

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 27, 2023

MEMORANDUM

SUBJECT: Amendment to the Sulfuryl Fluoride Revised Mitigation and Response to

Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum,

Jun A Costello

June 2023 (Docket ID: EPA-HQ-OPP-2009-0163)

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THROUGH: Kevin Costello, Branch Chief

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TO: Sulfuryl Fluoride Registration Review Docket

EPA-HQ-OPP-2009-0136

INTRODUCTION

This document amends the *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum*, dated June 28, 2023, and published on June 29, 2023, to clarify the requirements and the label language. In response to registrant and stakeholder comments, EPA is providing additional clarification for the stewardship training requirements and updated label language for Appendix B of this decision document.

BACKGROUND

The Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum (PC Code 078003, case 0176), is the Agency's response to the EPA Office of the Inspector General's (OIG) published report entitled Additional Measures Can Be Taken to Prevent Deaths and Serious Injuries From Residential Fumigations. The OIG conducted its investigation to determine the extent and nature of adverse impacts caused by structural fumigation, after two incidents in 2015, including one with the chemical sulfuryl fluoride. The OIG Report sought to determine whether regulatory, program execution (e.g., training, funding, inspections, enforcement, etc.), or other factors were associated with adverse impacts from the use of sulfuryl fluoride in residential use sites. The focus of this response to the OIG Report is specific to sulfuryl fluoride use on residential sites². Sulfuryl fluoride is the only fumigant currently registered for residential use. This involves placing a tarp or tent over the home, which could include multi-unit residences, to trap gas inside and then filling the structure with sulfuryl fluoride to kill pests.

In May 2021, the Agency released the *Sulfuryl Fluoride Draft Interim Re-entry Mitigation Measures Memorandum* for a 60-day public comment period, which was extended for 60 days and later closed on September 23, 2021. During the public comment period, EPA received over 130 comments from different sources. Submitters included registrants, states, state lead agencies, the pesticide industry, and Pest Control Operators (PCOs). Comments addressed the overall effort of the early mitigation, the potential burden on the fumigation industry and states, specifics of the proposed mitigation, and the timeframe for requiring the mitigation.

In June 2023, EPA released the *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum*, which required sulfuryl fluoride product labels to be submitted to the Agency with the new label language within 60 days of issuance. In July 2023, sulfuryl fluoride registrant, Douglas Products (Douglas), submitted a letter with comments on the Agency's early mitigation decision³. This Amendment reflects the Agency's response to those comments, as detailed in the Memorandum, "Response to Comments Submitted by Douglas Products on July 24, 2023, Sulfuryl Fluoride Revised Mitigation Measures; Outstanding Issues Requiring Attention", which will publish in the sulfuryl fluoride docket along with this amendment.

Notwithstanding this action, sulfuryl fluoride is still undergoing EPA's re-evaluation process, Registration Review, wherein all uses of sulfuryl fluoride are included. The Agency has allowed

https://www.epa.gov/sites/production/files/2016-12/documents/epaoig 20161212-17-p-0053.pdf

² A residential use site is a structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories.

³ Letter to Dr. Mary Elissa Reaves, Director, Pesticide Re-evaluation Division, "Sulfuryl Fluoride Revised Mitigation Measures; Outstanding Issues Requiring Attention", July 24, 2023.

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30 days from the issuance of this amendment to submit sulfuryl fluoride labels with residential structural uses to be submitted to the Agency with revised language.

LABELING CHANGES AND REGULATORY RATIONALE

The Agency has amended the following requirements of *Sulfuryl Fluoride Revised Mitigation* and *Response to Comments on the Draft Interim Re-Entry Mitigation Measures Memorandum*, including label changes for Warning Signs and Site-Specific Fumigation Log and clarifying requirements for the Registrant Stewardship Training. The changes to each requirement are described below along with the complete label table (Appendix B), which reflects the amended label language.

