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WILLIAMS MULLEN
ENVIRONMENTAL NOTES

THE BIGGEST PHASE I ESA MISTAKE YOU CAN MAKE

BY: CHANNING J. MARTIN

If your company is planning to buy commercial or industrial real estate, it's probably your standard practice to have a Phase I Environmental Site Assessment ("Phase I") performed. When you do so, it's important to ensure the Phase I report you receive from your environmental consultant fully complies with ASTM Standard E1527-13. Why? Because your company cannot qualify as a Bona Fide Prospective Purchaser ("BFPP") under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") and, in some instances, state law unless the Phase I complies with the ASTM Standard. Qualifying as a BFPP provides your company with a defense to CERCLA liability for existing contamination on the property, even if it is common knowledge the property is contaminated.

We review Phase I reports for clients regularly to ensure the reports comply with the ASTM Standard. What's the biggest mistake we see? It's failure by the environmental consultant to issue the report to the entity that will take title to the property. Frankly, though, it's not always the consultant's fault. Here's how this often unfolds: A development company enters into a contract to purchase real estate. An environmental consulting firm is engaged to perform a Phase I for the developer, and the firm sends the developer a user questionnaire. The developer completes the user questionnaire, sends it back to the consultant, and the consultant issues the report to the developer. A couple of weeks before closing, the developer forms a special purpose entity to take title, such as an LLC, and assigns the contract to the LLC. The LLC then closes on the property. Result? The LLC cannot qualify as a BFPP. Why? Because the Phase I was issued to the developer, not to the LLC that took title. In most instances, the developer never told the consultant that it planned to form an LLC to take title.

This seems like an easy mistake to avoid, but we see it happen over and over. Smart real estate purchasers will advise their consultants that they intend to form an LLC to take title, and smart consultants will advise their clients to let them know if an entity different than the client will take title. Securing the BFPP defense is cheap insurance against environmental liability, but this common mistake will leave the buyer unprotected.

VIRGINIA CO2 RULE APPROVED, BUT CANNOT BE IMPLEMENTED

BY: JOHN M. "JAY" HOLLOWAY III

At its April meeting, the Virginia Air Pollution Control Board (the "Board") approved a final CO2 Cap and Trade Rule, (9 VAC 5-140-6045), (the "Rule") to limit CO2 emissions from the power sector by a vote

of 5-2. This outcome was expected. However, just prior to the Board's action, language was inserted by the Virginia General Assembly into the 2018-2020 biennial budget bill prohibiting Virginia's membership or participation in the Regional Greenhouse Gas Initiative ("RGGI") until the General Assembly decides otherwise. (RGGI is a cooperative cap and trade program among nine northeastern states to reduce CO2 emissions from the power sector.) Considering the Rule requires participation in RGGI, the prohibition effectively halts implementation of the Rule. The Governor signed the budget bill despite pressure from environmental groups to veto it, thus making the implementation restriction the law for the moment. This restriction can be changed in a future budget or through legislation.

The language in the budget bill restricting implementation is as follows:

> LIMITATIONS ON USE OF STATE FUNDING
>
> "a. Notwithstanding any other provision of the Code of Virginia, no expenditures from the general, special, or other nongeneral fund sources from any appropriation by the General Assembly shall be used to support membership or participation in the Regional Greenhouse Gas Initiative (RGGI) until such time as the General Assembly has approved such membership as evidenced by language authorizing such action in the Appropriation Act, with the exception of any expenditures required pursuant to any contract signed prior to the passage of this act by the General Assembly, nor shall any RGGI auction proceeds be used to supplement any appropriation in this act without express General Assembly approval."

DEQ cannot pick up a pen to implement the Rule without that action being considered an illegal expenditure. While in Virginia the Governor has a line item veto, the prevailing legal position is that the Governor cannot use a line item veto to strike a substantive restriction. The Governor decided not to challenge this legal restriction. Nevertheless, he did direct DEQ to "identify ways to implement the regulation and achieve our pollution reduction goals."

The final rule adopts the text of the proposed rule, except that DEQ made a revision and an addition to it. No prior notice was provided for the changes, and DEQ presented them to the public for the first time at the meeting. In fact, no writing addressing them was prepared. The first time the public saw them was in the PowerPoint presentation made to the Board at the meeting by DEQ. This action arguably violates the Administrative Process Act (APA), with some contending this means the Rule should be rescinded and re-proposed by the Board.

