

Assessment of Public Comments

Proposed DAR-1: Guidelines for the Evaluation and Control of Ambient Air Contaminants under Part 212

Comments received from January 13, 2021 – February 12, 2021

General:

Comment 1: The American Chemistry Council has been unable to locate the documentation supporting the proposed annual guideline concentration for Perfluorooctanoic acid (PFOA) on the Department's website. We request an extension of the comment deadline to allow us time to review the documentation – once it is made available. (Commenter 5)

Response to Comment 1: The Department does not list background documentation for all Annual and Short-term Guideline concentration (AGC/SGC) changes on its website. The AGC/SGCs are used as guidance for implementing 6 NYCRR Part 212, "Process Operations" (Part 212) and are not ambient air standards. The commenter is directed to the New York State Department of Health's (NYSDOH) finding found in comment number 5.

Comment 2. The commenter questioned Part 212's applicability for municipal waste landfills. The comment specifically regarded the applicability of New Source Performance Standards (NSPS) and the National Emission Standards for Hazardous Air Pollutants (NESHAP) under Part 212-1(e). (Commenter 7)

Response to Comment 2: This comment is in relation to the application of Part 212 on solid waste landfills and is therefore outside the scope of this assessment of public comment. The Department

encourages the commenter to reach out to regional permitting staff with such questions in the context of a specific proposal.

Comment 3: The NY State Chapter of the National Waste and Recycling Association requests that this new policy and guidance procedures document be held from further consideration and adoption and be withdrawn. (Commenter 9)

Response to Comment 3: DAR-1 formerly known as Air Guide-1 has been available to our regional staff and the public for over forty years. The guidance allows staff to interpret Part 212 consistently throughout the State. Part 212 regulates the numerous air contaminants being emitted into the environment and has been extremely effective in reducing the public's exposure to air contaminants and protecting the environment, accomplishing its goal. The Department further believes that withdrawing DAR-1 would lead to confusion in the regulated industry and increased emissions of toxic air pollutants jeopardizing public health.

Per and polyfluoroalkyl substances, otherwise known as PFAS:

Comment 4: Rather than setting a proposed limit of 5.3 ng/m³ (nanograms per cubic meter), we urge New York to set an AGC of "non-detectable" for PFOA, which according to the United States Environmental Protection Agency's (EPA) new monitoring method OTM-45 for stack gases, would be less than 1 ng/m³. This limit should be revisited and lowered as more sensitive analytical techniques allow detection of smaller quantities of PFOA in air samples. (Commenter 2)

Response to Comment 4: The proposed limit of 5.3 ng/m³ was recommended by DOH after evaluation and interpretation of EPA's data and applying a more sensitive endpoint. The finalization of the EPA monitoring

method will assist the DEC in characterizing and prioritizing sources of PFAS emissions. The characterization of PFAS emissions is the first step in reducing the numerous PFAS and PFAS precursors currently being emitted nationwide. At this time, it is unlikely that all uses of PFAS can be removed from commerce and it will be ubiquitously present in numerous waste streams for the foreseeable future. NYSDEC is committed to reducing the emissions of this entire class of compounds as the science improves our understanding of their release to the environment and impacts on public health and the environment.

Comment 5: DEC should set guideline values for other PFAS chemicals such as perfluorooctane sulfonic acid (PFOS) and perfluorohexanoic acid (PFHxS). DEC should set AGCs for the 29 individual PFAS chemicals quantified in EPA's new analytical method OTM-45 in stack gases and DEC should eventually set air emissions limits on all organofluorines. (Commenter 2, 4)

Response to Comment 5: In the 2021 AGC/SGC tables, the Division of Air Resources (DAR) listed perfluorooctanoic acid (PFOA). PFOA is one contaminant in a class of compounds known as PFAS. It is known that thousands of PFASs are currently in commerce. The 2016 AGC/SGC tables listed only PFOA ammonium salt, which had been listed in the AGC/SGC tables since the 1990s. This listing was based on data from occupational studies and was used in the decision-making process to control some of the earlier known emissions of PFOA. Since the publication of the 2016 tables, the NYSDEC has been made aware of the numerous sources of PFAS in our water, soil and air and has concentrated work on the control and remediation of these contaminants from the environment.