A. Warning Signs

The Agency has amended the following statement to remove the "residential structural" references to the Warning Signs requirements. The amended language will read as follows:

"The following is a baseline of requirements for warning signs to be posted for fumigations using [Product name]. States that currently have requirements that are comparable to the elements listed here, can maintain those requirements for warning signs. Additional elements imposed by states may also be added to these warning signs."

B. Site-Specific Fumigation Log Requirement

The Agency has made the following changes to the Fumigation Log requirements:

- The Agency will remove the statement, "Comparable elements that are currently required under state regulations can be used to satisfy the equivalent requirement of each element on this label."
- The Agency will remove the "Number of Fans" under #2. Fumigant introduction.
- The revised language for #5, now reads: Emergency response information: "Get exposed person to fresh air. Call 911 or an ambulance. Keep exposed person warm and at rest. Make sure person can breathe freely. If breathing has stopped, give artificial respiration. Do not put anything in the mouth of an unconscious person."

The amended label statements for Site-Specific Structural Fumigation Logs for sulfuryl fluoride labels are listed here and in Appendix B.

"Structural Fumigation Log requirements. The following elements for structural fumigation for each site must be documented.

The Site-Specific Structural Fumigation Log is intended to ensure a safe and effective fumigation. The certified applicator in charge of fumigation is responsible for verifying that a Fumigation Log must contain, as a minimum, the information listed below. The information followed by a "(B)" below must be documented before the initiation of the

fumigation; other information not followed by a "(B)" must be documented during the fumigation process, if not before. Contracts, site graphs, dose calculation reports, state or federally required forms and/or other documents prepared for or used during the fumigation can be used as documentation for these Fumigation Log requirements. Fumigation employees who introduce chloropicrin and sulfuryl fluoride, initiate aeration, and/or conduct final clearance testing must have participated in the registrant's sulfuryl fluoride training, as required by the registrant's stewardship plan.

1. General Information:

- Fumigation company (B)
- Fumigation site address (B)
- Structure type (B)
- Target pest(s) (B)

2. Fumigant introduction:

Dosing calculations:

- Dosage factor
- Tarp condition
- Under seal type
- Seal condition
- Wind (mph)
- Volume of fumigated space (1000 cubic feet) (B)
- Underseal
- Temperature
- Hours of Exposure

Introduction of chloropicrin and sulfuryl fluoride:

- Name license number, and signature of certified applicator responsible for introduction of chloropicrin and sulfuryl fluoride.
- Name(s) of second trained person(s) and certified applicator(s) assisting with introduction of chloropicrin and sulfuryl fluoride.
- Total ounces of warning agent chloropicrin introduced and number of introduction sites.
- Cylinder serial number(s) of sulfuryl fluoride applied.
- Pounds of fumigant applied.
- Date and time of fumigant release.

3. Aeration:

- Name, license number, and signature of certified applicator responsible for initiating aeration.
- Name(s) of certified applicator(s) and second trained person(s) assisting with initiating aeration.
- Date and time of aeration initiated.

4. Final clearance testing:

• Name, license number, and signature of certified applicator responsible for conducting final clearance testing.

- Name(s) of certified applicators assisting final clearance testing.
- Date and time final clearance testing completed.
- Clearance device model type
- **5. Emergency response information:** Get exposed person to fresh air. Call 911 or an ambulance. Keep exposed person warm and at rest. Make sure person can breathe freely. If breathing has stopped, give artificial respiration. Do not put anything in the mouth of an unconscious person.
- **6. Open Comment field:** Provide an open field for additional comments or issues that is not captured in other sections of this Structural Fumigation Log."

C. Registrant's Stewardship Training

The Agency has amended the language for the Registrants Stewardship training requirements under the Initial Training and Annual Recurrent Training, to include a metric for enforcement. The language will read as follows:

"iii. Attendees must demonstrate knowledge and understanding of the training content with a passing grade of 80%."