The revision made by the Board to the Rule addresses and simplifies the allowance allocation methodology for 2031 forward. In response to comments by RGGI that post-2030 caps should be determined by a consensus of the RGGI states, the language now provides that "[f]or 2031 and each succeeding calendar year, the Virginia CO2 Budget Trading Program base budget is 19.60 million tons unless modified, as the result of a program review and future regulatory action."

The Board added a new section to the Rule to address future actions to be taken under the Rule if and when the General Assembly's restriction is lifted. Here are the three concerns about future implementation addressed by the new section:

- If the allocation of conditional allowances is not complete before January 1, 2020, the program will be considered to be operating and effective as of the calendar year following the date the conditional allowances are allocated.
- Permitting and compliance dates, including the due date for a permit, shall be adjusted to be in force 6 months after the date DEQ allocates the conditional allowances.

- Any excess emissions tonnage identified by the new program implementation date may be addressed through program review and regulatory action as necessary to ensure compliance with the final compliance date. DEQ will notify the Board and each affected CO2 budget source accordingly.
- The Board added this section to make the Rule effective as quickly as possible after the budget language restriction is resolved.

The final Rule contains two wins for industry: (i) biomass is excluded from the final rule, and (ii) the rule clarifies that the industrial exemption applies on a unit basis, not a facility basis. On the other hand, the final Rule still applies to fossil fuel-fired electric generating units at new industrial sources, meaning industrial sources constructed on or after January 1, 2019, none of whom will receive allowance allocations.

Potential Appeal

The final Rule was published in the Virginia Register on May 27, 2019. If the Rule is appealed, a notice of appeal must be filed with DEQ Director Paylor within 30 days after its publication. No later than 30 days after filing the notice of appeal, a petition for appeal must be filed in the Circuit Court of the City of Richmond. The petition for appeal must state why the petitioner believes the regulation is unlawful and must conclude with a specific statement of the relief requested.

Here are some of the potential arguments that could be made in an appeal:

1. The Board approved the Rule with a revision and addition for which public notice was given only at the meeting via a PowerPoint presentation. The argument here would be that this violated the Administrative Process Act.
2. The Board arbitrarily included new industrial sources in the Rule without allowances.
3. The Board should have deferred to the cost impact analysis of the State Corporation Commission ("SCC"), because the SCC has the exclusive Virginia constitutional authority to analyze utility costs and set rates. DEQ acknowledged this fact multiple times in its responses to comments.
4. DEQ acknowledged that much of the substance of how the program will be implemented is not in the Rule. It says it intends to cure this with instructions to be issued to those parties subject to the Rule. At a minimum, these details should be handled through guidance, not instructions. Guidance is recognized as much more substantive and must go through notice and comment rulemaking. Instructions do not.
5. The Rule should be withdrawn and re-proposed with adequate notice and comment to incorporate the correct cost impacts and details of how the Rule will be implemented.
6. Neither the Board nor DEQ has been granted authority by the Virginia General Assembly to regulate CO2.

Regulation for Emissions Trading Programs, 35 Va. Reg. 2332 (May 27, 2019); HB1700 (conference report) (2019 Session).

THE RISK GAME: ENVIRONMENTAL LITIGATION ISN'T ALL CHANCE

BY: LIZ WILLIAMSON

There is no magic formula to prevent an industrial source from becoming the target of a costly third-party administrative or legal environmental challenge. These legal actions from environmental non-governmental entities (eNGO) may come in the form of objections to permit changes or renewals, citizen suit civil claims, or intervention in public

service commission proceedings. Coal ash and other groundwater claims are particularly popular at present.

Environmental compliance information made available by industry to the public should be limited to what is required, while ensuring that it is accurate. Consider the following suggestions:

1. Monitor the Content on the Company's Internet Site, in Press Releases, in the Company's SEC 10K, and in Publicly Posted Company Newsletters.

The internet is fertile ground for eNGOs to obtain information concerning environmental compliance about a Company. Many companies maintain internet sites that report facility specifications, facility operation details, and environmental compliance information. While a company might be proud of a successful installation of an air pollution control device or expansion of manufacturing operations, regulators and eNGOs use the internet as a tool to identify whether the facility is in compliance with environmental laws. Examples of possible information of interest may include: New emission unit installations, details concerning closure of emission units and their waste streams, facility outage improvements, air emission source life extension projects, and future operation expansion plans.

eNGOs and regulators also review public information such as SEC 10Ks and company newsletters. In a lawsuit against Dynegy Midwest Generation, the eNGO that sued the utility for impacts to groundwater from coal ash disposal identified statements in Dynegy's 10K in which the company admitted that coal ash disposal at its Vermilion plant impacted groundwater that had migrated off-site to the river. It is unclear whether these statements directly led the eNGO to choose its target; however, the statement was included in the notice letter that the eNGO provided Dynegy prior to filing the lawsuit.

