December 21, 2022

The Notice of Revision to the NJDEP Division of Air Quality Risk Screening Worksheet for Long-Term Carcinogenic and Noncarcinogenic Effects and Short-Term Effects (RSW) as Listed in Technical Manual 1003 "Guidance on Preparing a Risk Assessment for Air Contaminant Emissions" was posted on June 8, 2022 on the Department's website at https://dep.nj.gov/boss/ under "Program Update" and at https://dep.nj.gov/airplanning/ under "What's New." In addition, the Notice of Revision was announced in a June 8, 2022 Air Quality Regulation Listserv email. The deadline in the Notice of Revision for submission of comments was July 8, 2022.

Summary of Public Comments and Agency Reponses:

The following individuals provided written comments:

1. Shannon Sked, Western Fumigation
2. Tim McPherson, Douglas Products
3. Michael Bickel, Ecolab
4. Thomas P. Hogan, Cocoa Merchants Association of America
5. Taylor McFarland, New Jersey Chapter of the Sierra Club

1. **COMMENT:** The Department's proposed sulfuryl fluoride temporary reference concentrations are extremely conservative, not scientifically justified, and infeasible for the majority of fumigations within the state. The Department is proposing to use the California Environmental Protection Agency (CalEPA) Department of Pesticide Regulation (DPR) upper range 24-hour reference concentration of 0.75 ppm (3,128 µg/m^3) as a temporary short-term reference concentration and a long-term reference concentration of 0.012 ppm (50 µg/m^3) for sulfuryl fluoride. CalEPA used inappropriate uncertainty factors to calculate its preliminary proposed sulfuryl fluoride reference concentrations, resulting in short and long term reference concentrations that are overly conservative. Appropriate reference concentrations, as proposed by Douglas Products (Douglas), can be derived from the same toxicology studies and end points that CalEPA used, if different uncertainty factors are applied. Douglas' proposed acute and chronic sulfuryl fluoride reference concentrations of 2.50 ppm (10,425 µg/m^3) and 0.12 ppm (500 µg/m^3), respectively, are more appropriate and protective of public health without eliminating the ability of facilities to use this fumigant. These proposed values were derived using appropriate scientific methodologies.

   CalEPA applied a database uncertainty factor of 3 for the calculation of their proposed sulfuryl fluoride short-term reference concentration. However, Douglas Products proposes a database uncertainty factor of 1 is more appropriate since the sulfuryl fluoride toxicology database is complete based on EPA guidelines. The same difference in the database uncertainty factors applies to the calculation of the proposed long-term reference concentrations in addition to a difference in the interspecies uncertainty factor applied. CalEPA applied an interspecies uncertainty factor of 10 and Douglas proposes an uncertainty factor of 3 is more appropriate. (2 and 4)

2. **COMMENT:** The Department has arbitrarily decided to enforce temporary sulfuryl fluoride reference concentrations that have not yet been adopted by any other state or the United States Environmental Protection Agency (EPA). The Department is proposing to use the upper range number (0.75 ppm) of CalEPA's preliminary 24-hour short-term reference concentration range 0.25 -

0.75 ppm as a temporary short-term reference concentration and a long-term reference concentration of 0.012 ppm (50 µg/m^3). However, the risk screening worksheet Fact Sheet (dated June 8, 2022) implies that the Department will adopt whatever reference concentrations CalEPA finalizes. The Department should forgo the use of temporary sulfuryl fluoride reference concentrations and wait until the EPA or CalEPA finalizes their reference concentrations. If the Department decides to proceed with adopting temporary sulfuryl fluoride reference concentrations, it should use those proposed by Douglas (acute reference concentration: 2.50 ppm or 10,425 µg/m^3, chronic reference concentration: 0.12 ppm or 500 µg/m^3) which were determined using appropriate methodologies and are protective of public health without eliminating the ability of facilities to continue using this fumigant. (2)

3. **COMMENT:** There is a great deal of uncertainty in the regulated community regarding the air permitting and risk assessment of sulfuryl fluoride. The Department intends on temporarily adopting the proposed acute and chronic sulfuryl fluoride reference concentrations with the potential to change these regulated standards at an unknown future date but has not considered the operational and economic impacts of such actions on industry.

