



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 27, 2023

MEMORANDUM

SUBJECT: Response to Comments Submitted by Douglas Products on July 24, 2023, “Sulfuryl Fluoride Revised Mitigation Measures; Outstanding Issues Requiring Attention”

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Overview:

This memorandum represents the Agency’s response to a letter submitted by Douglas Products (Douglas), a registrant of the fumigant sulfuryl fluoride. The Douglas letter contained comments on the Agency’s early mitigation decision¹, the *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum*, which published on June 29, 2023. The early mitigation decision represents the Agency’s response to the Office of Inspector General’s (OIG) 2016 Report, *Additional Measures Can Be Taken to Prevent Deaths and Serious Injuries From Residential Fumigations* (No. 17-P-0053). Douglas’ comments and Agency responses are summarized below under the required mitigation title.

¹ Letter to Dr. Mary Elissa Reaves, Director, Pesticide Re-evaluation Division, “Sulfuryl Fluoride Revised Mitigation Measures; Outstanding Issues Requiring Attention”, July 24, 2023.

A. Warning signs

Douglas Comment: The labeling text should be changed to delete “residential structural” fumigations from the description, so it can be more inclusive to other fumigations on its label. Making the change would ensure that there is a single set of warning sign requirements which apply to all Vikane fumigations as opposed to potentially one set for residential and one set for non-residential fumigations.

Agency Response: The Agency accepts the recommendation and will include the revised definition to avoid confusion and allow a single set of warning sign requirements. The language will read as follows:

“The following is a baseline of requirements for warning signs to be posted for ~~residential structural~~ 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

Douglas Comment: EPA should confirm that California and Florida Structural Fumigation Log requirements are “comparable” and may continue to be used without modification. The question for EPA is not whether State regulators will require changes to State logs to comply with Federal requirements, but whether EPA views the current State logs as satisfying the newly proposed Federal requirements. Douglas understood that EPA deemed existing California and Florida Structural Fumigation Log requirements to be satisfactory and that EPA intended to exempt fumigators in California and Florida from any changes to fumigation log requirements, meaning that fumigators in those states would continue to be able to use the logs presently in use, which are created based on state regulations. The Revised Mitigation documents provide no such confirmation, however, and thus leave the concept of “comparability” to case-by-case interpretation in the field. This is not desirable or efficient. EPA should permit the label to confirm that the current California and Florida logs are “comparable” and may continue to be used without alteration.

Douglas also commented on the Emergency preparedness/response information. Douglas suggested listing 911 rather than the nearest hospital in case of a human health emergency. Douglas claims this is an outdated requirement and that an ambulance attendant is best equipped to get the person to the correct treatment or hospital.

Douglas requested two days to complete the fumigation log, rather than the current requirement to complete the log on the day of fumigation. Douglas claims the Fumiguide app can store the relevant information in the field and then it can be transferred to a log form.

Agency Response: The basic elements that must be recorded for every structural fumigation is listed under the “Site-Specific Fumigation Log” requirement. The intent to allow “comparable”

elements already required by existing state regulations was to provide flexibility and avoid redundancy. The Agency determined that it could not exempt states from the required elements because state regulations could change, and the elements may not be met. The only other option was to require a separate template for the Fumigation Log requirement that would need to be filled out for each structural fumigation, in addition to the existing regulations of the state. This would result in a new requirement that would be in addition to existing state requirements and may represent a burden for fumigators in states that already require similar and comparable information. In a follow-up meeting with Douglas on August 9, 2023, the company recommended contacting Florida and California state regulators to determine if the requirements, as written, would be confusing and if they are comparable to existing state requirements.

In response to Douglas concerns, EPA contacted the state lead agencies in both Florida and California with regards to the potential impact/confusion of the sulfuryl fluoride Fumigation Log requirements.

Florida: EPA contacted Courtney Frazier, Assistant Director, Division of Agricultural Environmental Services on August 15, 2023. According to Ms. Frazier, there were only two areas where the new requirement differed from Florida regulations, which included the listing of the number of fans and the emergency preparedness/response information.² Ms. Frazier indicated that other than these items, the sulfuryl fluoride Fumigation Log requirements were the same as current Florida state requirements and were not confusing.

California: EPA met on September 18, 2023, with the directors and staff of the Enforcement, Environmental Monitoring and Worker Health and Safety branches of the California Department of Pesticide Regulation (DPR). DPR officials provided comments on the sulfuryl fluoride label language to avoid confusion for fumigators in California.³ Comments included the recommendation to 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.” According to the California enforcement officials, the statement, “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” is sufficient to inform users in California that they can cite existing state requirements. Additionally, California does not require the number of fans to be listed on the Fumigation log.

