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Insights from the Firm's Public Policy Team

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By B. David Naidu, Molly E. Nixon

Forty years after it was first enacted, the Toxic Substances Control Act (“TSCA”) was substantially changed with the passage and enactment of The Frank R. Lautenberg Chemical Safety for the 21st Century Act (the “Lautenberg Act”). The new law, enacted on June 22, 2016, affects companies across a wide range of industries and gives the Environmental Protection Agency (“EPA”) new and expanded authority to regulate chemicals.

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FROM THE EDITORS

Welcome to the Fall 2016 edition of Environmental Policy Quarterly, published jointly by the Environmental, Land and Natural Resources and the Public Policy and Law Practice Groups of K&L Gates. Environmental Policy Quarterly highlights significant developments and issues of public policy relating to the environment and natural resources in the United States and globally.

This edition includes observations by leading members of our Policy Practice about the potential impact of the Presidential election upon our country's environmental legal landscape. This edition also continues our focus on reforms to the Toxic Substance Control Act and the congressional response, through the Water Resources Development Act, to the Flint Michigan water crisis. We are pleased that this issue includes the insights and contributions of K&L Gates lawyers who are actively involved in these matters on a daily basis.

We hope you find this edition of Environmental Policy Quarterly of interest, and we welcome and appreciate your feedback.

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A NEW ADMINISTRATION'S APPROACH TO ENVIRONMENTAL POLICY

Insights from the Firm's Public Policy Team

In January 2017, we will have a different president in the White House. With Election Day less than a month away, Environmental Policy Quarterly (EPQ) sat down with four of the firm's Democratic and Republican insiders to get a better understanding of what a Clinton or Trump administration may mean for national environmental and energy policy.

On the Republican side, EPQ sat down with K&L Gates Government Affairs Counselor and former Congressman Jim Walsh from New York who served 20 years in the House of Representatives as Appropriations subcommittee chairman overseeing the EPA's budget, and Government Affairs Advisor Amy Carnevale who served as a Trump delegate to the 2016 Republican National Convention and member of the Republican Platform Committee.

On the Democratic side, EPQ sat down with K&L Gates Partner and former Congressman Bart Gordon from Tennessee who served 26 years in the U.S. House of Representatives as Chairman of the Science and Technology Committee, and Rod Hall, Government Affairs Advisor and Clinton Delegate to the Democratic National Convention.

EPQ: Let's begin with the Republican candidate's vision. In a speech given in North Dakota in May of this year, Mr. Trump laid out positions that would dramatically change federal environmental policy. Can you describe how his views on energy and environmental regulations play into his broader goals for the country?

Walsh: Bolstered by his pledge to put Americans back to work, Mr. Trump promises to revitalize the oil & gas and coal industries; "cancel" the international climate agreement that came out of Paris earlier this year; and end many of the EPA's regulations put in place under the Obama administration. In its 2016 platform, the Republicans likewise laid out a vision for environmental stewardship that would be much different than the direction the current administration has headed.

A strong tenet of Mr. Trump's campaign is his promise to bring back coal jobs. Mr. Trump has repeatedly criticized Secretary Clinton's comments that she intends to "put a lot of coal miners out of work" by shifting the nation's energy priorities from fossil fuels to cleaner sources. Mr. Trump has stated he would lift what he views as burdensome environmental regulations and open up federal lands to coal production.



EPQ: Has Mr. Trump pointed to specific regulations he would change or eliminate that he views as detrimental to the economy?

Carnevale: Mr. Trump broadly believes that the impact of many EPA regulations on business does not justify any slight environmental benefits gained. Mr. Trump's experience in the construction industry and his policy positions in favor of robust infrastructure development also influence his views on environmental issues. In his North Dakota energy speech and later in an economic policy speech in New York, he promised to rescind a number of Obama-era regulations, including the Clean Power Plan, the Waters of the United States rule, and the Climate Action Plan within the first 100 days of his administration. He has stated that his broad environmental priorities are for clean air and clean water. His campaign, however, has not developed many specific environmental policy proposals so it is reasonable to look towards the Republican platform

and to priorities of Republican congressional leaders for potential insight into a Trump administration's future policy positions.

EPQ: You mentioned the Republican platform. What environmental recommendations does it make?

Carnevale: The 2016 Republican platform takes strong positions on environmental issues. It touts the progress already made towards improving the environment through technological efficiencies and educational efforts. The platform takes the stance that environmental regulations are best implemented at the state level and that the EPA should be transformed into a bipartisan commission—similar to the Nuclear Regulatory Commission—to handle oversight in a less politicized manner. As stated in the platform, the belief of the GOP is that “environmental problems are best solved by giving incentives for human ingenuity [...] not through top-down, command-and-control regulations [...].”

Both the platform and Mr. Trump express support for halting the COP-21 agreement signed by 170 countries in April 2016. They both believe that the agreement is too biased against the United States, and therefore not in the country's best interest. Mr. Trump has said he may seek to renegotiate the agreement or simply withdraw without seeking a new agreement.

EPQ: Aside from his North Dakota speech and comments made at other events, are there advisors or others close to the campaign that we should look to potentially shape an environmental agenda in a Trump administration?

Walsh: Mr. Trump may also consider well developed policy positions on environmental issues from a small handful of Members of Congress who have gained his trust. Among Mr. Trump's closest advisors is Senator Jeff Sessions (R-AL). Senator Sessions and similar minded Republicans have spearheaded proposals in Congress to reign in executive branch authorities (Separation

of Powers Restoration Act), modernize offshore oil and gas leases (Innovation in Offshore Leasing Act), and promote so-called "Good Samaritan" rules relating to mine cleanup (Locatable Minerals Claim Location and Maintenance Fees Act). It is reasonable to speculate that Mr. Trump would also largely support any proposals coming from the Appalachian congressional delegation that would favor coal development.

