 2002). In 2003 DPR carried out this designation, by amending the list of TACs within California Code of Regulations title 3, section 6860 (a). The amendment was approved in May 2003, and became effective in June 2003 (DPR 2003).

2003 comprehensive Risk Characterization Document

DPR's Risk Management Directive for resident and bystander exposure (Gosellin 2002) refers to an earlier “risk assessment” as the source of the No-Effects Level. However, DPR's complete Risk Characterization Document (RCD) for MITC was published after the Risk Management Directive, in July 2003 (Rubin 2003).

Regarding acute toxicity (the subject of this memorandum), the RCD evaluated two sources of data:

- 1) Analysis, after the fact, of accidental large-scale exposures to residents (one spill incident, and one offsite-movement incident); and
- 2) An experimental study with human volunteers with exposure to the eye region via special goggles.

The RCD concluded that all the data:

“generally support designation of the acute eye irritation NOEL of 220 ppb as the critical acute NOEL. This value will be used in the assessment of the risks of potential short-term human exposure to airborne MITC in residents and bystanders (adults and children). The use of a NOEL based on eye irritation is considered a prudent step to protect the population not only from MITC's ocular effects, but also from potentially more serious impacts, notably to the respiratory system.” (Rubin 2003, pages 71-72).

In short, the RMD and the RCD both agree that mitigation should protect against acute exposures greater than 220 ppb MITC averaged over an eight-hour period.

2002 – 2010 mitigation: DPR recommended permit conditions

As early as 2002, DPR began implementing MITC mitigation in the form of recommended permit conditions (Paulsen 2002). These are DPR's recommendations to County Agricultural Commissioners about how to design their own county-specific conditions for Restricted Materials Permits. Since 2010 (Gorder and Edmiston 2010), DPR's recommended permit conditions for MITC-generating fumigants have included several measures designed to protect residents and bystanders, namely:

- limits on size of application blocks, and on application dosage per acre;
- restrictions on application timing;
- use of post-application water treatments;
- limits on multiple fields undergoing fumigation during the same time period;
- method-specific buffer zones; and
- monitoring of wind direction and sensory irritation both during and after the application.

Initial buffer zone calculations were based on modeling (Barry 2006) intended to prevent exposure to the 220 ppb limit established in DPR's Risk Management Directive (Gosellin 2002). The modeled buffer zone distances were increased by 25% as an additional safety measure to deal with peak emissions (Linda O'Connell, personal communication, December 4, 2014). DPR's recommended buffer zones were established by DPR risk managers, after extensive consultation with stakeholders (Andrews 2007) and with DPR scientists.

The current version of DPR's recommended permit conditions is posted on DPR's public website at http://www.cdpr.ca.gov/docs/enforce/compend/vol_3/append_1.pdf

2011 – 2012 mitigation: U.S. EPA improvements to product labeling

In 2011 and again in 2012, U.S. EPA substantially improved labeling of MITC-generating field fumigants (Farnsworth 2012, U.S. EPA 2014). Current labeling contains many requirements similar to those established in DPR's recommended permit conditions, including:

- additional protection for fumigant handlers;
- limits on size of each application block, and on fumigant dosage per acre;
- restrictions for multiple fields undergoing fumigation during the same time period;
- monitoring requirements; and
- buffer zones.

However, in some cases, the specific requirements on labeling are less protective than the corresponding requirements in DPR's recommended permit conditions (Farnsworth 2013). There are also restrictions in the permit conditions that are not included on labeling.

Current labeling also contains additional mitigation tactics (U.S. EPA 2014) not found in DPR's recommended permit conditions, including:

- Emergency Preparedness and Response Measures (if people reside or work near the buffer zone, the applicator must either notify them or monitor for offsite movement); and
- additional training for applicators.

2015 mitigation: promoting compliance by reducing redundancy

DPR has revised the MITC recommended permit conditions to make them easier for users to understand, and to remove restrictions now included in labeling (Farnsworth 2015). This is in accord with the guidance in DPR's Risk Management Directive:

“Finally, the clarity of the use restrictions will be critical in terms of fostering compliance. We have seen that failure to follow existing restrictions can have devastating effects on surrounding communities. Typically, restrictions are based on the presumption that the rules are followed. We will continue to follow this premise. However . . . we must strive to maximize the likelihood of compliance.”
(Gosselin 2002, page 3).

All California users are legally required to follow registered product labeling (California Food and Agricultural Code section 12973). Therefore, because U.S. EPA has added requirements to labeling, DPR streamlined its recommended permit conditions by removing redundant requirements. For example, DPR has deleted the soil moisture restrictions from the MITC recommended permit conditions, and removed the language dealing with buffer zones extending into properties of occupied structures or bystander areas. These restrictions are now included in labeling.