In addition to comments on the sulfuryl fluoride Fumigation Log requirements, DPR enforcement officials expressed concerns with the enforceability of some of the training metrics of the Registrant Stewardship plans. DPR recommended the following changes to the **Timing and Frequency of Training**, under Initial Training and Annual Recurrent Training:

² Email from Courtney Frazier, Assistant Director Division of Agricultural Environmental Services, Florida Department of Agricultural and Consumer Services, 8/15/2023.

³ Meeting between USEPA Sulfuryl Fluoride team and Cal DPR on September 18, 2023.

“iii. Attendees must demonstrate knowledge and understanding of the training content ~~to the satisfaction of the registrant’s instructor~~ with a passing grade of 80%.”

Neither Florida nor California brought up concerns over the requirement to complete the Fumigation log on the day of the fumigation.

After communications with Florida and California on the Fumigation Log requirement for sulfuryl fluoride, 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 Agency received no information to support extending the timing to complete the Fumigation Log requirements to two days, and therefore there are no changes in the timing.

The Agency has revised the language for the Registrants Stewardship training requirements to include the recommendation from DPR, under the Initial Training and Annual Recurrent Training, to include:

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

C. Aeration Requirements

Douglas Comment: Douglas identified a typographical error in the label table where conflicting fan requirements were listed.

Agency Response: The Agency agrees the sentence from the previous (current) label language has now been superseded. The following sentence will be removed, “Total fan capacity, using one or more fans, shall be capable of displacing a total of 5,000 cfm.”

Douglas Comment: 2-hour vs. 1-hour Active Aeration. Douglas objects to the requirement of an additional hour of Active Aeration, citing data it claims to support only needing 1 hour of active aeration and potential impacts to fumigators from the requirement.

Agency Response: As stated on page 13 of the *Sulfuryl Fluoride Revised Mitigation and Response to Comments on the Draft Interim Re-entry Mitigation Measures Memorandum*, the

Agency reviewed the Shurdut⁴ data presented by Douglas and reached a different conclusion. According to the Agency review of the study, the MIRAN readings take place at Time point 0 and then again at Time point 2, which indicate a 2-hour difference, and which represents 2 hours of aeration, containing a mix of active and passive aeration. The study stated that active aeration (i.e., all operable windows and doors opened) was conducted for a minimum one hour. However, detailed aeration information, including recorded durations of active aeration, were not provided in the study report. The amount of time each structure underwent active aeration versus passive aeration in the first two-hour monitoring period is not clear in the study report. The study also noted that the fumigation circulation fan, as well as ceiling fans if present, were left running for the duration of the entire (~6 hour) aeration phase. Therefore, it would not be appropriate to assume that only 1 hour of active aeration is needed when the data were based on a combination of both active and passive aeration over a two-hour period. As incidents have continued, some have occurred when the current label aeration requirements may have been exceeded. EPA concluded that the 2-hour active aeration period is required in order to be protective of human health and reduce the potential for exposure upon re-entry. Additionally, due to the inability of some clearance devices to accurately measure the amount of sulfuryl fluoride at the current clearance level and in light of ongoing incidents, the Agency determined that additional aeration time including an additional hour of active aeration is necessary.

Regarding the impact to fumigators from the additional hour of active aeration, the Agency reminds the commenter that the original aeration proposal to adopt the California Aeration Plan (CAP) would have had potentially greater impacts on fumigation firms than the current requirement. For the active aeration period, the fumigators can remove the tarps and begin to prepare for a fumigation at another site.

Douglas Comment: California Procedures Following a Blow Open. Douglas wants to include a clause that allows CA in the event of a Blow Open to only aerate for 6 hours rather than the revised requirement, which will extend the aeration time to a minimum of 12 hours.

Agency Response: The Agency has determined that the most effective way to disperse sulfuryl fluoride adequately is with longer aeration times, which are included in the new label requirements. The Agency will not retain two sets of aeration times in the event of a Blow Open in California. There is no justification to allow a shorter aeration time of 6 hours rather than the new requirement of 12 hours, which would be required for all fumigations in other states in the event of a Blow Open. During the discussion with DPR, this requirement was brought up.