   Permit applicants will now have to endure additional costs, amounting to several tens of thousands of dollars, for the construction and installation of additional control technology including stacks and new ductwork. These actions are unnecessary since safety precautions for sulfuryl fluoride fumigations are already in place due to the registration of this pesticide under FIFRA. Operational expenses should not be taken lightly as the Department may later change their proposed sulfuryl fluoride reference concentrations when the EPA and CalEPA finalize their toxicity values. (4)

4. **COMMENT:** The Department's proposed short-term sulfuryl fluoride reference concentration is overly conservative and will make it nearly impossible for clients to obtain a fumigation air permit. Therefore, the Department should withdraw the proposed short-term sulfuryl fluoride reference concentration and instead engage with relevant stakeholders, including Western Fumigation and Douglas Products, to determine a standard which is protective of public health and can be reasonably met by air permit applicants. (1)

   RESPONSE TO COMMENTS 1 THROUGH 4: The Department understands and agrees with the need for certainty for regulated entities, the public, and the Department. To provide this certainty, the Department proposed to update the risk screening worksheet by adding sulfuryl fluoride reference concentrations (acute and chronic) that would be utilized in the worksheet as presumptive values. The proposed update to the risk screening worksheet follows the Department's adoption of rules that clarified the permitting obligations for fumigation operations. As explained in response to comments 9 and 14 below, the risk screening worksheet is an optional tool for applicants.

   The Department periodically updates its reference concentrations and unit risk factors using well-established federal and state sources including EPA's Integrated Risk Information System (IRIS), California Environmental Protection Agency (CalEPA), and the Agency for Toxic Substances and Disease Registry (ASTDR). Based on a recommendation from the Department's Division of Science and Research (DSR), the Department proposed to use sulfuryl fluoride acute and chronic reference concentrations of 0.75 ppm (3,128 µg/m^3) and 0.012 ppm (50 µg/m^3), respectively, based on a 2020 California Department of Pesticide Regulation (CalDPR) assessment (CalDPR, 2020).

In response to the Department's proposed values, the Department received comments requesting that the sulfuryl fluoride acute and chronic reference concentrations proposed by Douglas Products be used instead. In a follow-up discussion with Douglas, representatives requested that the Department consider utilizing the label clearance value of 1.00 ppm (4,170 µg/m^3) as the presumptive acute reference concentration for sulfuryl fluoride.

The Department evaluated the materials submitted by the commenters. The Department also notes that EPA is still undergoing its registration review of sulfuryl fluoride. Given the pending review by EPA, as well as California's still pending review, the Department has determined to utilize the label clearance level of 1.00 ppm (4,170 µg/m^3) as the presumptive acute reference concentration for sulfuryl fluoride in the risk screening worksheet. The Department believes this will provide the greatest consistency and certainty for owners/operators utilizing sulfuryl fluoride in the State, while protecting public health. Applicants may continue to propose to use an alternate reference concentration on a case-by-case basis by providing appropriate documentation and risk assessment in support of such use. The Department will also continue to monitor EPA's and California's reviews and take further action if appropriate, when these reviews are completed.

In terms of the chronic reference concentration for sulfuryl fluoride, Douglas requested that the Department utilize a sulfuryl fluoride chronic reference concentration of 0.12 ppm (500 µg/m^3), which is 10 times greater than the value that the Department proposed in its notice (0.012 ppm or 50 µg/m^3). After its review, the Department's Division of Science and Research (DSR) recommended the use of 0.036 ppm (150 µg/m^3) as the presumptive chronic sulfuryl fluoride reference concentration. This recommendation is based on sulfuryl fluoride toxicity involving a systematic circulation pathway, rather than the multiple exposure pathway assumption approach taken by CalDPR (2020) in deriving a RfC of 0.012 ppm.