Stewardship Plan Criteria

Training

- 1. All employees (including owner or licensed employee responsible for managing/supervising the fumigation operations as required by state regulations) who introduce chloropicrin and sulfuryl fluoride, initiate aeration, and/or conduct final clearance testing must take initial registrant-provided stewardship training before administering, overseeing, or applying the fumigant. This stewardship plan requirement is specific to the use of sulfuryl fluoride and may be beyond the scope of state fumigation requirements. The fumigation company is responsible for requiring all their employees who meet the above criteria to participate in the registrant-provided stewardship training.
- 2. An objective metric to gauge individual knowledge and understanding should be incorporated into the training for both the initial and the annual stewardship training. This includes specific guidance for instructors on how to assess knowledge and understanding. The stewardship plan must include a process for what happens if a person does not demonstrate knowledge and understanding.
- 3. Require an annual recurrent training.

Applicator Training Elements Required to be included as part of the Sulfuryl Fluoride Registrant-Provided Stewardship Training

1. Persons required to take the training:

• <u>Customers:</u> including any person, partnership, firm, corporation, or other business entity engaged in the business entity that purchase and apply the registrant's sulfuryl fluoride product.

• <u>Fumigation employees</u>: All employees (including owner or licensed employee responsible for managing/supervising the fumigation operations as required by state regulations) who introduce sulfuryl fluoride, initiate aeration, and/or conduct final clearance testing.

2. Timing and Frequency of Training

- **a.** Initial Training:
 - i. Initial training must be completed by a company's fumigation employee prior to the first sale of fumigant to any newly licensed fumigation company.
 - **ii.** Initial training must be completed prior to the first sale of fumigant to a licensed fumigation company that has not purchased sulfuryl fluoride fumigant within the past three calendar years.
 - **iii.** Attendees must demonstrate knowledge and understanding of the training content with a passing grade of 80%.

b. Annual Recurrent Training:

- i. Every fumigation company's employee must complete Annual Training at least once per calendar year and no later than 18 months after the date of the fumigation employee's prior completion of an Annual Training session.
- ii. New fumigation employees must complete Initial Training within 90 days of hire and prior to any role in fumigation. This requirement includes fumigation employees that have transferred from a non-fumigation role into a fumigation role.
- **iii.** Attendees must demonstrate knowledge and understanding of the training content with a passing grade of 80%.
- **3.** Training Content Registrants are responsible for developing product-specific training modules that meet the content requirements below:

a. Initial Training:

- i. Fumigation good practices and requirements
- ii. Proper use, handling, and storage of fumigant
- iii. Label-required procedures for fumigation
 - Preparation
 - Sealing
 - Securing the fumigation site
 - Posting at the fumigation site
 - Introduction of chloropicrin warning agent and sulfuryl fluoride
 - Aeration
 - Final clearance testing
- **iv.** For information on the effectiveness of clearance devices, please visit the EPA website: <u>Sulfuryl Fluoride | US EPA</u>
- **v.** The proper use and calibration requirements for clearance detection devices are listed in the [Registrant] product stewardship plan.
- vi. The proper use of label-required safety equipment including the self-contained breathing apparatus (SCBA)

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- **vii.** Review of the label, manual, Safety Data Sheets, safety procedures, and Stewardship Policy for the registrant's residential fumigant
- viii. Dosage calculation for the registrant's residential fumigant

b. Annual Training:

- i. Fumigation good practices and requirements
- **ii.** Review of the proper use, handling, and care of safety equipment and clearance detection devices
- **iii.** Review of the labeling and stewardship requirements for worker protection and public safety
- iv. Review of any updates to registrant's residential fumigant labeling
- v. Review of any updates to registrant's residential Stewardship Policy

The Agency has determined it is necessary for all sulfuryl fluoride registrants with residential structural fumigation use to submit to the Agency stewardship plans for their product that include the generic criteria listed above. The plans will be made available on the EPA website and a reference to the plan and annual training must be listed on product labels.