D. Website

Douglas Comment: Douglas objected to adding a reference to an EPA-maintained website to list acceptable clearance devices, rather it wants to retain the list of devices on the product label. Douglas claims this information must be retained on a written product label, while it questions the availability of the website. Douglas also objects to EPA retaining the ability to unilaterally modify a website containing requirements affecting the ability to apply sulfuryl fluoride.

⁴ Shurdut, B. A., P. G. Murphy, and K. K. Beard. 1995. Amended Report for Evaluation of Concentrations of Sulfuryl Fluoride Inside Houses Following Fumigation With VIKANE Gas Fumigant. DowElanco Report No. 29141, US EPA MRID No .43593801. 193 pp

According to Douglas, EPA lacks the authority to make such modifications unilaterally and cited *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) (“A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute”). Douglas believes EPA is asking Douglas to make it a term of the registration that EPA may modify the scope of the registration at any time by making modifications to the website.

Douglas stated they would discuss alternatives with the Agency, such as a website maintained by Douglas. Or, if the Agency can propose some mechanism by which it would be bound to obtain Douglas’ consent before modifying an EPA-maintained website, Douglas would reconsider adding a reference to an EPA-maintained website.

Additionally, Douglas believes that information concerning acceptable clearance devices must remain on the product label for the reasons stated above. If an EPA or Douglas maintained website were to be referenced in the future, the written label could refer to all devices permitted for use at the time of the amendment “plus any additional devices listed on [the website].” This approach would retain the flexibility to add additional devices to a website as they become available (and are confirmed to be effective and acceptable for use, see Issue J) and also provides redundancy in the event of website outage or unavailability.

Agency Response: Contrary to Douglas’ assertion, adding a reference to the EPA website to Douglas’ product label does not give EPA unilateral authority to change the terms and conditions of Douglas’ registered sulfuryl fluoride products through that website. The website simply lists portable clearance devices that EPA has determined to be effective, based on testing criteria for evaluating efficacy⁵. See <https://www.epa.gov/ingredients-used-pesticide-products/sulfuryl-fluoride-clearance-devices>. The website reference on the label would direct the user of the pesticide to a website that lists portable clearance devices that meet certain conditions for efficacy. Users of the pesticide could check EPA’s website to identify effective portable clearance devices that meet the conditions for efficacy and make informed choices about which device to use to ensure that the structure is safe for re-entry. As more products become available that meet EPA’s conditions, they may also be listed on this website; if additional information were developed that indicated certain devices listed on the webpage no longer met the conditions, they could be removed from the website. But the website itself does not affect or impact existing terms and conditions of separately registered sulfuryl fluoride products.

EPA agrees that the FIFRA registration is essentially a license that allows for the sale and distribution of the registered pesticide, but there may be restrictions on the sale, distribution, or use of that pesticide. When EPA grants a registration, that registration contains terms and conditions for that registration to remain compliant with FIFRA, which are reflected in a registration notice and with which the registrant must comply. That registration also consists of a label for that pesticide that provides instructions to the user to ensure that the pesticide when used will not pose unreasonable adverse effects to human health and the environment. It is important to note that the existence of a registration does not allow a registrant to act with impunity nor does it guarantee that the product will always remain registered under the same terms and conditions. FIFRA provides various mechanisms for removing registered but non-

⁵ Protocol for Conducting Laboratory Testing of Portable Clearance Devices with Sulfuryl Fluoride Standards, Analytical Chemistry Branch (ACB), Office of Pesticide Programs, U.S. EPA, December 30, 2019. Available in the docket, <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0136-0106>.

compliant products from the market, e.g., cancellation, suspension, enforcement action, see 7 U.S.C. 136d(b), (c), 136j(a), 136k. Moreover, a registrant's rights to the license are limited; courts have recognized that "there is no property interest in using property in a manner that is harmful to the general public." *American Vanguard Corporation v. United States*, 142 Fed.Cl. 320, 328 (Ct. Fed. Cl. 2019) (citing *Mitchell Arms, Inc. v. United States*, 7 F.3d 212 (Fed. Cir. 1993)).

E. Effectiveness of SF-ExplorIR

Douglas Comment: Douglas objected to a number of issues with regards to the clearance device SF-ExplorIR, including a question on the effectiveness determination, the resolution as criteria for effectiveness, the potential impact on the industry if the device is determined to be ineffective, and the method for determining acceptable clearance devices.