In May of 2016, the USEPA published an extensive review of the health effects of PFOA and identified the adverse toxicological properties of PFOA and other PFASs. DAR recognized the importance of this document and asked the New York State Department of Health (NYSDOH) for its help and ability to

derive AGCs for this class of compounds. NYSDOH responded to our request by stating that the EPA and NYSDOH were able to derive acceptable drinking water (oral toxicity) concentrations for PFOA using generally accepted risk assessment practices. The NYSDOH recently evaluated authoritative-body risk assessments and derived cancer and noncancer toxicity values for PFOA based on systemic effects observed in oral studies of laboratory animals. NYSDOH recommended that these oral toxicity values be used for deriving guidelines for PFOA in air using route-to-route extrapolation. NYSDOH suggested that these air concentrations could be considered by DAR for the current update of the tables as a basis for AGCs for PFOA and ammonium perfluorooctanoate instead of using occupational guidelines. Work will continue to address the listing of PFOS when sufficient health-based data exists to allow NYSDOH to follow the necessary risk assessment practices when establishing health-based concentrations.

NYSDEC recognizes that many PFAS contaminants are persistent, bioaccumulative, and toxic. However, it is highly unlikely that the robust data sets needed for NYSDOH to establish health based AGC values for all these contaminants will exist in the near future using traditional risk assessment practices. DEC believes that control of these emissions is the first and foremost step to prevent future contamination. Commenters correctly point out that there are numerous ongoing studies for Perfluorobutanoic acid and perfluorobutane sulfonic acid (PFBA/PFBS) and other PFASs currently being emitted, and there is scientific data showing health concerns. The development of ambient guideline concentrations requires that the NYSDEC and other authoritative bodies follow a set of procedures when establishing AGCs or reference concentrations to be used in a regulatory environment. While NYSDEC also sees the need for these compounds to have established health-based guideline values the process of developing those guidelines is not yet complete. It is why air pollution control and replacement of these persistent chemicals used in commerce is the needed interim step.

Comment 6: Polytetrafluoroethylene (PTFE) is listed, but is rather confusing as it is a mixture, it is not explained or broken down with potential byproducts, and the perfluorinated compounds of which it is comprised are not identified. Further clarification should be provided. (Commenter 4)

Response to Comment 6: PTFE Decomposition Products are listed in Part 212-2 and have been identified as high toxicity air contaminants. They are listed in the DAR-1 Table with an AGC of 2.0E-5 ug/m³ (micrograms per cubic meter). This AGC is our high toxicity de minimis value which is used to screen sources producing PTFE products in order to prevent the formation and release of the highly acutely toxic PTFE decomposition products when PTFE is overheated. Some of the PTFE decomposition products include hexafluoroethane, hexafluoropropylene, octafluorocyclobutane, perfluoroisobutylene and carbonyl fluoride. This listing has been used by NYSDEC to require temperature controls on the process operations and in some instances air pollution controls to prevent the release of these highly toxic air contaminants. These fluorinated compounds are toxic but are not in the PFAS family of chemical compounds.

Comment 7: Bioaccumulation with PFAS chemicals is a fact. Being exposed to a variety of toxic PFAS and the total body burden of mixtures should also be a factor in decision making. (Commenter 4)

Response to Comment 7: The scientific community worldwide is investigating the toxicity of PFAS chemicals and trying to determine if there is a level of exposure to be deemed acceptable. With PFAS compounds' ability to bioaccumulate, NYSDEC agrees with commenters that more work needs to be done to understand the nature and exposure of these contaminants.

Comment 8: NYSDEC's proposed action attempts to regulate PFOA emissions, for the first time, from process operations by revising a guidance document instead of subjecting the proposal to the rulemaking process, and it impermissibly seeks to regulate PFOA emissions without providing a legally-defensible

rationale. NYSDEC should follow SAPA rulemaking procedures to the extent it seeks to regulate PFOA emissions from process operations. (Commenter 10)

Response to Comment 8: The commenter is incorrect that DAR-1 is regulating PFOA through guidance. PFOA ammonium salt has been included in the AGC/SGC tables for many years and the ambient concentrations listed in DAR-1 are used by regional staff to help make the appropriate risk management decision when regulating a process source.

The PFOA AGC listed is not a standard but a guideline concentration. The guideline concentration is one factor to be considered in generating a final Environmental Rating (ER) which determines the degree of air cleaning or air pollution control to be required on the emission source under Part 212. The regulatory procedures used for the control of process emission sources has been done consistently through the workings of Part 212 and DAR-1 for the past 50 years. The offsite concentrations of an air contaminant in conjunction with its toxicity and nearby residential populations, along with the AGC, are used in the process of deriving an Environmental Rating (ER) to protect public health and the environment (see Part 212). ERs are used in conjunction with the emission rate of the air contaminant to determine the necessary degree of air cleaning to reduce emission of criteria and non-criteria air contaminants, as laid out in Part 212, which is subject to the formal SAPA rulemaking process. The AGCs/SGCs included in DAR-1 are intended to help facilitate the regulated community's determination of the correct level of air pollution control as mandated by Part 212. This guidance provides transparent scientific and engineering judgement as an aid to facilitate the consistent implementation of Part 212 for process operations.

