ENVIRONMENTAL NOTES

July 2018

IS THE CLEAN POWER PLAN GONE?

BY: JOHN M. "JAY" HOLLOWAY III

Likely not. While most EPA observers are focused on repeal of the prior administration's Clean Power Plan ("CPP") rule limiting CO_2 emissions from power plants, there is less focus on the CPP replacement rule EPA is presently drafting. At this point, the CPP replacement rule is moving on a parallel path with the CPP repeal rule.

The CPP replacement rule process started in December of last year when EPA issued an Advanced Notice of Proposed Rulemaking ("ANPR") seeking input on what to include in a proposed rule. The comment period on the ANPR closed at the end of February. EPA is committed to issuing a proposed rule soon and to finishing the rulemaking by the end of the year. Presumably, the CPP repeal rule also will be finalized by the end of the year. Many see advantages to minimizing any gap between CPP repeal and replacement.

There is consensus among EPA, industry and states in favor of a CPP replacement rule. However, those in industry providing input on that rule are finding that making rules is much harder than attacking them. EPA, industry and states also agree that the Clean Air Act requires that states have the primary role in setting CO_2 standards. The open question is how much guidance EPA needs to provide to states. It is likely that the CPP replacement rule will adopt an approach where:

- EPA provides guidance to states on how to analyze potential CO_2 reductions and a procedure for states to follow.
- States submit their plans to EPA to implement the rule.
- States apply the plans to set standards for utility boilers.
- The state process will be different from state to state.

Industry comments on the ANPR favor two basic approaches. The first is focused on looking at the operating history of each unit and using the past CO_2 emissions performance to set standards going forward. The second approach is to analyze

potential efficiency improvement projects and practices. EPA would outline the CO_2 reducing projects and practices that are potentially feasible and effective. States would then establish a process where units demonstrate that these efficiency measures have been or will be implemented.

As this process unfolds, it is important to consider that implementing a CPP replacement rule will require a great deal of effort by EPA and the states. It is unclear whether states will be able to do what is being asked of them. Will EPA try and minimize the burden on the states by providing more than just guidance? Of course, if or when the CPP replacement rule goes final, the litigation battle before the U.S. Court of Appeals for the D.C. Circuit will begin. Is it realistic to think that a final enforceable CPP replacement rule will be in place by the end of 2020? Likely not.

80 Fed. Reg. 64662 (Oct. 23, 2015); 82 Fed. Reg. 48,035 (October 17, 2017) (Proposed Rule); 82 Fed. Reg. 61507 (Dec. 28, 2017) (Advanced Notice of Proposed Rulemaking)

PRUITT DIRECTS STAFF TO GET "BACK TO BASICS" FOR NAAQS REVIEWS

BY: JESSICA J.O. KING

EPA is required under the Clean Air Act (CAA) to periodically review the National Ambient Air Quality Standards (NAAQS) to ensure they reflect the most current scientific information while protecting human health and the environment. In May, EPA Administrator Pruitt issued an eleven-page memorandum to all EPA Assistant Administrators setting out five "back-to-basics" principles to be used in reviewing future NAAQS and State Implementation Plans (SIPs). The mission: to ensure these reviews are performed in a "timely, efficient, and transparent manner."

Pruitt's memo comes less than a month after the White House published a Presidential Memorandum promising to develop policies and procedures for NAAQS reviews that promote domestic manufacturing and job creation. The memorandum is written to Pruitt and "directs the Administrator to take specific actions to ensure efficient and cost-effective implementation of the NAAQS program." President Trump states his goal is to fix costly and burdensome measures created over the past four decades.

A. Economics & Cooperative Federalism

The President's memo states that overly stringent NAAQS are having direct adverse economic effects. These effects include (i) a risk of less federal funding for new transportation projects, (ii) the inability of applicants to obtain pre-construction permits for new and expanding industrial facilities, (iii) excessive costs to meet standards that are

almost to "background levels" in some areas, and (iv) delays in obtaining necessary pre-construction permits.

Trump also finds that overly stringent NAAQS and EPA's related Regional Haze Program are negatively affecting the states' ability to grow and maintain control of their air permitting programs. The President believes stringent NAAQS and the Regional Haze Program have created more Federal Implementation Plans (FIPs) in lieu of SIPs. These FIPs allow the federal government to tell states how they must comply with revised NAAQS and how they must improve visibility in national parks and wilderness areas. Trump explains that the trend of having FIPs instead of SIPs does not meet his Administration's goal of cooperative federalism – allowing states to set regional policies and make decisions that promote growth while achieving reasonable compliance objectives.