After review, the Department has determined to utilize a chronic reference concentration value of 0.036 ppm (150 µg/m^3) based on the Department's DSR's recommendation to date. The Department is continuing to evaluate materials provided by Douglas but determined to include this chronic reference concentration as the presumptive value for sulfuryl fluoride in the risk screening worksheet, which will allow applicants to utilize the risk screening worksheet as a screening tool. As with the acute reference concentration, applicants may continue to propose to use an alternate reference concentration on a case-by-case basis by providing appropriate document and risk assessment in support of such use. The Department will continue to monitor EPA's and California's reviews and take further action if appropriate, when these reviews are completed.

5. **COMMENT:** The Department failed to provide a socio-economic impact analysis, a regulatory flexibility analysis, a jobs impact statement, or an analysis of applicable federal regulations as required by the New Jersey Administrative Procedure Act. The new sulfuryl fluoride standards will increase fumigation costs for fumigation clients and decrease the flow of cargo from warehouses to receiving customers (MARS, Lindt etc.). The efficiency of fumigation operations within the state will decline as more fumigation staff will now be required to stay onsite during mechanical aeration of sulfuryl fluoride through a stack. (2, 3, and 4)

RESPONSE: Technical Manuals, including the risk screening worksheet and the presumptive unit risk factor and reference concentration values used for this screening tool, are not subject to the APA's rulemaking procedures. See N.J.S.A. 13:1D-111. A reference concentration is an estimate of

a daily inhalation exposure concentration for the human population that is likely to be without an appreciable risk of deleterious non-carcinogenic effects. A reference concentration is a quantification of the air contaminant's hazard and is derived by incorporating uncertainty factors to account for uncertainties in toxicity studies. The Department compiles inhalation information available from EPA's Integrated Risk Information System (IRIS), California Environmental Protection Agency (CalEPA), and the Agency for Toxic Substances and Disease Registry (ATSDR) into lists of unit risk factors and reference concentrations to guide applicants as they assess risk. See Technical Manual 1003 at p. 9; Toxicity Values for Inhalation Exposure (December 2022), https://dep.nj.gov/boss/risk-screening-tools/. The risk screening worksheet is a screening tool that applicants may use, rather than conducting their own refined modeling. As a screening tool, the worksheet is intended to be conservative. Applicants may choose to propose use of an alternative reference concentration value or values with supporting documentation and risk assessment/modeling.

6. **COMMENT:** The Department failed to promulgate or propose reference concentrations for sulfuryl fluoride during the proposal of its air toxics rule (fumigation rule). Regulated industries could not fully understand the potential impact of the fumigation rule on their operations as they were not provided with reference concentrations to model during the fumigation rule adoption process. The Department's informal addition of sulfuryl fluoride reference concentrations to the risk screening worksheet without promulgation of a separate rule proposal violates the procedures required by the New Jersey Administrative Procedure Act. (2 and 4)

   RESPONSE: As explained in response to comment 5, reference concentration values are not regulatory standards subject to the APA. The Department explained the reasons and supporting information for proposing and adopting the air toxics rule which included clarification of air permitting requirements for fumigation operations. See 53 N.J.R. 317(a) (March 1, 2021); 54 N.J.R. 560(a) (April 4, 2022). The adopted rules and amendments established reporting thresholds and regulate fumigants based on potential to emit, which is not dependent on a reference concentration. As explained in the rulemaking, the Department publishes lists of presumptive reference concentrations, which are utilized in the optional screening tool known as the risk screening worksheet. The Department provides guidance on risk assessments in Technical Manual 1003, which is not subject to the APA. The reference concentration is used to assess risk, which is part of the permitting process. As part of the application, an applicant may propose use of alternate reference concentration values.

7. **COMMENT:** Sulfuryl fluoride is regulated as a pesticide by the United States Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and has long been used for structural fumigation within the United States. Potential health risks associated with exposure to this chemical are regulated as part of the registration requirements under FIFRA. The EPA approves labeling for products granted FIFRA registration. The product label includes guidance on the proper use and application of the product to safeguard public health and the environment. The EPA's fumigation procedures for sulfuryl fluoride include guidance on application rates, aeration requirements, applicator training requirements, and requirements for re-entry into a fumigated space. FIFRA registration requires manufacturers of pesticides to submit data illustrating that their pesticide does not pose unreasonable adverse effects to public health and the environment when label instructions are adhered to.

