



REGION 4

ATLANTA, GA 30303

Mr. Richard Rogers
Director, Division of Water Resources
North Carolina Department of Environmental Quality
1617 Mail Service Center
Raleigh, North Carolina 27699-1617

Dear Mr. Rogers:

Pursuant to Section 402 of the Clean Water Act (CWA), 40 C.F.R. § 123.44, and the Memorandum of Agreement (MOA) between the U.S. Environmental Protection Agency and North Carolina, EPA Region 4 received for review the above-referenced proposed National Pollutant Discharge Elimination System (NPDES) permit (Proposed Permit) from the North Carolina Department of Environmental Quality (NC DEQ) on October 7, 2024. The EPA performed an initial review, and by letter dated October 31, 2024, provided notification of the EPA's general objection to the Proposed Permit pursuant to 40 C.F.R. § 123.44(a)(1).

NC DEQ submitted the Permit to the EPA for review on October 7, 2024, following a decision by North Carolina's Office of Administrative Hearings (OAH) in a permit appeal proceeding initiated by the permittee opposing the original final permit issued by NC DEQ on August 21, 2023. The original permit contained a water quality-based effluent limit (WQBEL) for the toxic pollutant 1,4-dioxane. In his decision, the OAH Administrative Law Judge (ALJ) determined "the 1,4-dioxane effluent discharge limitations is **VOID AND UNENFORCEABLE**. All other conditions remain enforceable," (capitalization, bolding and underlining contained in original ALJ decision). The Proposed Permit currently under review by the EPA implements the OAH decision and does not contain a limitation on the discharge of 1,4-dioxane. In the EPA's general objection letter the EPA noted that the removal of the effluent limits for 1,4-dioxane may not be consistent with CWA Section 301(b)(1)(C) and 40 CFR 122.44(d), which require NPDES permits to include effluent limits as stringent as necessary to meet state water quality standards. The EPA is hereby exercising its authority under Section 402(d) of the CWA, federal regulations at 40 CFR § 123.44(b), and Section IV.B.7 of the North Carolina/EPA NPDES Memorandum of Agreement (MOA) to issue a specific objection to the Proposed Permit for the reasons described herein.

The state or any interested party may request a public hearing on the objection within 90-days of the EPA's specific objection. If a public hearing is not held, and NC DEQ does not submit a proposed permit that has been revised to meet a specific objection within 90-days of receipt of a specific objection, exclusive authority to issue the permit passes to the EPA in accordance with 40 CFR 123.44(h). In accordance with 40 CFR 122.4(c) and 123.44, a final NPDES permit may not be issued until completion

of the objection process. Any requests for a hearing on the objection and the procedures for resolving any objection shall be governed by 40 CFR §123.44, as provided in Section IV.B.7 of the MOA.

I. Specific Grounds for Objection

a. The Proposed Permit Does Not Include Effluent Limitations Necessary to Achieve Water Quality Standards

All NPDES permits must contain effluent limits as stringent as necessary to meet applicable water quality standards, as required by Section 301(b)(1)(C) of the CWA and the EPA regulations at 40 CFR §122.44(d)(1). The Proposed Permit does not include effluent limits stringent enough to meet applicable water quality standards, and therefore is subject to specific objection under 40 CFR §123.44(c)(1) and (8).

The EPA regulations at 40 CFR §122.44(d)(1) specifically require that NPDES permits contain effluent limitations “necessary to achieve water quality standards under Section 303 of the CWA, including State **narrative criteria** for water quality.” (Emphasis added.) The water quality standard giving rise to this objection is a North Carolina narrative criterion for toxic pollutants (Rule 15A NCAC 02B .0208), approved by the EPA as an applicable requirement for CWA purposes. Rule 15A NCAC 02B .0208 (hereinafter Narrative Criterion) contains a number of relevant requirements.