B. The President's Directives to Pruitt

In his memorandum, the President directed Pruitt to perform nine specific tasks to implement his economic growth and cooperative federalism policies. These tasks include practical as well as policy changes. On the practical side, Trump provided EPA with hard deadlines to take final action on SIP permit applications, review exceptional events and international emissions petitions, replace FIPs with SIPs, and issue regulations and guidance to states simultaneously with new NAAQS.

On the policy side, Trump instructed Pruitt to give the states more flexibility by:

1. Providing relief to states experiencing exceptional events or international emissions. This includes taking into consideration a state's inability to meet NAAQS affected by the international transport of pollutants; allowing states not located on the borders of Mexico or Canada to file international emissions petitions and use emissions from non-bordering countries like Asia; and assessing background concentrations from foreign sources and exceptional events, such as wildfires, stratospheric ozone intrusions and volcanic seismic activities.

2. Making better use of monitoring and modeling data. This includes using EPA-approved air monitoring and modeling data appropriately in making designations of attainment and non-attainment; for permitting decisions, SIPs, exceptional event and international emissions demonstrations, consulting with applicants and states on whether modeling should be used in lieu of monitored data; approving alternative models and promoting innovative state approaches; and, identifying types of permitting that do not require modeling or that can use streamlined modeling through set values.

3. Developing Flexible Offset Policies. This includes providing flexibility to states in identifying and achieving offsets, including allowing intrastate and regional inter-precursor trading, as well as developing and implementing flexible offset policies in rural areas where few facilities exist to promote economic expansion.

Finally, the President ordered Pruitt to make the newly revamped Clean Air Scientific Advisory Committee (CASAC) follow the law by including policy-driven impacts of new and current NAAQS when making recommendations. These include advice on background levels and resulting economic and energy effects.

C. Pruitt's Directives to Assistant Administrators

In response to the President's memorandum, Administrator Pruitt issued his own memorandum to EPA's Assistant Administrators directing them and their staff to adhere to five principles in implementing the NAAQS program. Those principles are:

Principle 1: Meet Statutory Deadlines

The CAA requires that EPA review each NAAQS every five years, something that often failed to happen. Pruitt insists that all statutory deadlines be met. His memo directs the agency to begin review of the ozone NAAQS to meet the October 2020 deadline, to continue the particulate matter NAAQS review to meet the December 2020 deadline, and to evaluate whether to reconsider, modify or maintain other 2015 NAAQS. Regarding the 2015 ozone NAAQS, Pruitt promises to open the docket and call for scientific information and nominations for the CASAC ozone review panel and to use the principles set forth in his memo to guide all future and ongoing reviews.

Principle 2: Address all CAA Provisions for NAAQS Reviews

Pruitt directs the agency to ensure that the CASAC does not "unduly narrow" its review of important effects of revised or current NAAQS. He firmly states EPA will ask the CASAC in the NAAQS review process to respond to the following specific inquiries:

- Show what scientific evidence has been developed since the last review to support any proposed revisions to the current standards needed to protect public health;
- Identify the relative contribution to air pollution concentrations of natural and anthropogenic activities and identify their relative proximity to peak "background levels"; and,
- Identify any adverse public health and welfare, social, economic or energy effects from attainment strategies.

This direction is consistent with the new administrative push for a thoughtful consideration of all relevant evidence and of the effects of regulatory actions, including economic impacts, in rulemaking activity.

Principle 3: Streamline and Standardize the Process for Development and Review of Policy-Relevant information

To streamline NAAQS development and review, Pruitt suggests specific changes such as automatic outreach to other federal agencies using already synthesized available data for each pollutant. More importantly, Pruitt directs EPA staff to use assessments that are "policy-relevant." He says such assessments should look at the adequacy of the current NAAQS by analyzing the causal effects (health, economic, social, and energy) of levels both above and below current standards. He indicates that policy-relevant information considered by the CASAC should include appropriate background levels of each pollutant for context, as well as the items outlined above.

Principle 4: Differentiate science and policy judgments in the process

Pruitt reminds staff that, under the CAA, the Administrator makes the final decision using his discretion and weighing all the facts and policy considerations. Pruitt advises staff to make sure that EPA, with the help of the CASAC, provides

him with a "range of options" to consider in setting NAAQS. He requires that all options include different interpretations of scientific evidence and risk/exposure information. In the spirit of cooperative federalism, Pruitt directs that all information be made available for public comment prior to his decision to allow states, tribes and local governments to provide feedback on how they can meet their economic goals while protecting their citizens.

Principle 5: Issue timely implementation regulations and guidance.