Agency Response: EPA has completed its review of the most recent submission on the SF-ExplorIR from Douglas (MRID No. 52213401) "*Testing of the SF-ExplorIR (Portable Clearance Device) Operating in the Normal Mode with Nominal 1 and 3 ppm Sulfuryl Fluoride Samples*" (Laboratory Study ID DP-00045; July 10, 2023, 53 pages). As further explained in the Data Evaluation Record sent to Douglas on August 17, 2023, EPA finds the study to be unacceptable in the ability of the SF-ExplorIR to accurately read concentrations of sulfuryl fluoride.

In meetings with Douglas in the fall of 2022, EPA provided specific protocol criteria and recommendations, which included conducting the study under the device "Normal" mode and ensuring the use of certified SF standards for calibrating the instrument and for testing the devices. EPA further asserted that if a laboratory prefers to prepare working standards (calibration standards and test sample standards) by serial dilution of a high concentration stock standard in ambient air, independently sourced and certified SF standards must be used to verify the prepared working standards. EPA's recommendations were not followed in the study submitted to the Agency by Douglas (MRID 52213401). The Douglas study used a 1.4 SF standard from Praxair (not 1ppm), which the study conductor, Wiley Hall, said he verified the reliability by another diluted SF standard. In discussions with Mr. Hall⁶, he was asked if he tested the SF-ExplorIR device with the certified SF standards, and he answered "no". Mr. Hall indicated he was not aware of the Agency protocol for clearance device testing, prior to testing with the sulfuryl fluoride standards. Mr. Hall indicated that the lowest standard (intended to read the 1ppm clearance level) was off the calibration line by about 60%. Given the issue with the study relying on non-certified standards, the Agency cannot validate the effectiveness of the SF-ExplorIR device to accurately and reliably perform at the clearance level. For further details, please refer to the data evaluation record.

Regarding the potential impacts to fumigators if the SF-ExplorIR were no longer available and the impact of listing clearance device information on the EPA website. The results of the Agency clearance device study, *Laboratory Testing of Portable Clearance Devices with Sulfuryl Fluoride Standard*, was announced and published two years ago, in May 2021. This Agency study provided the results of testing of four models of portable clearance devices, including that

⁶ Meeting with Wiley Hall, USDA on SF-ExplorIR testing conducted at USDA lab for Douglas Products (9/5/23)

of the SF-ExplorIR. In addition to listing the results on both published documents in May 2021 and just prior to the publication of these documents, the Agency hosted two webinars to announce the results of the Agency study. The webinars included the sulfuryl fluoride registrants, all the clearance device manufacturers, state lead agencies, and other industry stakeholders, and discussed the details and results of the study. Therefore, the industry has had two years to review/reevaluate clearance devices to meet the standards, based on the EPA protocol, of the device effectiveness⁷ in detecting sulfuryl fluoride at the current clearance level of 1 ppm. As mentioned above, the Agency posted all of the information supporting the Agency study, including the protocol development, communication with device manufacturers, and the raw data in the public docket on May 25, 2021 (EPA-HQ-OPP-2009-0136). Moreover, as the sulfuryl fluoride labels will not be updated and stamped for a few months, the Agency believes that providing the information on the website will aid in preparing the industry for the forthcoming label changes.

With regard to Douglas' questioning the method for determining acceptable clearance devices, the Agency has provided the protocol for testing and effectiveness and has discussed the details with Douglas in multiple meetings. The Agency stands by the current results of the clearance device study and the requirements for devices to be determined to be effective.

The Agency objects to the current reference to clearance devices on product labels as "approved" and has determined that the current list, which includes old devices that are no longer used and those that do not meet the criteria for effectiveness, based on the EPA protocol, would represent misbranding. The Agency does not "approve" clearance devices and therefore cannot continue to list them on the product label.

F. Timing for Implementation of Updated Labels

Douglas Comment: Douglas is requesting additional time beyond August 28, 2023, to complete discussions concerning these issues and submit label amendments. It is also requesting 18 months for existing stocks.

Agency Response: The Agency intends to issue an amended label table for sulfuryl fluoride labels to reflect a few clarifications, by the end of September 2023. The Agency will allow 30 additional days from the issuance of the amended label table for updated labels to be submitted to the Agency. The Agency will provide a 12-month period for use of existing stocks from the date of the stamped labels.

⁷ Protocol for Conducting Laboratory Testing of Portable Clearance Devices with Sulfuryl Fluoride Standards, Analytical Chemistry Branch (ACB), Office of Pesticide Programs, U.S. EPA, December 30, 2019. Available in the docket, <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0136-0106>.