Air Monitoring Data

Since implementation of DPR's 2010 recommended permit conditions (Gorder and Edmiston 2010), air monitoring results have been substantially below the 220 ppb MITC exposure target value set by the Risk Management Directive (Gosselin 2002).

In February 2011, DPR implemented a multi-year statewide Air Monitoring Network for measuring pesticide volatiles in selected agricultural communities (Vidrio et al. 2013). Once per week, ambient air was sampled for 24 consecutive hours in each community. During 2011-2013, the most recent years for which final results are available, MITC consistently was one of the top three chemicals with the highest number of detections. In samples of the ambient air near the communities being monitored, MITC was detected in:

- 31% of the samples in 2011 (Vidrio et al. 2013a);
- 28% of the samples in 2012 (Vidrio et al. 2013b); and
- 30% of the samples in 2013 (Vidrio et al. 2014).

Although these are high rates of detection, it should be noted that the MITC concentrations detected were low. The analytical method was capable of detecting very low levels of MITC.

In each of the three years, the detection limit was 5.6 nanograms MITC per cubic meter (Vidrio et al. 2013a, 2013b, 2014), equivalent¹ to about 0.002 ppb MITC.

The highest 24-hour concentrations detected were:

- 930 nanograms MITC per cubic meter in 2011 (Vidrio et al. 2013a), equivalent to 0.3 ppb MITC;
- 346.6 nanograms MITC per cubic meter in 2012 (Vidrio et al. 2013b), equivalent to 0.1 ppb MITC; and
- 852.2 nanograms MITC per cubic meter in 2013 (Vidrio et al. 2014), equivalent to 0.3 ppb MITC.

In summary, three consecutive years of Air Monitoring Network results have been substantially below the 220 ppb MITC exposure target value set by the RMD (Gosellin 2002).

Illness data for residents and bystanders

DPR's recommended permit conditions went into effect in November 2010 (Gorder and Edmiston 2010). During the subsequent two years - - in other words, from December 2010 through December 2012 (the most recent statistics available) - - only one incident involving a MITC-related illness to residents or bystanders was reported within California (DPR 2014). This was due to an equipment malfunction that delayed the post-water application that should occur within 30 minutes of the completion of application.

In contrast, during the 10 years preceding the recommended permit conditions, from 1 – 4 incidents involving MITC-related illness to residents or bystanders were reported per year in most² years. The higher frequency of incidents before, versus after, the recommended permit conditions suggests that the recommended permit conditions have mitigated the risk to residents and bystanders.

Incidents in which only handlers experienced MITC-related illness are not included in this summary, because occupational exposure is beyond the scope of this memorandum.

¹ Conversion formula for standard pressure (1 atmosphere) and 25°C (298.15°K) is:
ppb MITC = 0.3346 x (micrograms MITC per cubic meter)

The coefficient 0.3346 comes from temperature (298.15 °K) multiplied by the universal gas constant (82.057 liter atm mol⁻¹ K⁻¹) divided by a unit-conversion factor (1,000 liters/m³) and divided by the molecular weight of MITC (73.12 g mol⁻¹).

² There were zero incidents involving residents or bystanders reported in 2006 and 2009.

Assessment of need for additional mitigation measures

In December 2010, DPR provided recommended permit conditions to mitigate MITC exposure to residents and bystanders (Gorder and Edmiston 2010). In particular, DPR incorporated the use of post-application water treatments to prevent offsite movement of MITC. In 2015, DPR streamlined and strengthened the recommended permit conditions, harmonizing buffer zones with federal product labeling (Farnsworth 2015). Post-application water treatments, combined with other measures such as restrictions on application timing and buffer zones, appear to prevent exposure to the 220 ppb MITC exposure limit established in DPR's Risk Management Directive (Gosellin 2002). U.S. EPA subsequently added similar requirements to product labeling (U.S. EPA 2014).

All available data indicate that acute exposure of residents and bystanders has been mitigated effectively. These supporting data include:

- air monitoring results well below the MITC exposure target value (Vidrio et al. 2013a, 2013b, 2014); and
- absence of reports of MITC-related illnesses to residents or bystanders during the two years following the recommended permit conditions (DPR 2014) that would not have been prevented by the mitigation measures.

Given the mitigation already put in place by both DPR and U.S. EPA, and its apparent effectiveness, I conclude that no additional mitigation measures are needed for acute exposures of residents and bystanders to MITC from field soil fumigations.

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