The Narrative Criterion begins with the statement that “the concentration of toxic substances, either alone or in combination with other wastes, in surface waters shall not render waters injurious to aquatic life or wildlife, recreational activities, or public health, nor shall it impair the waters for any designated uses.” The Asheboro facility discharges to Hasketts Creek, 43.5 miles upstream from its confluence with Deep River, which has a designated use of water supply, which includes drinking water purposes. Fact Sheet for Asheboro NPDES Permit (“Asheboro Permit Fact Sheet”) (Aug. 29, 2022), at page 13. NC DEQ found that Asheboro’s discharge of 1,4-dioxane, which is completely miscible¹ in water and resistant to biodegradation, is expected to persist in the water column and impact Deep River at the water supply boundary. The Narrative Criterion further provides that “[t]he concentration of toxic substances shall not exceed the level necessary to protect human health,” and mandates that for carcinogens, the concentrations of toxic substances shall not result in unacceptable health risks and shall be based on a Carcinogenic Potency Factor (CPF)². It specifies that an unacceptable health risk for cancer shall be more than one case of cancer per one million people exposed (10⁻⁶ risk level). NC DEQ’s effluent limits for 1,4-dioxane were calculated to protect the designated use of water supply waters from carcinogenic risk exceeding the 10⁻⁶ cancer risk level.

Under 40 CFR §122.44(d)(1)(i), NPDES permits must contain limitations to control all pollutants which the permitting authority determines may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any state water quality standard, including state narrative criteria for water quality. As described in the Asheboro Permit Fact Sheet, at

¹ Miscible means they will blend with each other to form an equally distributed, homogeneous solution.

² The Narrative Criterion defines Carcinogenic Potency Factor: “The CPF is a measure of the cancer-causing potency of a substance estimated by the upper 95 percent confidence limit of the slope of a straight line calculated by the Linearized Multistage Model or other appropriate model according to U.S. Environmental Protection Agency Guidelines, FR 51 (185): 33992-34003; and FR 45 (231 Part V): 79318-79379.”

page 14, NC DEQ conducted a reasonable potential analysis to determine whether Asheboro's discharge of 1,4-dioxane had a reasonable potential to cause or contribute to a violation of the Narrative Criterion and determined that it did.³ A review of effluent data, instream data and toxicity information indicates that NC DEQ's reasonable potential determination is well supported.⁴

The EPA's regulations require that where a state has not established a water quality criterion for a chemical pollutant that has the reasonable potential to cause or contribute to an excursion above a narrative water quality criterion, the permitting authority must establish limits using one of the specified regulatory options. 40 CFR 122.44(d)(1)(vi). These options include "establishing effluent limits using a calculated numeric water quality criterion for the pollutant, which the permitting authority demonstrates will attain and maintain applicable narrative water quality criteria and will fully protect the designated use." The regulations further specify that this calculated numeric water quality criterion can be based on an explicit state policy or regulation interpreting its narrative water quality criterion, supplemented with other relevant information including risk assessment data, exposure data, and current EPA criteria documents.

Consistent with these regulatory requirements, NC DEQ established effluent limits for 1,4-dioxane using a calculated numeric water quality criterion. This numeric water quality criterion was calculated using the translator established in the Narrative Criterion, "an explicit state policy or regulation interpreting its narrative water quality criterion" (40 CFR 122.44(d)(1)(vi)), which is specifically required under the Narrative Criterion to be used for toxic pollutants for which no numeric water quality criterion has been established.⁵ Using this translator mechanism, NC DEQ calculated an instream water quality criterion of .35 µg/l for a water supply use at the water supply boundary. The limit set in the NC DEQ final permit issued on August 21, 2023, prior to its appeal and subsequent removal pursuant to the OAH decision was 21.58 µg/L as a monthly average, and a daily maximum limit of 49.4 µg/l, based on the 1×10^{-6} cancer risk level required under the Narrative Criterion. NC DEQ included in its original final permit a three-phase compliance schedule with initial (phase one) interim limits, phase two (after three years) interim limits, and the final (phase three) limits of 21.58 µg/l as a monthly average, and a daily maximum limit of 49.4 µg/l. The phase three limits are not applicable until five years from the permit's effective date. The compliance schedule would allow the facility to gradually reduce its 1,4 dioxane discharge over a period of five years, in accordance with the EPA regulations authorizing the use of compliance schedules at 40 CFR §122.47. The compliance schedule NC DEQ established appears reasonable and would allow the facility to work with the industrial users discharging 1,4-dioxane to the facility to implement improved controls at the industrial facilities, and potentially shift the cost of controls from the facility to the industrial dischargers.