Finally, Pruitt directs the agency to issue simultaneous implementing regulations and guidance to assist co-regulators and states in the planning process. He believes that this will assist states in submitting approvable SIPs and provide them with tools to obtain regulatory relief to address background concentrations and pollutant sources outside the states' control.

Conclusion

Administrator Pruitt's memorandum is a good first step in changing how the agency will review and revise the NAAQS. Pruitt recognizes that the plodding pace of NAAQS review affects economic growth and the ability of states to stay in attainment. When states can't stay in attainment, facilities can't be built or expanded, transportation projects can't be funded, and costs go up. By requiring that any revisions to NAAQS be supported by current and complete science, realistic public health concerns, and a balancing of scientifically-based health risk concerns with economic effects and costs, Pruitt is taking the agency in a direction that has long been advocated by industry and many states. The policies stated in his memorandum mirror those of President Trump. Therefore, regardless of whether Pruitt keeps his position – something that is far from assured – the policy shift set forth in his memo should remain as long as President Trump is in the White House.

Memorandum from EPA Administrator Scott Pruitt to Assistant Administrators: Back-to-Basics Process for Reviewing National Ambient Air Quality Standards (May 9, 2018); Memorandum from The President to the Administrator of the EPA: Promoting Domestic Manufacturing and Job Creation-Policies and Procedures Relating to Implementation of Air Quality Standards; 81 Fed Reg. 16761 (April 12, 2018).

EPA PROPOSES INCREASED TRANSPARENCY FOR SCIENTIFIC STUDIES

BY: HENRY R. "SPEAKER" POLLARD, V

EPA has proposed a major change in how it uses and relies upon scientific data and analysis for its rulemakings. The proposed rule would increase the transparency and availability of such data and analysis "pivotal to [EPA's] significant regulatory actions," so that third parties may independently validate the agency's scientific support for such

actions. EPA states that this increased transparency will help EPA fulfill its core mission with better scientific analysis and increased public trust in its regulatory actions. While EPA's objectives seem laudable in several respects, the agency will need to balance transparency with legal protections that may apply to disclosure of the information.

More specifically, the proposed rule targets "*dose response data and models underlying pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science." The net effect of these defined terms is that the proposed rule would apply to the data and modeling used in support of "significant regulatory actions" as defined by Executive Order 12866 (issued by President Clinton in 1993) to establish standards for allowable exposure to pollutants or contaminants. These standards are in turn used to set or otherwise influence emission and discharge limits, chemical and waste management criteria, and cleanup risk standards. Therefore, this standard-setting process affects pollution control requirements and costs for facility compliance and site remediation under many federal environmental statutes and regulatory programs. The proposed rule would not apply to other agency actions, such as enforcement or permitting matters.

The proposed rule would impose certain duties on EPA to fulfill the proposed rule's objectives. First and foremost, EPA would have to provide the public with access to covered "dose response data and models," whether generated by EPA or third parties, so they can be independently validated. To this end, the data and model information must be sufficient "for the public to understand, assess, and replicate findings." EPA's regulatory actions would be required to include descriptions of "any assumptions and methods used" and any "variability and uncertainty" associated with the underlying dose response data and modeling. In addition, EPA would ensure independent peer-review of the "pivotal regulatory science" underpinning its regulatory decisions, including "information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments." EPA is looking to "open science" advocates for recommendations on how to proceed in these respects. If adopted as currently drafted, the proposed rule would apply prospectively to final rulemakings relying on such data and modeling. However, EPA states in the proposed rule's preamble that the agency "should be guided by [the policy set forth in the proposed rule] to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained." This suggests that the proposed rule is being considered as guidance for pending or planned EPA rulemaking efforts before the proposed rule is finalized.

To address potentially conflicting laws and other concerns about revealing confidential or sensitive information, the proposed rule would require

that such public access occur "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." The preamble notes that "[n]othing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections," and EPA is examining how other agencies have handled and protected such sensitive information. The proposed rule also allows for certain case-by-case exceptions to the proposed public accessibility and peer-review obligations. Despite these stated considerations, some argue that reliance only on publicly available data may effectively block use of otherwise suitable peer-reviewed data and related studies, given their reliance on confidential personal health information for study subjects. Others have concerns about whether the proposed rule's approach is too narrowly focused - why is it limited to just dose response data and models? – and whether EPA will offer more specific guidance for implementation. Still, the regulated community and some environmental groups would likely gain greater insights into how EPA relied upon scientific data and modeling when developing its regulations if the proposed rule is adopted as a final rule.