We recommend that environmental professionals and public relations professionals within a company coordinate and develop a protocol for review of information that could bear on environmental liability.

2. Monitor Government and eNGO Information Concerning the Company.

eNGOs and EPA host internet sites with environmental compliance information for specific companies. Examples of these sites include SourceWatch, SierraClub.org, EPA.gov, ashtracker.com, and ECHO. The sites may have inaccurate data. A company should be aware of the information that is publicly available concerning the facility. Inaccuracies may be corrected, particularly for government-hosted websites.

3. Critically Review all Required Environmental Filings and Postings.

Regulators base environmental compliance on a company's required filings, such as compliance tests and reports required by a facility's permits. eNGOs are also requesting this information through FOIA. It is critical to have a peer-reviewed quality review of key compliance reports and certifications. EPA rounding policies and permit exclusions can become crucial if an emissions result is close to a permitted limit. A company will want to ensure it avails itself of all applicable relief that could negate or otherwise forgive an issue of concern, such as an upset condition or equipment malfunction. Since some compliance reports have compliance certifications, these reports can easily be used as evidence of an event of noncompliance in litigation. It is harder for a company to backtrack from such a certification.

4. Control How Contractors Can Use and Disseminate Information About The Company.

Contractors and consultants are an integral part of a facility's operational and environmental success. However, these third parties' communications with the company are not confidential. Third parties may post photographs or details concerning work on projects at a facility on their website, use company information in marketing materials, or discuss the projects with prospective clients. In addition, a facility may want to conduct a study to identify environmental compliance options that could be sensitive. Depending on the nature of the work to be done, the company should consider protecting the information through a confidentiality agreement, at the least, or by attorney-client privilege if the study is being performed at the direction of an attorney.

Letter from EarthJustice to Dynegy Midwest Generation, LLC, January 31, 2018 (60-Day Notice of Intent to File Citizen Suit). *Prairie Rivers Network v. Dynegy Midwest Gen., LLC*, Case No. 18-CV-2148 (C. D. Ill. Nov. 14, 2018).

EPA CLARIFIES ITS STANCE ON THE REGULATION OF GROUNDWATER UNDER THE CLEAN WATER ACT

BY: BENJAMIN C. MOWCZAN

EPA recently issued an interpretive statement ("Interpretive Statement") setting forth its position on the Clean Water Act's ("Act") regulation of discharges to groundwater, offering much-needed clarity on an issue subject to significant debate.

The Interpretive Statement lays out EPA's interpretation of the Act's National Pollutant Discharge Elimination System (NPDES) permitting requirements for the discharge of pollutants from a point source to groundwater. According to the Interpretive Statement, EPA interprets regulation under the NPDES program to *exclude* the release of pollutants from a point source to groundwater, regardless of any hydrological connection between the groundwater and jurisdictional surface waters.

The Interpretive Statement comes in the wake of controversial decisions from the Fourth Circuit in *Upstate Forever v. Kinder Morgan Energy Partners, L.P.*, 887 F.3d 637 (4th Cir. 2018), and the Ninth Circuit in *Hawai'i Wildlife Fund v. County of Maui*, 886 F.3d 737 (9th Cir. 2018), where the courts determined the Act extended not just to discharges to surface waters, but also to discharges of pollutants to groundwater that migrate to surface waters. The United States Supreme Court has agreed to review *Hawai'i Wildlife Fund*, with a decision possible later this year that could be the final word on the Act's regulation of groundwater.

Pending resolution of *Hawai'i Wildlife Fund* by the Supreme Court, the Interpretive Statement is an unequivocal disclaimer by EPA of the hydrological connection theory of Clean Water Act jurisdiction. Contrary to the decisions by the Fourth and Ninth Circuits and prior views expressed by EPA and other federal agencies, EPA makes clear in the Interpretive Statement that it does not interpret the NPDES program to apply to any point source discharges of pollutants to groundwater, regardless of any hydrological connection to surface waters. EPA finds support for this position in its analysis of the text, structure, and legislative history of the Act. Citing the lack of express language extending NPDES permitting requirements to groundwater when Congress could have readily included such language, EPA concludes that releases of pollutants to groundwater are categorically excluded from NPDES permitting requirements.