³ Using the Narrative Criterion's translator mechanism, NC DEQ calculated an instream water quality criterion of .35 µg/l for a water supply use at the water supply boundary. According to the Asheboro Permit Fact Sheet, effluent monitoring results from January 2018 through August 2022 (123 samples) show that the facility's discharges contained 1,4-dioxane (in µg/l) at an average of 116, maximum of 1011, and minimum of <1. In addition, in-stream data from Hasketts Creek include the following results upstream and downstream of the facility, also in µg/l: Upstream – based on 9 samples in 2018-19, average 1.3, minimum .54, maximum 2.2; Downstream – based on 27 samples from January 2020 to September 2022, average 102.2, min 1.9, maximum 900.

⁴ Notwithstanding the regulatory requirement to limit all pollutants determined to have reasonable potential to cause or contribute to a water quality standards violation, the OAH decision contains no discussion of NC DEQ's reasonable potential determination or the corresponding regulatory requirement to limit 1,4-dioxane in the permit as a result of that determination.

⁵ "Water quality standards or criteria for water quality-based effluent limitations shall be calculated using the procedures given in this Part and in Part (A) of this Subparagraph." 15A NCAC 02B .0208(a)(2)(B).

Based on the effluent and instream monitoring data described in footnote 3, the EPA has determined that NC DEQ properly determined that the discharge had the reasonable potential to cause or contribute to an excursion above a state water quality standard, and that a WQBEL was therefore required. The EPA has also determined that NC DEQ calculated its 1,4-dioxane water quality-based effluent limit that was included in the original final permit in a manner that was consistent with the applicable water quality standard, as required by the CWA and the EPA's implementing regulations. The OAH decision set forth a variety of bases for removing NC DEQ's effluent limit for 1,4-dioxane, all of which are inconsistent with CWA requirements, as discussed below.

b. The Proposed Permit Applies Narrative Criterion to Probable or Likely Carcinogens

The Narrative Criterion contains the following language:

For carcinogens, the concentrations of toxic substances shall not result in unacceptable health risks and shall be based on a Carcinogenic Potency Factor (CPF). An unacceptable health risk for cancer shall be more than one case of cancer per one million people exposed (10⁻⁶ risk level). The CPF is a measure of the cancer-causing potency of a substance estimated by the upper 95 percent confidence limit of the slope of a straight line calculated by the Linearized Multistage Model or other appropriate model according to U.S. Environmental Protection Agency Guidelines, FR 51 (185): 33992-34003; and FR 45 (231 Part V): 79318-79379. Water quality standards or criteria for water quality-based effluent limitations shall be calculated using the procedures given in this Part and in Part(A) of this Subparagraph.

The OAH decision asserts that the translator mechanism for "carcinogens" in the Narrative Criterion does not apply to toxic pollutants classified by the EPA as "probable" or "likely" carcinogens. OAH decision at page 13-14. This narrow interpretation is not consistent with the EPA and NC DEQ's historical treatment of probable or likely carcinogens for regulatory purposes and is not sufficient to attain and maintain the Narrative Criterion, including the water supply designated use.

The EPA has assessed 1,4-dioxane as "likely to be carcinogenic to humans" based on evidence of multiple tissue carcinogenicity from animal studies. 2013 EPA IRIS Tox Review for 1,4-dioxane (2013 IRIS Review), p. 148-49 (explaining that the "likely to be carcinogenic" descriptor "is based on evidence of carcinogenicity from animal studies"). As explained in the 2013 IRIS Review, at page 145, "A thorough review of the available toxicological data available for 1,4-dioxane provides no scientific justification to propose that the liver adenomas and carcinomas observed in animal models due to exposure to 1,4-dioxane are not relevant to humans." NC DEQ appropriately considered such information in applying the translator mechanism to 1,4-dioxane. See 40 CFR 122.44(d)(1)(vi)(A) (specifying that "risk assessment data" and "exposure data" may be considered in establishing effluent limits to meet narrative state water quality criterion).