I. NEXT STEPS AND TIMELINE

A Federal Register Notice (FRN) will announce the availability of this amendment to the early mitigation to address the OIG Report for sulfuryl fluoride. Once the "Amendment to the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum" is issued, the sulfuryl fluoride registrants must submit amended labels that include the label changes in Appendix B. The revised labels and requests for amendment of registrations must be submitted to the Agency (Pesticide Re-evaluation Division) for review within 30 days following the issuance of the document in the sulfuryl fluoride docket.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels. Two copies for each label must be submitted, a clean copy and an annotated copy with changes clearly marked. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum and EPA regulations at 40 CFR Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum and 40 CFR Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

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Within the required timeframe, registrants must submit the required documents to the EPA's Pesticide Submission Portal (PSP), which can be accessed through the EPA's Central Data Exchange (CDX) using the following link: https://cdx.epa.gov/.

The Next Steps and Timeline is listed in **Table 1.**, below.

Table 1. Next steps: Requirements mitigation implementation timeline		
Next steps	Timeline	
Publish "Amendment to the Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum."	September 2023	
Require submission of revised sulfuryl fluoride labels to be submitted to the Agency (Pesticide Re-evaluation Division) to address the OIG Report	30 days after the publication of this document	
Complete and publish the dietary and aggregate risk assessments for sulfuryl fluoride for a 60-day comment period	TBD	
Publish the Sulfuryl Fluoride Proposed Interim Decision (PID) for a 60-day comment period	TBD	
Publish the Sulfuryl Fluoride Interim Decision (ID)	TBD	
Require revised sulfuryl fluoride labels to be submitted to the Agency within 60 days of publication of the ID	TBD	

APPENDIX B. Required Label Changes for Sulfuryl Fluoride Products

Description	Amended Label Language for Sulfuryl Fluoride Products for Residential Fumigation	Placement on Label
	End Use Products	
Warning Sign Label Language. Posting of Fumigated Areas Language is for Residential Fumigants. List includes a baseline of requirements for warning signs. States that currently have requirements for warning signs that include these elements listed here, can maintain those requirements for warning signs. Additional elements imposed by states may also be added for residential structural fumigations.	"The following is a baseline of requirements for warning signs to be posted for fumigations using [Product name]. States that currently have requirements that are comparable to the elements listed here, can maintain those requirements for warning signs. Additional elements imposed by states may also be added to these warning signs. 1. The applicator must post the fumigated areas with warning signs with a white background stating the following: a. The signal word DANGER/PELIGRO at a minimum height of 2 inches, the SKULL and CROSSBONES symbol at a minimum height of 1 inch, and the statement "Area under fumigation, DO NOT ENTER/NO ENTRE" - all printed in one or more colors contrasting with the white background b. The date of fumigation. c. Brand name of fumigant used (minimum height ½ inch). d. Name, address, and telephone number of the applicator, or company performing the fumigation. 2. Information on warning signs must remain legible and visible for the duration of the fumigation and aeration periods. 3. Warning signs must be placed on the structure at or near all doors and entrances. 4. On tented structures, additional warning signs must be placed on the outside of the tarp so that they are clearly visible from all accessible sides, and from any direction from which the site may be approached."	In the Directions for Use under the heading "Posting of Fumigated Areas"
Site-specific Structural Fumigation Log for all end-use	"Structural Fumigation Log requirements. The following elements for structural fumigation for each site must be documented.	In the Directions for Use under the heading "Site-Specific
products containing directions for residential uses. Listed elements are a baseline of requirements for fumigation logs. Comparable elements that are currently required under state regulations can be used to	The Site-specific Structural Fumigation Log is intended to ensure a safe and effective fumigation. The certified applicator in charge of fumigation is responsible for verifying that a Fumigation Log must contain, as a minimum, the information listed below. The information followed by a "(B)" below must be documented before the initiation of the fumigation; other information listed below without a "B" must be documented during the fumigation process, if not before. Contracts, site graphs, dose calculation reports,	Structural Fumigation Log"