EPA's position does not leave groundwater totally unregulated. In addition to state groundwater regulation, federal regulation of groundwater remains intact under the Safe Drinking Water Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act.

The Interpretive Statement gives the regulated community a sense of certainty and uniformity when it comes to NPDES permitting requirements for discharges to groundwater, but a note of caution to those in the Fourth and Ninth Circuits: while awaiting a final outcome on the issue from the Supreme Court, EPA will not apply the Interpretive Statement in the Fourth and Ninth Circuits. In those jurisdictions, the *Kinder Morgan* and *Hawai'i Wildlife Fund* decisions, respectively, remain in effect pending resolution by the Supreme Court. Moreover, while the Interpretive Statement may be indicative of EPA's position in terms of agency enforcement actions, courts are not bound by the interpretation and may rule to the contrary if presented with an action brought under the Act's citizen suit provision.

Memorandum from EPA General Counsel Matthew Z. Leopold and Assistant Administrator for Water David P. Ross to EPA Regional Administrators, Regions I–X: Application of the Clean Water Act National Pollutant Discharge Elimination System Program to Releases of Pollutants from a Point Source to Groundwater (Apr. 12, 2019).

EPA RESTRICTS MANUFACTURE AND USE OF METHYLENE CHLORIDE FOR CONSUMER PAINT AND COATING REMOVAL

BY: ETHAN R. WARE

EPA recently published a final rule restricting the manufacture, processing, and import of methylene chloride in the United States for consumer paint and coating removal. The rulemaking is a result of risk assessments completed under the Toxic Substance Control Act (TSCA).

TSCA requires EPA to perform a risk assessment for qualifying chemical substances distributed in the United States. Pursuant to Section 6(a), EPA must determine if those chemical substances present an "unreasonable risk of injury to health or the environment without consideration of costs of non-risk factors." Where risks are found (even if only for sub-populations), EPA must by rule "apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risks." In the preamble to the final rule, EPA concludes "methylene chloride is such a chemical when used in consumer paint or coating removal."

Pursuant to the rule, it will be unlawful after November 22, 2019, to manufacture (including import), process, or otherwise distribute into commerce methylene chloride for consumer paint and coating removal. On that same date, retailers are banned from selling methylene chloride for consumer paint and coating removal, including any products used for that purpose that contain methylene chloride.

Any company manufacturing, processing, or distributing consumer paint or coating removers with methylene chloride on August 26, 2019, must notify downstream users of this prohibition. Written notification must occur by inserting the following text in the Safety Data Sheet ("SDS") provided with the methylene chloride or any consumer paint or coating removal product that contains it:

> **SDS Section I(c) and 15:** This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal.

Moreover, companies manufacturing, processing, or distributing in commerce any methylene chloride after August 26, 2019, must retain in one location at its headquarters for three years the following information:

- Name, address, contact, and telephone number of companies to whom methylene chloride was shipped;
- Copies of the required notifications included on SDS; and
- The amount of methylene chloride shipped.

There is no provision in the final rule for extensions of the August and November 2019 deadlines, nor is a company relieved of the requirements due to economic hardship. Although EPA has proposed a determination of unreasonable risk from the use of methylene chloride in commercial paint and coating removal, the final rule does not ban commercial uses of methylene chloride in paint and coating removal. EPA is soliciting comment on alternatives to an outright ban on commercial uses, such as increased training and certification requirements.

Methylene Chloride: Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Federal Register 11420 (March 27, 2019).

A NEW PILL TO SWALLOW: EPA'S HAZARDOUS WASTE PHARMACEUTICALS RULE

BY: RYAN W. TRAIL

Certain pharmaceuticals are regulated under the Resource Conservation and Recovery Act (RCRA) as "hazardous waste" when they are discarded. EPA recently finalized new management standards for hazardous waste pharmaceuticals from health care facilities and "reverse distributors" handling those wastes.

The final rule applies to health care facilities and to reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. A "health care facility" is defined to include retail pharmacies, hospitals, primary care physicians, veterinary care operations, and any business providing health care or dispensing pharmaceuticals. "Reverse distributors" include facilities receiving or accumulating unused pharmaceuticals no longer needed, for which the manufacturer may provide a credit. Facilities not subject to the final rule include manufacturers of pharmaceuticals and production facilities. The final rule also exempts certain nicotine replacement therapies ("NRT") from hazardous waste regulation.