The EPA and NC DEQ have both historically treated substances classified as probable or likely carcinogens to be carcinogenic in regulatory actions. For example, the EPA's National Recommended Water Quality Criteria developed pursuant to Section 304(a) of the CWA include many examples of criteria developed to address the carcinogenicity of probable and likely carcinogens. The NC DEQ

appropriately considered such “current EPA criteria documents” (40 CFR 122.44(d)(1)(vi)(A)) in establishing limits to meet the Narrative Criterion. Similarly, North Carolina’s Environmental Management Commission (EMC) has promulgated numeric water quality standards to address “carcinogens” classified by EPA as probable or likely carcinogens. For example, in 1989, the EMC promulgated defined numeric water quality standards “to protect human health from carcinogens through consumption of fish (and shellfish)” for seventeen toxic substances. 15A NCAC 2B .0208(a)(2)(B) (1989). Included in this list are Aldrin, Carbon Tetrachloride, Chlordane, DDT, Dieldrin, Heptachlor, and Tetrachloroethane. The EPA has classified these compounds (i.e., Aldrin, Carbon Tetrachloride, Chlordane, DDT, Dieldrin, Heptachlor, and Tetrachloroethane) as probable or likely human carcinogens.⁶

Typically, the classification of a pollutant as a probable or likely carcinogen is based on the existence of evidence drawn from animal studies rather than data from human exposures. The ability to confirm carcinogenicity in a human population is often limited because, for obvious ethical reason, cancer studies are not intentionally conducted on humans. Where direct evidence exists of human exposure impacts it is usually based on exposures that occur due to the presence of a pollutant in the environment or workplace and cancer incidence can be assessed in the exposed population. However, the Clean Water Act does not require permitting authorities to wait until carcinogenicity in humans is demonstrated to a scientific certainty before protecting drinking water supply waters, or protection against other routes of exposure. The OAH decision inappropriately dismisses and voids a properly calculated effluent limit for a pollutant that is scientifically established to be a probable human carcinogen.

As noted above, the Narrative Criterion begins with the statement that “the concentration of toxic substances, either alone or in combination with other wastes, in surface waters shall not render waters injurious to aquatic life or wildlife, recreational activities, or public health, nor shall it impair the waters for any designated uses.” The WQBEL established by NC DEQ in original final permit was calculated to protect the water supply use of downstream waters. NC DEQ properly derived the effluent limit based on a Carcinogenic Potency Factor (CPF⁷), as necessary to fully protect the Narrative Criterion, including the designated uses.

c. NC DEQ Appropriately Relied on EPA’s 2013 IRIS Toxicology Review for 1,4-dioxane in Calculating the Carcinogenic Potency Factor (CPF)

The OAH decision held that NC DEQ improperly relied on the EPA’s 2013 IRIS Review to find the CPF it used to calculate the instream water quality criterion of .35 µg/l for a water supply use from which the effluent limit in NC DEQ’s original permit was derived. The OAH decision concluded that the Narrative Criterion’s reference to two EPA Carcinogenic Risk Assessment Guideline documents from 1980 and 1986 barred NC DEQ from taking into account updated toxicology information. The OAH decision is

⁶ Since 1989, there have been multiple updates to EPA’s 304(a) criteria and the methodology used to develop those criteria, as new science becomes available. Most recently, in a June 18, 2024 letter to NC DEQ, the EPA confirmed that EPA’s historical criteria development considers probably or likely carcinogens classifications as belonging with carcinogens because of the Agency’s long history of considering cancer versus noncancer effects in risk assessments. The OAH decision ignores the past and current practices of NC DEQ and the clear position of the EPA.

⁷ CPF’s exist for most “probable” and “likely” carcinogens for which EPA has 304(a) guidance, and use of a CPF to develop effluent limits is required by the Narrative Criterion.

inconsistent with the plain language of the Narrative Criterion, the cited EPA guidance documents, and NC DEQ's obligation to protect designated uses in its NPDES permits.