Comment 9: The latest iteration of the policy document lists PFOA in the Annual and Short-term Guideline Concentration (AGC/SGC) Tables and asserts, via an annotation in those Tables, that PFOA

is a “High Toxicity Air Contaminant.” In the past, NYSDEC has followed rulemaking procedures when seeking to revise the Part 212 HTAC list and it should do so here if it intends to regulate PFOA as a HTAC under Part 212.(Commenter 10)

Response to Comment 9: The commenter mischaracterizes the action NYSDEC is taking in its most recent update to DAR-1, in regard to the inclusion of PFOA in the AGC/SGC Tables. The mere inclusion of PFOA in the AGC/SGC lists does not equate to adding PFOA to the Part 212 HTAC list. Part 212 regulates, and DAR-1 provides guidance on a number of containments that are not HTACs but are nonetheless subject to NYSDEC’s authority to regulate air containments, as defined in 6 NYCRR Part 200.1(d). The annotations to AGC/SGC tables are used to help the regulated community set an initial ER, which is then adjusted based on the other factors considered in DAR-1. Air contaminants being regulated as HTACs are clearly delineated in 6 NYCRR Part 212-2.2 Table 2: “high toxicity air containment list.” If in the future NYSDEC believes PFOA warrants being added to that list, it will do so through an amendment to Part 212. Such amendment would be done following the formal rulemaking procedures outlined in SAPA.

Comment 10: NYSDEC’s policy document fails to provide an adequate rationale for its proposed regulation of PFOA emissions from process operations and therefore is arbitrary and capricious (Commenter 10)

Response to Comment 10: PFOA ammonium salt has been included in the AGC/SGC tables for many years and the ambient concentrations listed are for regional staff to make the appropriate risk management decision when regulating a process source. The AGC listed is not a standard but a guideline concentration. NYSDEC believes that there has been ample evidence provided to justify the AGC for PFOA. Numerous scientific studies support the regulation of PFOA emission and the AGC provided as guidance in DAR-1. See further discussion in Response to Comments 5 and 8 above.

Ethylene oxide:

Comment 11: NYSDEC has made changes to their AGC level for ethylene oxide (EtO) for facility operations in the state. The new EtO AGC is 2.0E-04 ug/m³ from the previous 1.9E-02 ug/m³. We oppose the change and request that NYSDEC reconsider the change. EPA's derivation from the Integrated Risk Information System (IRIS) included various technical flaws, and commenters recommend the value developed by the Texas Commission on Environmental Quality (TCEQ) be considered instead for regulatory use.

(Commenter 3, 6,11)

Response to Comment 11: We have reviewed the basis of the derivation for both AGC values. The NYSDOH supports the use of the EPA IRIS value and the Department selected this value over other scientific data developed by the TCEQ. TCEQ developed an ambient concentration value for EtO two orders of magnitude less conservative than IRIS and the Department agreed with NYSDOH that it was appropriate to use the more conservative approach on this chemical. NYSDOH concluded that the EPA IRIS cancer risk assessment calculated several inhalation unit-risks for EtO based on lymphoid and breast cancer incidence in a large occupational study of male and female workers. The one-in-one million increased lifetime cancer risk level of 2.0E-04 µg/m³, which has been proposed as the AGC, corresponds to an upper-bound unit risk estimate (5.0E-03 per µg/m³). This unit risk includes the application of age dependent adjustment factors to address possible early life-stage sensitivity to the carcinogenic effects of EtO based on its mutagenic mode of action, consistent with the EPA's recommendation. In addition, support for use of EPA's inhalation unit risk is strengthened by the agency's selection of a key study with a large sample size (approximately 18,000 workers), a long

follow-up period, individual exposure estimates, and by the robust evidence for EtO carcinogenicity from short-term genotoxicity studies and long-term cancer studies in laboratory animals.