Many health care facilities face a complex regulatory scenario when dealing with hazardous waste. For a large hospital, small quantities of various forms and types of hazardous waste may be generated at hundreds of points throughout the facility (e.g. patient rooms, operating rooms, nursing stations, emergency rooms). Under RCRA, hazardous waste determinations must be made by the generator at the point of generation. In part, the final rule is intended to relieve facilities employees, who are often undertrained in hazardous waste management, from some of the regulatory burdens of RCRA. The final rule sets sector-specific standards that apply to waste pharmaceuticals in lieu of existing hazardous waste generator requirements.

Health care facilities will no longer be deemed large quantity generators when generating more than 1 kg of acute hazardous waste pharmaceuticals in a calendar month. Covered facilities will no longer be responsible for meeting satellite accumulation area provisions of RCRA and may accumulate hazardous waste pharmaceuticals on site without a permit for up to one year. In addition, health care facilities will no longer be required to specify hazardous waste codes on manifests.

However, the final rule includes a number of new requirements for health care facilities, including new reporting, notification, recordkeeping, labeling, and training requirements. In addition, the final rule prohibits health care facilities and reverse distributors from disposal of hazardous waste pharmaceuticals by flushing them down a drain or a toilet.

When health care facilities have unused pharmaceuticals, a reverse distributor assists the facility by returning them to the manufacturer. If the unused product still has a legitimate use, the facility may receive a credit. If not, the reverse distributor must dispose of the product. The final rule clarifies that, because prescription pharmaceuticals handled by reverse distributors are almost always unusable, prescription pharmaceuticals moving through the reverse distribution system are solid waste (and, therefore, potentially hazardous waste) at the health care facility. Therefore, the point of generation for these prescription pharmaceutical wastes will be at the health care facility. For nonprescription pharmaceuticals, as long as there is a reasonable expectation of legitimate reuse or reclamation, the products are not considered a solid waste at the healthcare facility. This is an important distinction because the point in time at which a given pharmaceutical is deemed to be a waste controls when management standards under the final rule apply.

The effective date of the final rule is August 21, 2019. However, with one important exception, it will not apply to health care facilities and reverse distributors in states authorized by EPA to operate their own hazardous waste management program. The final rule won't apply in those states until the state adopts the final rule and incorporates it into the state's regulations. The important exception? The ban on flushing hazardous waste pharmaceuticals down the drain becomes effective in all states on August 21st.

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 84 Fed. Reg. 5816 (February 22, 2019).

VIRGINIA'S DRAFT CHESAPEAKE BAY TMDL PHASE III WATERSHED IMPLEMENTATION PLAN: ENDGAME, OR JUST ANOTHER EPISODE IN A LONG SERIES?

BY: HENRY R. "SPEAKER" POLLARD, V

In early April 2019, Virginia released its draft Phase III Watershed Implementation Plan ("Draft Plan") to achieve compliance with EPA's 2010 Chesapeake Bay Total Maximum Daily Load Rule ("Bay TMDL"). The Bay TMDL sets allowable loadings of nutrients (nitrogen and phosphorous) and sediment into the Bay from various sources in Virginia and other Bay watershed states and compels Bay states to develop plans to achieve compliance by the 2025 deadline. Prepared after significant stakeholder consultation, the Draft Plan builds on the earlier Phase I and Phase II Watershed Implementation Plans ("WIPs") and progress in nutrient and sediment reductions achieved to date. Based on the Draft Plan, however, the finale of the WIP series is expected to continue and even increase the challenging roles for regulated parties in the Bay cleanup saga to achieve Bay TMDL goals.

Several themes of the Draft Plan influence stakeholder roles. First, Virginia is seeking to identify and document any previously unaccounted for progress toward nutrient and sediment load reductions to help demonstrate compliance. Second, as before, the relative burden of meeting Bay TMDL objectives generally depends on the type of nutrient or sediment source sector involved. Third, the Draft Plan offers several new tools and options to meet these increased challenges. Finally, each of the major Bay watersheds – the Potomac, Rappahannock, York, and James Rivers and the Eastern Shore – has its own implementation goals tailored to that watershed's water quality.

The Draft Plan also calls for much action by various Virginia agencies, including 50 multisector and sector-specific policy and regulatory initiatives. To the degree actually performed, they would have major impacts on different regulated parties and create new options for compliance. They include the following major proposed steps:

(a) **Multisector:** (i) enhanced reporting of best management practice ("BMP") implementation; (ii) extension of Chesapeake Bay Preservation Act applicability to Bay watershed localities west of Interstate 95; (iii) reliance on interbasin exchanges of nutrient reductions to balance burdens and costs of nutrient load reductions among the main watersheds; (iv) finalization of carbon trading regulation and determination of method to determine related nitrogen reduction; and (v) development of a new coastal resilience master plan to assist localities in planning for flood risks.