The Narrative Criterion contains the following language:

For carcinogens, the concentrations of toxic substances shall not result in unacceptable health risks and shall be based on a Carcinogenic Potency Factor (CPF). An unacceptable health risk for cancer shall be more than one case of cancer per one million people exposed (10⁻⁶ risk level). The CPF is a measure of the cancer-causing potency of a substance estimated by the upper 95 percent confidence limit of the slope of a straight line calculated by the Linearized Multistage Model or other appropriate model according to U.S. Environmental Protection Agency Guidelines, FR 51 (185): 33992-34003; and FR 45 (231 Part V): 79318-79379. Water quality standards or criteria for water quality based effluent limitations shall be calculated using the procedures given in this Part and in Part(A) of this Subparagraph.

The cited guidelines, EPA Guidelines for Carcinogen Risk Assessment, 51 Federal Register 33992 (September 24, 1986), were never intended to establish a binding method for risk analysis that ignored further scientific developments. Rather, these guidelines set forth principles and procedures to guide the EPA scientists and others in assessing the cancer risks from chemicals or other agents in the environment and inform the public about these procedures. The EPA continues to revise its risk assessment guidelines and to develop new guidelines as experience and scientific understanding evolve. These guidelines contemplate that risk managers would make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. As stated in one of the cited guideline documents, "Guidance is given in general terms since the science of carcinogenesis is in a state of rapid advancement, and overly specific approaches may rapidly become obsolete." The EPA Guidelines for Carcinogen Risk Assessment, 51 Federal Register 33992, at page 33993 (September 24, 1986).⁸ Moreover, the sentence in the NC DEQ's Narrative Criterion referencing the EPA guidelines is simply an explanation of what a CPF is, a concept which is further explained in the cited guidelines. The 2013 IRIS Review that NC DEQ relied on in developing its 1,4-dioxane effluent limit contains a CPF based on a linear, multistage low dose extrapolation, as required by the Narrative Criterion. Moreover, NC DEQ's reliance on the 2013 publication appropriately takes into account updated scientific information to provide greater assurance that the limit is neither over-protective or under-protective. Nothing about NC DEQ's process for developing the WQBEL for 1,4-dioxane is inconsistent with the EPA Guidelines cited in the Narrative Criterion.

d. The Proposed Permit Places The Responsibility to Develop Numeric Effluent Limits Implementing a Narrative Criterion Without Going Through Rulemaking Process

⁸ The 1986 Guidelines further state: "These Guidelines describe the general framework to be followed in developing an analysis of carcinogenic risk and some salient principles to be used in evaluating the quality of data and in formulating judgments concerning the nature and magnitude of the cancer hazard from suspect carcinogens. It is the intent of these Guidelines to permit sufficient flexibility to accommodate new knowledge and new assessment methods as they emerge. It is also recognized that there is a need for new methodology that has not been addressed in this document in a number of areas, e.g., the characterization of uncertainty." 51 Federal Register 33992, at page 33993.

The OAH decision incorrectly characterized NC DEQ's action as the establishment of a new water quality standard, something that can only be accomplished through rulemaking. However, the NC DEQ permitting action did not constitute adoption of a new water quality standard; rather, it was the implementation of an existing narrative water quality standard. NC DEQ's Narrative Criterion contains a translator mechanism for deriving an instream criterion from which numeric effluent limits can then be developed. By following procedures mandated in an existing water quality standard to derive numeric limits to meet the existing water quality standard, NC DEQ was not creating a new water quality standard. Indeed, as discussed above, the EPA's regulations require that permits include limits to meet narrative water quality criterion, specifically providing that such limits can be established using a calculated numeric water quality criterion based on state policy or regulation interpreting the narrative criterion. 40 CFR 122.44(d)(1)(vi)(A). The derivation of numeric effluent limits based on translation of existing narrative water quality criteria does not amount to creation of a new water quality standard. *See American Paper Inst. v. EPA*, 996 F.2d 346 (D.C. Cir 1993) ("As we understand it, the regulation does not supplant--either formally or functionally--the CWA's basic statutory framework for the creation of water quality standards; rather, it provides alternative mechanisms through which *previously adopted* water quality standards containing narrative criteria may be applied to create effective limitations on effluent emissions.")