The FIFRA registration and review process, along with EPA's approved labelling for the proper use, application, and exposure mitigation measures such as the use of appropriate buffer zones and clearance levels, are adequate for safeguarding the health of unprotected workers and the public. The NJDEP characterized sulfuryl fluoride as "highly toxic" and has failed to recognize that fumigation operations involving this chemical are adequately addressed under FIFRA. Additionally, the Department has neglected to provide scientific data to illustrate the need to adopt overly conservative sulfuryl fluoride reference concentrations in order to be protective of public health. (1, 2, and 4)

RESPONSE: The Department recognizes that the EPA imposes requirements for the use of fumigants, including sulfuryl fluoride, under FIFRA. As the Department explained in its recent rulemaking, see 53 N.J.R. 317(a) (March 1, 2021) and 54 N.J.R. 560(a) (April 4, 2022), the air permitting requirements for fumigation operations include a risk assessment to ensure that an operation does not result in off-site health impacts. As explained in response to comment1 1 through 4, the Department has determined to use the FIFRA label clearance value of 1.00 ppm (4,170 $\mu g/m^3$) as the presumptive acute reference concentration for sulfuryl fluoride. The Department believes that utilizing this value provides consistency for the regulated community while protecting public health. The Department will continue to monitor EPA's and California's reviews and take further action if appropriate, when these reviews are completed.

8. **COMMENT:** The Department should suspend the Fumigation rule and the revised risk screening worksheet as it applies to sulfuryl fluoride fumigation and instead engage with stakeholders to assess the need for sulfuryl fluoride risk assessment requirements in the state and develop appropriate standards for use in evaluating such risks. (4)

   RESPONSE: To the extent the comment refers to the recent rulemaking clarifying the permit requirements for fumigation operations, the Department refers the commenter to the rulemaking documents. 53 N.J.R. 317(a) (March 1, 2021); 54 N.J.R. 560(a) (April 4, 2022). Please see response to comments 1 through 4 regarding the reference concentrations for sulfuryl fluoride that the Department will utilize in the risk screening worksheet. The Department will continue to monitor EPA's and California's reviews and take further action if appropriate, when these reviews are completed.

9. **COMMENT:** The Department did not consider whether warehouses can feasibly accommodate changes that will allow them to meet the proposed sulfuryl fluoride standards. Global fumigations of cocoa bean warehouses, which are necessary to control pests such as rodents and Indian meal moths in the entire warehouse, will not be able to meet the proposed sulfuryl fluoride short-term reference concentration. Based on a review of the draft June 2022 risk screening worksheet, warehouse operators may need to exclude larger cocoa bean warehouses from fumigation treatments unless a 150-foot stack can be used to mechanically aerate fumigations. The construction of these 150-foot stacks is unlawful in some New Jersey jurisdictions due to development and zoning regulations. The Department has not considered real-world scenarios, such as the impact of local regulations, when considering the practical applications of the proposed sulfuryl fluoride standards. (3)

   RESPONSE: As is required for any industry, if a facility has the potential to emit an air contaminant above the respective reporting threshold listed in N.J.A.C. 7:27-17, the facility must demonstrate negligible health risk in order to receive an air pollution control permit. The "Instructions" tab of the Risk Screening Worksheet has a list of mitigating actions that may be considered, at the discretion of

the facility, in order to produce an operation that results in negligible health risk. There is no requirement that the stack height must be adjusted. Options to mitigate risk can include any of the following or a combination of these options: Install Air Pollution Controls, use less toxic substance, modify hours of operations, increasing stack height, and/or relocating stack. To be clear, this list of mitigating actions is not all-inclusive or prescriptive, as the available mitigating actions will vary from case to case, and any appropriate mitigating action shall be determined by the facility. As noted, the risk screening worksheet is optional and the reference concentrations for sulfuryl fluoride are presumptive values. An applicant may propose use of an alternative value.