EPA requests comment on a number of aspects of its proposal, including: (i) the sufficiency of or alternatives for legal authority for this proposal; (ii) whether the proposal's principles and duties for increasing transparency and reliability of data should be incorporated into contracts that EPA has with researchers and others who provide scientific data to EPA in support of its regulatory functions; (iii) to what degree other means, laws or compelling reasons, such as privacy or national security, exist for protection of confidential information for business and individuals; (iv) phasing in of the increased obligations for transparency and data rigor; (v) how this proposal should apply to past data reviews and analyses (such as periodic reviews of the National Ambient Air Quality Standards under the Clean Air Act); and (vi) how to address previously developed dose response data and models lacking the level or transparency or third-party validation contemplated under the proposed rule.

Based on the initial strong interest by a variety of stakeholders, EPA has extended the public comment period for the proposed rule to August 16, 2018 and will hold a public hearing on July 17, 2018. The proposed rule's emphasis on greater transparency and validation of scientific analysis and the related confidentiality concerns can be expected to generate many comments from all quarters.

Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768-18774 (April 30, 2018); *Strengthening Transparency in Regulatory Science; Extension of Comments Period and Notice of Public Hearing*, 83 Fed. Reg. 24255-24256 (May 25, 2018). Exec. Order No. 12,866, 58 Fed. Reg. 51735 (October 4, 1993).

TIME TO MAKE A CHANGE: DECONSTRUCTING CLEAN AIR ACT STATIONARY SOURCE AGGREGATION

BY: LIZ WILLIAMSON

When facilities with air emissions are contiguous, the permitting authority may consider them part of the same stationary source for Clean Air Act permitting purposes (Title V and New Source Review). This is commonly called source aggregation. Source aggregation has significant impacts on the permitting path for a facility. For example, a facility may trigger Prevention of Deterioration ("PSD") thresholds for a pollutant if aggregated with the emissions from a nearby facility when the facility would not reach these thresholds

alone. A PSD permit can result in the installation of expensive Best Achievable Control Technology controls.

EPA employs a three-factor test to determine if two facilities should be aggregated. The three factors are whether the facilities: (1) have the same industrial grouping; (2) are located on one property or on contiguous or adjacent properties; and (3) are under common control of the same person(s). The analysis is fact-specific.

EPA recently re-examined the application of these factors in a letter (the "2018 Source Aggregation Letter") concerning the Meadowbrook Energy LLC's biogas processing facility (the "Meadowbrook Facility"). The Meadowbrook Facility plans to convert landfill gas from the contiguous Keystone Sanitary Landfill (the "Keystone Landfill") to natural gas transportation fuel, receiving it via a pipeline between the two facilities. The facilities have no cross-ownership. The facilities operate independently, maintaining full responsibility for emissions compliance. Each has the ability to function without reliance on the other: The Meadowbrook Facility can purchase landfill gas from another source, while the Keystone Landfill can flare 100% of its gas consistent with its permit. EPA recommended that the Meadowbrook Facility and the Keystone Landfill should not be aggregated, which departs from previous EPA implementation of the three-factor test.

EPA expressed its intent to change the agency's position broadly on the common control factor in the 2018 Source Aggregation Letter. Previously, EPA has hinged its analysis of common control on a dependency relationship between two facilities based on beneficial economics – such as a contractual relationship in which one facility was obligated to purchase all of the product of another – even though the facilities had no common ownership. In the 2018 Source Aggregation Letter, EPA stated that it is refining its viewpoint to emphasize that control should focus on "*the power or authority of one entity to dictate decisions of the other that could affect the applicability of, or compliance with, relevant air pollution regulatory requirements.*" 2018 Source Aggregation Letter at 6 (emphasis in original). EPA clarifies that control should be interpreted more narrowly to mean more than the ability to influence another entity when there are no ownership ties. EPA clarified that facilities that have a dependency relationship are no longer presumed to be aggregated.

The 2018 Source Aggregation Letter could change the permitting equation for facilities that have a dependency relationship. For example, many utilities own landfill-gas-to-energy engines that generate electricity. The engines are often located adjacent to a landfill, which provides the engines with fuel. Previously, aggregation of the landfill with the facility operating the engines was likely. EPA's new interpretation may also enable manufacturing facilities to engage in business relationships with neighboring facilities that might have been avoided out of concern for aggregation of emissions. The 2018 Source Aggregation Letter is good news for industry, although EPA cautions that the source aggregation evaluation must be performed by the permitting authority. It is also a fact-specific determination.