Description	Amended Label Language for Sulfuryl Fluoride Products for Residential Fumigation	Placement on Label
satisfy the equivalent requirement of each element on this label. A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories.	state or federally required forms and/or other documents prepared for or used during the fumigation can be used as documentation for these Fumigation Log requirements. Fumigation employees who introduce chloropicrin and sulfuryl fluoride, initiate aeration, and/or conduct final clearance testing must have participated in the registrant's sulfuryl fluoride training, as required by the registrant's stewardship plan. 1. General Information:	
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Description	Amended Label Language for Sulfuryl Fluoride Products for	Placement on Label
	Residential Fumigation	
	 Name, license number, and signature of certified applicator responsible for initiating aeration. Name(s) of certified applicator(s) and second trained person(s) assisting with initiating aeration. Date and time of aeration initiated. Final clearance testing: Name, license number, and signature of certified applicator responsible for conducting final clearance testing. Name(s) of certified applicators assisting final clearance testing. Date and time final clearance testing completed. Clearance device model type Emergency response information: "Get exposed person to fresh air. Call 911 or an ambulance. Keep exposed person warm and at rest. Make sure person can breathe freely. If breathing has stopped, give artificial respiration. Do not put anything in the mouth of an unconscious person." Open Comment field: Provide an open field for additional comments or issues that is not captured in other sections of this Structural Fumigation Log." 	
Product Stewardship Plan reference for residential structural fumigations. A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories.	"[The registrant]'s Product Stewardship Plan that includes EPA's stewardship plan criteria is available at Sulfuryl Fluoride US EPA. Applicators and distributors of [product name] must participate in [the registrant's] Product Stewardship Plan for residential structural fumigations. This plan is also available at Sulfuryl Fluoride US EPA for [Product name]. [Product name] must only be used by application personnel who satisfactorily comply with the [product name] Stewardship Plan, including the initial and annual training requirements."	In Directions under heading "[the registrant]'s Product Stewardship Plan

Description	Amended Label Language for Sulfuryl Fluoride Products for Residential Fumigation	Placement on Label
Language Regarding Portable Clearance Devices	Registrants, remove all references to clearance devices being "approved." Replace language with the following statement: "Confirm concentration of sulfuryl fluoride of 1ppm or less, with clearance devices determined to be effective by meeting the Agency performance criteria. Refer to EPA's website at Sulfuryl Fluoride US EPA (https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride) for more information and a list of effective clearance devices."	In the Directions for Use under the heading "Aeration and Reentry"
Aeration and Reentry Requirements for residential structures. A residential structure is where people typically live (temporarily or permanently) and sleep, such as single-family residences, mobile homes, apartments, townhouses, condominiums, hotels, motels, assisted care facilities, nursing homes, hospitals, barracks, and dormitories	Registrants, for residential fumigations, replace the language for Aeration Procedures 1 & 2 with the revised language, which reflects the new aeration times: "Preparation Section Prepare for Aeration Procedures 1 and 2 by doing the following: Open all operable attic doors and accesses and direct a fan into the attic. Position introduction and circulation fans to provide for air circulation throughout the fumigated space. For example, a circulation fan in the hall could be used to aid air circulating in bedrooms and bathrooms. Use a minimum of one fan of at least 18 inches in diameter for every 22,500 cubic feet of space to be fumigated. Select the appropriate procedure based on the fumigation rate: All structures fumigated at 16 oz/MCF (1,000 cubic feet of gas) or less may be aerated using Aerations Procedures 1 or 2. All structures fumigated at concentrations greater than 16 oz/MCF must be aerated using Aeration Procedure 2. Aeration Procedure 1 These steps must be completed in sequence. Step (1): Aerate structure with all operable windows and doors open, aided by at least one fan (of at least 18 inches in diameter) for every 22,500 cubic feet of fumigated space, for a minimum of 2 hours following the directions in the Preparation section. If the structure has an attached garage, the door between the garage and structure should	In the Directions for Use under the heading "Aeration and Reentry"