10. **COMMENT:** Sulfuryl fluoride fumigations have been conducted safely throughout New Jersey for more than 50 years and the Department cannot identify a single event whereby a bystander or resident suffered an injury or adverse health effect resulting from fumigant exposure within the state. NJDEP has not provided state specific information that sulfuryl fluoride poses an actual risk to New Jersey communities. (1)

    RESPONSE: In humans, acute inhalation exposure to high concentrations of sulfuryl fluoride, a colorless, odorless gas, results in respiratory irritation, pulmonary edema, nausea, abdominal pain, central nervous system depression, numbness in the extremities, muscle twitching, seizures, and even death. Chronic exposure damages the central nervous system and respiratory tract. Direct contact with concentrated sulfuryl fluoride liquid causes tissue damage to eyes, mucous membranes, or skin. At lethal concentrations, sulfuryl fluoride disrupts carbohydrate and lipid metabolism of humans. As this gas is colorless and odorless, the sensitive population, if affected, would not know the cause. The Department expects the neighboring residents to benefit from the application of sulfuryl fluoride reference concentrations in assessing health risks. Although the Department cannot quantify the benefits associated with health improvement, preventing any of the adverse health effects and symptoms of exposure is a benefit.

11. **COMMENT:** The adoption of the proposed sulfuryl fluoride standards will burden the fumigation industry and the clients they serve. Fumigation customers will be faced with greater expenses and cargo will be moved considerably more slowly from warehouses due to limited fumigation personnel. Fumigation clients may experience economic losses from untreated infestations due to limited fumigator personnel resources within the region and their inability to achieve compliance with the new sulfuryl fluoride standards (3)

    RESPONSE: As explained in response to comment 5, reference concentrations are not regulatory standards. Please see response to comments 1 through 4 regarding the use of 1.00 ppm (4,170 µg/m^3) as the presumptive acute reference concentration for sulfuryl fluoride and 0.036 ppm (150 µg/m^3) as the presumptive chronic reference concentration for sulfuryl fluoride. To the extent the commenter is referring to the adopted rules clarifying the requirements for fumigation operations, the Department refers the commenter to the rulemaking documents. See 53 N.J.R. 317(a) (March 1, 2021); 54 N.J.R. 560(a) (April 4, 2022).

12. **COMMENT:** The NJDEP should continue to provide facilities with the risk screening worksheet as an optional screening tool. However, the Department should ensure the responsible use of this screening tool so that refined risk assessments are conducted when necessary. The proposed sulfuryl fluoride long- and short-term reference concentrations should be incorporated in the evaluation of all air permits that present a risk of sulfuryl fluoride exposure to the public. (5)

    RESPONSE: The Department will continue providing the risk screening worksheet as an optional screening tool and periodically update the reference concentrations and unit risk factors, which are derived from well-established Federal and State sources including EPA's Integrated Risk Information System (IRIS), California Environmental Protection Agency (CalEPA), and the Agency for Toxic Substances and Disease Registry (ASTDR), as needed. The Department will continue to advise permit applicants to follow guidance provided in Technical Manual 1003 regarding assumptions made when generating the model behind the risk screening worksheet to ensure that refined risk assessments are conducted when necessary.

References

Albee, R. R., Spencer, P. J., and Bradley, G. J. 1993. Sulfuryl fluoride: Electrodiagnostic, FOB and motor activity evaluation of nervous system effects from short-term exposure. Dow Chemical Company Study ID K-016399-045. California Department of Pesticide Regulation Vol. 50223-030; Rec. 126302.

CalDPR, 2020. Sulfuryl Fluoride, Final Addendum to the 2006 Risk Characterization Document Update of the Toxicology and Reference Concentrations. California Department of Pesticide Regulation (CalDPR). May 2020. Available at https://www.cdpr.ca.gov/docs/risk/rcd/sulfuryl-fluoride_addendum.pdf

Technical Manual 1003 (Guidance on Preparing a Risk Assessment for Air Contaminant Emissions) https://dep.nj.gov/boss/risk-screening-tools/