EPA Letter from William L. Wehrum, Office of Air and Radiation, EPA to the Honorable Patrick McDonnell, Secretary, Pennsylvania Department of Environmental Protection (April 30, 2018).

KNOW YOUR CHEMICAL'S POTENTIAL WITHOUT TSCA OVERSIGHT: THE TEST MARKETING EXEMPTION EXPLAINED

BY: RYAN W. TRAIL

Manufacturers, importers and processors of chemical substances in the United States, know full well the regulatory burdens placed on their industry by the Toxic Substances Control Act (TSCA). TSCA requirements can be cumbersome and difficult to understand. Luckily, TSCA contains several exemptions offering relief for companies in certain circumstances. One exemption available for companies considering bringing products to market that contain new chemical substances (not already registered in the U.S), is the Test Marketing Exemption (TME). TSCA exempts from Premanufacture Notification (PMN) requirements new chemical substances manufactured solely for test marketing. Chemical substances manufactured pursuant to the TME are also excluded from the Active Chemical List notification rule promulgated under the recent TSCA amendments.

The manufacture and import of chemical substances in the United States is governed by TSCA. TSCA mandates that all chemical substances manufactured in the United States be included on the "TSCA Inventory." Manufacturers of a chemical substance not currently on the TSCA Inventory must submit a PMN to EPA at least 90 days prior to manufacturing the substance. Pursuant to the 2016 amendments to TSCA, EPA promulgated regulations in 2017 requiring companies manufacturing chemical substances from June 21, 2006 to June 21, 2016 to upload information concerning the substances into a database being developed by EPA ("Notification Rule"); those TSCA Inventory chemicals not registered on the Active Chemical List (ACL) revert to the Inactive Chemical List (ICL) and are barred from distribution in commerce in the U.S. after the ICL/ACL lists become effective.

The TME enables manufacturers to focus on the market's interest in and demand for a product where it will be competing with other goods. "Test Marketing" is defined as:

> [T]he distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

EPA may exempt a manufacturer from PMN requirements and permit them to manufacture new chemical substances for test marketing, but only if the agency finds the import, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment.

The TME is not automatic. A company must first request it from EPA. A TME application must include information regarding health and environmental effects of the chemical substance to be manufactured, including physical and chemical properties. Importantly, this information should be generated using "all existing data," although the manufacturer need not conduct new studies of the substances' effects. The TME application must designate the maximum quantity of the substance to be manufactured, the maximum number of people who will be provided the substance during test marketing, and the maximum number of people to be exposed (including duration and route of exposure) to the substance during test marketing. The manufacturer must describe the test marketing activity, state its duration, and state how the test marketing activity will be different from full-scale production.

Immediately following receipt of a TME application, EPA is required to publish a notice in the Federal Register summarizing information in the application. The notice will give the public an opportunity to submit comments on the application. EPA must either approve or deny the TME application within 45 days of receipt. Upon approval or denial, EPA must publish a second notice in the Federal Register explaining the reasons for its decision. EPA may approve the TME with conditions if the agency determines the conditions are necessary to ensure that no unreasonable risk of injury to health and the environment is presented.

If the TME application is granted, the manufacturer may manufacture the approved volume of the chemical substance and conduct the test marketing activities in the approved manner for the approved time. Following the expiration of the approved TME period, EPA guidance suggests that residual exempt material may continue to be used for approved marketing activities until the expiration of a 90-day PMN review period, if (1) the only test marketing activities are distribution or use (i.e., no additional exempt material may be manufactured after the TME period); and (2) the volume and recipients of the exempt material were accounted for in the original TME application.

A substance that is granted TME (which is not added to the TSCA Inventory) is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance." Thus, the TME substance cannot become an "active substance" or an "inactive substance." The ACL notification rule specifically exempts the manufacture of substances "solely for test marketing purposes," stating that this is an activity "for which notification is not required."

If a company is considering manufacturing a product with chemical substances not currently on the TSCA Inventory solely for test marketing, it should take the following steps to comply with the TME:

Step No. 1: Apply to EPA for a TME at least 45 days prior to manufacture; the application must contain information regarding any health or environmental effects of the substance, a description of the test marketing activities and intended duration, a statement of the maximum volume of the substance to be manufactured, and the maximum number of people who will be provided with or exposed to the substance.

Step No. 2: If the TME application is approved, the company may only manufacture, distribute and use the exempt materials in compliance with the approved Test Marketing purposes and for the approved time.

Step No. 3: Substances that are manufactured pursuant to an approved TME are not subject to the Active Chemical List Notification Rule and need not be on the Active Chemical List to be test-marketed in the U.S.

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