Comment 12: EtO sterilization is critical to ensuring the safe delivery of sterile devices to the healthcare field and is crucial to a functioning and effective healthcare system. (Commenter 3, 11)

Response to Comment 12: The Department agrees with the commenter. NYSDEC has always known the importance of EtO to the medical industry but also recognizes the inherent toxicity of the chemical when not properly controlled. We have worked with the healthcare industry for many years to significantly reduce emissions. As a result, EtO facilities in New York State are some of the best controlled in the nation and are not expected to cause exceedances of the AGC value and are well within NYSDEC's risk management policy found in DAR-1 for carcinogenic compounds.

ortho-toluidine (o-toluidine):

Comment 13: Do you have a report that explains the proposed changes in DAR-1 for Ortho-toluidene (Cas. No. 95-53-4)? In light of the many shortcomings and limitations that have been identified, the NYSDEC should carefully examine the carcinogenicity evidence base for o-toluidine – particularly as it pertains to inhalation exposure – and reevaluate the proposed AGC to ensure that it reflects the current state of the science. (Commenter 1, 8)

Response to Comment 13: The current AGC of 21 $\mu\text{g}/\text{m}^3$ for ortho-toluidine was derived from an American Conference of Governmental Industrial Hygienist (ACGIH) Threshold Limit Value (TLV). However, the additional epidemiological study data indicating ortho-toluidine's carcinogenicity by both, the International Agency for Research on Cancer (IARC) and the United States Department of Health

and Human Services' National Toxicology Program (NTP), that ortho-toluidine is a known human carcinogen, along with the cancer unit risk value derived by the California Environmental Protection Agency's (CalEPA's) Office of Environmental Health Hazard Assessment (OEHHA), required the updating of the AGC for ortho-toluidine.

The NTP annually prepares its Report on Carcinogens (RoC). "The RoC contains a list of identified substances (i) that either are known to be human carcinogens or are reasonably anticipated to be human carcinogens and (ii) to which a significant number of persons residing in the United States are exposed."

The NTP evaluated and listed ortho-toluidine as reasonably anticipated to be a human carcinogen in 1983 (RoC 3rd edition) based on sufficient evidence from studies in experimental animals. Ortho-toluidine was selected as a candidate substance for review for possible change in its listing status in the 13th Annual RoC because several cancer studies in humans exposed to ortho-toluidine have been published in the peer-reviewed literature since 1983. Also, IARC concluded that ortho-toluidine is carcinogenic to humans (Group 1) in both 2010 and 2012. After reviewing all the human, animal, and mechanistic evidence data, the NTP concluded the following:

"Evidence that ortho-toluidine is a known human bladder carcinogen comes from human cancer studies finding increased risks of urinary bladder cancer in humans, in concert with studies showing that it causes cancer in experimental animals, including site concordance at the same tissue site in rats and studies demonstrating the biological plausibility of mechanisms of its carcinogenicity in humans. There is credible evidence of an association between increased urinary bladder cancer risk and exposure to ortho-toluidine based on consistent findings across studies, the presence of statistically significant, positive exposure-response relationships with cumulative rank exposure and duration, and large magnitudes of effect across studies. Potential confounding by occupational co-exposures can reasonably be ruled out in the studies of rubber chemical workers. Although there is limited information on cigarette smoking, potential confounding from smoking can reasonably be ruled out in the NIOSH cohort, and it is unlikely to explain the large risk estimates found in the smaller studies. Finally, the finding of increased urinary bladder cancer risk in different cohorts with different exposure conditions and different co-exposures lends strong support to the conclusion that ortho-toluidine is the common causal risk factor."

Based on the potential ability of ortho-toluidine to cause cancer in humans, the NYSDEC investigated other sources of data to determine an appropriate AGC. NYSDEC does not believe it is appropriate for a chemical identified as a “Known Human Carcinogen” to be assessed under occupational guidelines. Appendix A of DAR-1 describes the procedures NYSDEC uses to assign AGCs from occupational guideline concentration values. The procedures have been in DAR-1 guidance for over fifty years. NYSDEC adjusts the ACGIH TLV concentration for two concerns. First, it is the expectation that the public will be exposed longer than a weekly worker and second that the occupational health guideline does not address sensitive individuals such as children, pregnant woman and the elderly.

Commenter List:

1. Goodyear/David Seifert
2. Sierra Club/Sonya Lunder
3. AdvaMed/Manthan Bhatt
4. Hoosick Area CPWG/Loreen Hackett
5. American Chemistry/Stephen Risotto
6. American Chemistry Council/Bill Gullledge
7. SCS Engineers/Marcus Scrimgeour
8. Goodyear/David Seifert
9. Waste Recycling/Steve Changaris
10. 3M
11. The Ethylene Oxide Sterilization Association, Inc. (EOSA)