The EPA understands that the OAH decision has been appealed to Superior Court in North Carolina. If the OAH opinion is upheld in Court, it raises questions about the consistency with the CWA of North Carolina's NPDES permitting program and North Carolina's water quality standards. First, if NC DEQ is unable to implement narrative water quality standards in NPDES permits without first going through rulemaking, NC DEQ will be unable to carry out a fundamental obligation of the NPDES permitting program: to issue permits that ensure compliance with narrative state water quality standards. Second, to the extent that the Narrative Criterion is interpreted in a way that is inconsistent with its plain meaning and with the EPA's understanding of the meaning when the EPA approved it, the EPA may have to reexamine its approval of North Carolina's Narrative Criterion for toxic pollutants. The EPA will continue to monitor the progress of the Asheboro permit litigation and will assess whether the final outcome warrants further action by the EPA.

II. The Actions NC DEQ Must Take to Eliminate the Objections and the Effluent Limitations that the Permit Would Include if it was Issued by EPA

To address this objection, the NC DEQ must restore the WQBEL to the Permit. The limit set in the NC DEQ permit prior to its removal pursuant to the OAH decision was 21.58 µg/L as a monthly average, and a daily maximum limit of 49.4 µg/l, based on the 1×10^{-6} risk level required under the Narrative Criterion. The compliance schedule (including phased interim limits) included in the original NC DEQ permit appears reasonable and consistent with the requirements of 40 CFR §122.47 and may be included in the permit. If this objection is not resolved by the state, any permit that ultimately has to be issued by the EPA for Asheboro would include the WQBEL for 1,4-dioxane as established by the NC DEQ as necessary to meet the Narrative Standard.

III. Next Steps

To address the EPA's specific objections, the NC DEQ must submit to the EPA a revised proposed permit which addresses and meets the terms of this objection within 90-days of the receipt of this

letter, in accordance with MOA Section III.B.6 and 40 CFR § 123.44(j). Within 90-days of the receipt of this letter, the NC DEQ, or any interested person, may request that a public hearing be held on the specific objection in accordance with MOA Section IV.B.7 and 40 CFR § 123.44. If a public hearing is not requested and NC DEQ does not submit a proposed permit that has been revised to meet our specific objection within 90-days of receipt of this letter, exclusive authority to issue the permit passes to the EPA in accordance with 40 CFR §123.44(h). Any request for a hearing on an objection and the procedures for resolving any objection shall be governed by 40 CFR § 123.44, as provided in MOA Section IV.B.7.

The EPA understands that the impact of the OAH decision and the pending status of the appeal of the OAH decision to Superior Court may affect and complicate NC DEQ's ability to submit a revised permit addressing this objection. However, the time frames applicable to the objection process are mandatory and no extension can be granted for NC DEQ to wait for outcome of an appeal or to otherwise seek relief from the OAH decision.⁹

In accordance with 40 CFR § 123.44(a)(1), the EPA has forwarded a copy of this objection letter to the permit applicant.

If you have any questions related to EPA's review of this permit, please contact me or have your staff contact Craig Hesterlee, Branch Chief, at 404-562-9749.

Sincerely,

Kathlene Butler
Director
Water Division

Enclosures

cc: Mr. Michael Rhoney
Water Resources Director
City of Asheboro, North Carolina (via email)

⁹ On December 10, 2024, EPA received a letter from the City of Asheboro asserting that EPA's issuance of a specific objection for the Proposed Permit would be premature because the ALJ decision is under review in a North Carolina Superior Court. The Proposed Permit under review was submitted to us by NC DEQ in accordance with the North Carolina/EPA NPDES MOA. EPA's review of the Proposed Permit is governed by the MOA and applicable regulations, and we are required to complete our review of the Proposed Permit in accordance with the MOA and regulatorily-imposed time-frames, without regard to the status of any ongoing litigation in North Carolina.