(b) Construction/Development and MS4 Sectors: (i) addition of nutrient management plan ("NMP") obligations to erosion and sediment control requirements for land disturbing activities exceeding one acre; (ii) confirmation of contractor-applicator reporting of fertilizer application to urban

lands and related increase in enforcement and reporting authority over contractor-applicators; (iii) preparation of an annual estimate of the amount of local stormwater assistance needs for MS4 and non-MS4 localities pursuant to House Bill 1822 (2019) and seek sufficient funding; and (iv) reevaluation of post-construction water quality design criteria for the VSMP program to ensure they are sufficient to meet Bay TMDL objectives.

(c) Agriculture and Forestry Sectors: (i) update and reinstatement of the Commonwealth's Agriculture BMP Loan Program; (ii) various changes to the Virginia Agriculture Cost Share ("VACS") program, including increasing the state's cost-share funding contribution to 70%; (iii) an increase in the tax credits offered for agricultural BMPs and equipment and greater staffing of Soil and Water Conservation Districts providing tax credit assistance; (iv) NMP implementation on 85% of all cropland areas and new legislation to increase the number of farms subject to NMP requirements to ensure this goal is reached; (v) continued efforts toward the exclusion of livestock from all perennial streams through enhanced VACS program incentives and flexibility; (vi) expansion of the Poultry Litter Transport Program area and additional program reporting and recordkeeping; (vii) increase in vegetated buffer areas through the USDA Conservation Reserve Enhancement Program by raising the state match to landowners from 25% to 35%; and (viii) economic development support to localities for private sector farming of native plant species and for oyster aquaculture; and (ix) changes to the Healthy Watersheds Initiative Project to facilitate large-scale investment in forest conservation.

(d) Wastewater Sector: (i) additional nutrient reductions from certain significant wastewater treatment plants ("WWTPs") that have not yet upgraded to achieve current nutrient effluent criteria; (ii) reevaluation and potential adjustment of current allocation of nutrient loads to WWTPs per statutory requirements; (iii) reporting of sewer connections by wastewater utilities; (iv) completion of the transition of oversight and enforcement from localities to Department of Health ("VDH") for obligations to inspect and periodically pump out on-site sewage treatment systems in the Northern Neck, Middle Peninsula, and Eastern Shore localities and development of related legislative recommendations for plan implementation; (v) establishment of VDH as "state-certifying authority" for community wastewater systems (serving 10 or more households) that have total nitrogen reducing treatment systems and for related sales tax exemptions for such systems financed with public funds; and (vi) setting by new regulation total nitrogen limits for large conventional on-site sewage systems.

Once reviews are in on the Draft Plan through the public comment process ending June 7, and after EPA's separate review process, Virginia's WIP trilogy should wrap with a final Phase III WIP. Before then, stakeholders still have an opportunity to influence editing of the Draft Plan before its release in final form. Whether this is the Bay TMDL endgame for Virginia is unclear: the Phase III WIP is a plan of action, and whether the action unfolds as currently scripted is unknown. Also unclear at this point is whether these actions will ultimately achieve the Bay TMDL load reductions – and do so in a cost-effective manner. Regardless, in the epic effort to clean up the Bay, regulated parties, state agencies, and other stakeholders all have important roles to play.

Notice of Availability of Public Comment on Virginia's Draft Phase III Chesapeake Bay Watershed Implementation Plan, 35 Va. Reg. Reg. 2015 (April 1, 2019)

EPA PROPOSES RULE FOR CONFIDENTIAL BUSINESS INFORMATION CLAIMS UNDER TSCA

BY: JESSICA J. O. KING

The 2016 amendments to the Toxic Substances Control Act ("TSCA") made numerous changes to TSCA, including increasing public transparency of chemical information. To accomplish this, the amendments required EPA to establish a plan for reviewing all confidential business information ("CBI") claims for a specific chemical identity asserted by a manufacturer. EPA was required to do this no later than one year after it completed the TSCA inventory of active and inactive substances ("Inventory"). EPA released the updated Inventory on February 19, 2019, and published a proposed rule on April 23, 2019. Once the rule is effective, EPA is required to complete its review of all CBI claims no later than five years after the Inventory was released, or by February 19, 2024.