Description	Amended Label Language for Sulfuryl Fluoride Products for Residential Fumigation	Placement on Label
	each operational unit. As an alternative, a circulation fan may be placed in front of a furnace inlet to blow air into central heating and cooling ducts. Removal of all chloropicrin evaporation containers from the fumigated space during Step (1) will aid in the dissipation of the warning agent from the structure.	
	Step (2): Secure structure and do not allow reentry for a minimum of 12 hours from the start of aeration (first opening of the seal) for residential structures ¹ . During this time structures must remain posted with warning signs.	
	Step (3): After the minimum 12-hour waiting period in Step (2), measure the concentration of [Product name] in breathing zones of each room using a clearance device listed on the EPA website at Sulfuryl Fluoride US EPA. If the concentration of [Product name] is greater than 1 ppm, ventilate structure with operable doors and windows open and confirm concentrations are 1 ppm or less before the structure is reoccupied.	
	In California, for a structure in which aeration using the California Aeration Plan (CAP) failed during the minimum 12-hour aeration time specified in CAP, (e.g., the tarpaulins blew open, the ducted aeration fan failed, etc.), Aeration Procedure 1 or 2 must be conducted as described above using a minimum wait time of 12 hours from the initiation of aeration in Step (1).	
	Aeration Procedure 2 These steps must be completed in sequence. Step (1): Aerate structure with all operable windows and doors open, aided by at least one fan (of at least 18 inches in diameter) for every 22,500 cubic feet of fumigated space, for a minimum of 2 hours following the directions in the Preparation section. If the structure has an attached garage, the door between the garage and structure should be open. If the structure has a central air system, turn on only the fan (or blower) for each operational unit. As an alternative, a circulation fan may be placed in front of a furnace inlet to blow air into central heating and cooling ducts. Removal of all chloropicrin evaporation containers from the fumigated space during Step (1) will aid in the dissipation of the warning agent from the structure.	
	Step (2): Secure the structure and do not allow reentry the minimum number of hours as listed in the Table X. Determining Minimum Hours of Aeration Time Based on Initial Concentration of Sulfuryl Flouride Introduced, from the start of aeration	

Description	Amended Label Language for Sulfu Residential Fum	Placement on Label	
	(first opening of the seal) for residential structures remain posted with warning signs.		
	Step (3): After the minimum waiting period, measure the concentrations of [Product name] in breathing zones of each room using a clearance device listed on the EPA website at <u>Sulfuryl Fluoride US EPA</u> . If the concentration of [Product name] is greater than 1 ppm, ventilate structure with operable doors and windows open and confirm concentrations are 1 ppm or less before the structure is reoccupied.		
	Table X. Determining Mir Aeration Time Based on Initi Sulfuryl fluoride In		
	Initial Concentration of Sulfuryl Fluoride	Minimum Hours of Aeration	
	Introduced (ounces per thousand cubic	Time**	
	feet)		
	Greater than 16 to 32	14	
	Greater than 32 to 48	16	
	Greater than 48 to 64	18	
	Greater than 64 to 96	20	
	Greater than 96 to 112	22	
	Greater than 112	24	
	**When the high ambient temperature for the a at the fumigation site, a minimum of 24 hours		
	In California, for a structure in which aeration usi (CAP) failed during the aeration time specified in blew open, the ducted aeration fan failed, etc.), Acconducted using a minimum wait time using the T in Step (1).		
	¹ A residential structure is where people typically sleep, such as single-family residences, mobile ho condominiums, hotels, motels, assisted care facilit barracks, and dormitories."		