I. Background

In 2016, TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The 2016 amendments require EPA to keep a comprehensive list of active and inactive chemical substances processed or manufactured (including those imported) in the United States for nonexempt commercial purposes during the "Lookback Period." The Lookback Period for reporting purposes was June 21, 2006, through June 21, 2016. Under the TSCA regulations, a manufacturer/importer of a chemical substance subject to "commercial activity designation" during the Lookback Period was required to submit a Notice of Activity ("NOA") Form A between August 11, 2017, and October 5, 2018 ("NOA Deadline"). EPA reviewed the forms submitted, and, on February 19, 2019, released the active and inactive substances Inventory.

The TSCA Inventory has a confidential portion and a public, non-confidential portion. The TSCA regulations were amended in 2017 ("Amended TSCA Regulations"). The Amended TSCA Regulations allow persons submitting an NOA to request to maintain an existing claim of confidentiality for chemicals already listed on the confidential portion of the Inventory at the time the notice was submitted. If the request to maintain confidentiality is not made at the time the NOA Form A is submitted, the chemical was moved from the confidential Inventory list to the public Inventory list.

The Amended TSCA Regulations also require a person requesting a new CBI claim or seeking to maintain an existing CBI claim to substantiate the claim in accordance with existing or future EPA regulations. The deadline to substantiate is different for new claims versus maintenance of existing CBI claims. New claims had to be substantiated and certified by the NOA Deadline. Those requesting to maintain CBI were not required to substantiate the claim by the NOA Deadline. Rather, those requesting to maintain were allowed to either wait for EPA to issue new regulations or voluntarily offer substantiation by the NOA Deadline.

II. What does the Proposed CBI Rule require?

The Proposed CBI Rule provides: 1) mandatory "substantiation requirements" for claims to maintain chemical substances on the confidential portion of the TSCA active-list Inventory; 2) provisions clarifying the duration of protection for approved CBI claims; and 3) publication of annual review goals and results.

The Proposed CBI Rule does not apply to persons who already voluntarily provided substantiations during the initial submittal of the NOA Form A or during the 5-year period ending on the substantiation deadline. CBI claims by those exempt companies are reviewed under the procedures already set forth in TSCA and the TSCA regulations. If your company submitted an NOA Form A, requested to maintain a claim of confidentiality but did not voluntarily provide substantiation of that claim at that time, the Proposed CBI Rule, once finalized, will apply. Finally, the Proposed CBI Rule does not apply to CBI claims for specific chemical identity in an NOA Form B used to report the reintroduction of "inactive" chemical substances into the United States.

A. Substantiation Requirements

For companies that submitted substantiation to EPA in the past, but not with the NOA Form A, the Proposed CBI Rule requires they provide EPA with the following information within 90 days of the effective date of the final rule: (1) the submission date; (2) the submission type; (3) the case number, transaction ID, or equivalent identifier that uniquely identifies the previous submission; and (4) the substantiation upon which the company is relying.

EPA will review the submission to determine if the substantiation previously provided is sufficient.

For companies that never provided substantiation, but have claimed CBI in the NOA Form A, the Proposed CBI Rule requires they file their substantiations no later than 90 days after the effective date of the final rule. The Proposed CBI Rule specifically requires an authorized official for the company to provide substantiation in the form of certified answers to the following questions:

1. Do you believe that the information is exempt form substantiation pursuant to TSCA section 14(c)(2)? If yes, under what exemption?
2. Will disclosure of the information likely result in substantial harm to your business' competitive position? If so, how?
3. What precautions has your business taken previously in disclosing the identity to other persons (internally and externally)? Identify the measures or internal controls taken, including non-disclosure agreements prior to access, limited access on need-to-know business, physical safeguards of information, etc.
4. Does the identity already appear in any public documents, including safety data sheets, advertising, professional or trade publications, or other media available to the public?
5. If the confidentiality claim is for less than 10 years, how many years are requested?
6. Has EPA, other federal agency, or a court made any confidentiality determination regarding information associated with the chemical substance?
7. Is the chemical substance publicly known to have been offered for commercial distribution in the United States at any time?

The official submitting the CBI claim must also certify the following to be true and correct: (1) the company has taken reasonable measures to protect the confidentiality of the information; (2) the information is not required to be disclosed or made public under other Federal laws; (3) the disclosure is likely to cause substantial harm to the competitive position of the company; and (4) there is a reasonable basis to believe the information is not readily discoverable through reverse engineering.

The certified answers to the substantiation questions must be submitted electronically in the same manner the NOA Form A was previously submitted. Late submittals will be deemed deficient and will lead to the identity of the chemical substance being treated as non-confidential without further public notice.

To determine if a substantiation claim is sufficient, EPA will consider the facts provided, any pertinent previously issued confidentiality determinations, and other reasonably available information that EPA finds appropriate. Under the Proposed CBI Rule, EPA will consider whether: (1) the claim has not expired or been waived or withdrawn; (2) the business has taken reasonable measures to protect the confidentiality of the information and intends to continue to take such measures; (3) the information is not reasonably obtainable without the business' consent by other persons by use of legitimate means (not including in a judicial or quasi-judicial proceeding); (4) no statute specifically requires disclosure of the information; and (5) the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business' competitive position.

B. EPA CBI Review Process

Under the Proposed CBI Rule, if EPA decides to deny a CBI claim, it will notify the submitter in writing by certified mail or personal delivery, specify its reasons, and state its intent to disclose the specific chemical identity ("Denial Notice"). EPA will not disclose the chemical identity until 30 days after the date on which the submitter receives the Denial Notice. Submitters can challenge the Denial Notice by commencing an action in federal district court to prevent disclosure. If EPA approves a CBI claim, it will notify the submitter in writing, and the chemical will be identified by a unique identifier in subsequent publications of the TSCA Inventory. Chemicals with approved CBI claims will be protected from disclosure for a period of 10 years from the date on which the person asserts the claim, as required by TSCA. EPA states in the preamble to the Proposed CBI Rule that it interprets the date that starts the 10-year clock to be the date on which the first person asserts a CBI claim for a specific chemical – which in most circumstances (but not all) will be the date the person files the NOA Form A. EPA will notify the person claiming CBI of the date on which the 10-year

clock began. In any event, the non-disclosure period can be shorter than 10 years where the claimant withdraws the confidentiality claim or EPA otherwise becomes aware that the information does not qualify for protection from disclosure. For the latter case, EPA will notify the claimant of its intent to disclose the information prior to doing so.

C. EPA Annual Reviews

Finally, under the Proposed CBI Rule and as required by the 2016 TSCA amendments, EPA will publish annual goals for reviews completed at the beginning of each calendar year, starting with the goals for 2020. It will track the number of CBI reviews completed in the preceding year, to be published on the EPA website beginning in February of 2021.

III. Conclusion

EPA will accept public comment until June 24, 2019. Portions of the proposed rule that seem likely to elicit comment are how EPA calculates the 10-Year Period for non-disclosure and the process for appealing a denial. EPA estimates that 126 companies will be affected by the Proposed CBI Rule (i.e. not exempt). Of those, EPA estimates that 23 companies will be allowed to reference previous substantiations made during the 2016 Chemical Data Reporting. Companies that have submitted TSCA NOA Form A's and requested maintenance of an existing CBI claim on the identity of an active chemical should review their NOA Form A's and other applicable information to see if they have grounds to claim previous substantiations. Companies that believe they have already substantiated their claims in conformance with the rule will have 90 days after the effective date of the final rule to notify EPA of the previous substantiation. Those who have not previously provided substantiation will need to do so within that same 90-day period. The takeaway: companies affected by the Proposed CBI Rule should consider filing comments and should monitor it closely to ensure compliance after the final rule is issued.

Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, 84 Fed. Reg. 16826 (April 23, 2019).

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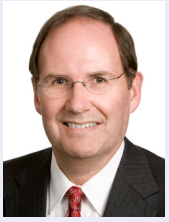
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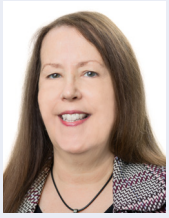
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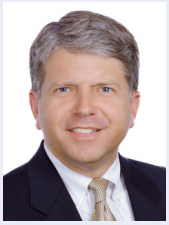
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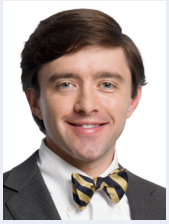
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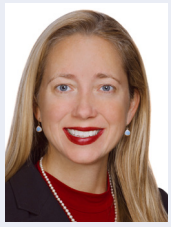
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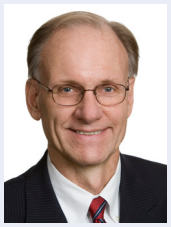
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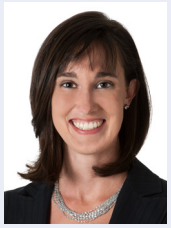
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