Mr. Trump also could be expected upon assuming office to freeze new regulations pending regulatory review like what occurred under President George W. Bush and quickly move forward to implement a rollback of Obama-era regulations. The pace of any legislative changes would largely depend on the scope of his proposal and, mostly importantly, whether the Senate remains in Republican control.

EPQ: Let's switch gears to the Democratic candidate. Congressman Gordon, when then-Senator Clinton served in the U.S. Senate, you



were serving in the U.S. House of Representatives. Have you noticed a change in her positions or approach to energy and environmental policy as a Senator versus presidential candidate?

Gordon: Secretary Clinton's stances on environmental policy are nothing new to the general public. During her time as Senator from New York, she cosponsored legislation to reduce carbon pollution, fought for clean water initiatives, and proposed environmental justice measures, including blocking funding cuts to the Superfund program. As Secretary of State, she appointed the first Special Envoy for Climate Change, formed the Climate and Clean Air Coalition between 37 countries to reduce short-lived climate pollutants, and worked on international climate negotiations in Copenhagen. Even as far back as her time as First Lady, Secretary Clinton was working to draw attention to the links between air pollution and childhood asthma.

EPQ: What should the American public reasonably expect as an immediate area of focus for a Clinton administration?

Hall: I think it's reasonable to expect policies that will address climate change, tackle a significant backlog of aging infrastructure, and continue the work to combat environmental hazards affecting disadvantaged communities initiated by the Obama administration. Secretary Clinton's presidential platform outlines specific proposals that would address infrastructure issues as well as climate change and

economic disparities that arise as the country shifts from fossil fuels to cleaner forms of energy. These include heavy investments aimed at modernizing drinking and wastewater systems, reducing air pollution, and broadening the clean energy economy to low-income communities and communities of color. She has discussed the issues facing Flint, MI, at length. She believes that there ought to be a federal role in addressing such issues, and that those responsible for the crisis should be held accountable.

EPQ: In terms of infrastructure investment, the threshold question of "How do you pay for it?" immediately comes to mind. What's Secretary Clinton's plan?

Hall: Secretary Clinton has suggested that these projects should be funded through a new National Infrastructure Bank that leverages public and private capital to invest in environmental and energy infrastructure. The campaign proposes the issuance of competitive grants to states, cities, and rural communities that lead in reducing carbon pollution. To make the process more efficient and effective, the campaign proposes streamlining the infrastructure review and permitting process. Secretary Clinton also proposes to work with Congress to close tax loopholes for companies that ship sands crude without paying into the Oil Spill Liability Trust Fund. And she proposes to bolster the Superfund program to provide more resources for environmental cleanup activities.

EPQ: “Clean energy” appears to be an anchoring policy thematic of Secretary Clinton’s campaign. Can you give us some examples of her definition of clean energy?

Gordon: Wind, solar, low-carbon transportation solutions, and other renewable energy sources would all receive attention under a Clinton administration. Ensuring safe and responsible natural gas production occurs by implementing new safeguards and raising labor standards would also be a priority. And increasing public investment in clean energy R&D, including advanced nuclear energy would play an important role in moving toward a clean energy future in a Clinton administration. These goals will supplement her desire to reduce carbon pollution and reach new renewable energy targets. Secretary Clinton has outlined a plan to reward communities, via a \$60 billion Clean Energy Challenge, that take the lead in phasing out inefficient fuel oil consumption. Additionally, Secretary Clinton will accelerate the deployment of high efficiency natural gas-fueled trucks, buses, ships, and trains, and aim to expand the Department of Interior’s geothermal, solar and wind energy areas on public lands and offshore waters.

EPQ: In years past, the use of coal has played a prominent role in domestic energy consumption. As the country continues its transition towards cleaner, renewable energy alternatives—what is Secretary Clinton’s approach to this energy segment?

Gordon: The world has been transitioning to low-cost renewable energy for years. As a result, the demand for coal is reducing in the United States and around the world. Currently, coal accounts for only one third of power generated in the United States. As she stated, “we’ve got to move away from coal and all the other fossil fuels, but I don’t want to move away from the people who did the best they could to produce the energy that we relied on.” So Secretary Clinton’s energy agenda includes a plan to create new jobs and deliver important health benefits to coal miners and a proposal to repurpose mine land and power plants financed through the Abandoned Mine Reclamation Fund.

These projects will be supplemented financially through private and public partnerships including New Markets Tax Credits and zero capital gains for private investors. Secretary Clinton has announced a \$30 billion plan to invest in economic diversification and job creation for coal miners and their families. This plan includes backstopping funding for families who have lost their jobs due to decrease in coal demand and coal company bankruptcies.



2016 ELECTION GUIDE: A Guide to Changes in Congress

To help you assess the results of the election, the K&L Gates Public Policy and Law team will again prepare a comprehensive guide that summarizes the results and their impact on the 115th Congress, which will convene in January. Published each election year, the Election Guide lists all new members elected to Congress, updates the congressional delegations for each state, and provides a starting point for assessing the coming changes to the House and Senate committees.

The Guide will be available for download on November 9, and will be updated on an ongoing basis as more of the close races are called and committees are finalized.

To download a copy of the 2016 Election Guide, please scan the QR code below or go to www.klgates.com/electionguide2016/

For additional information regarding the impacts and effects of the elections, please contact Tim Peckinpaugh or any member of the Public Policy and Law practice:

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**2016
ELECTION
GUIDE**

FINAL VERSION OF WATER RESOURCES DEVELOPMENT ACT OF 2016 MAY ASSIST FLINT, HELP WATER SYSTEMS THROUGHOUT THE COUNTRY AVOID A SIMILAR FATE

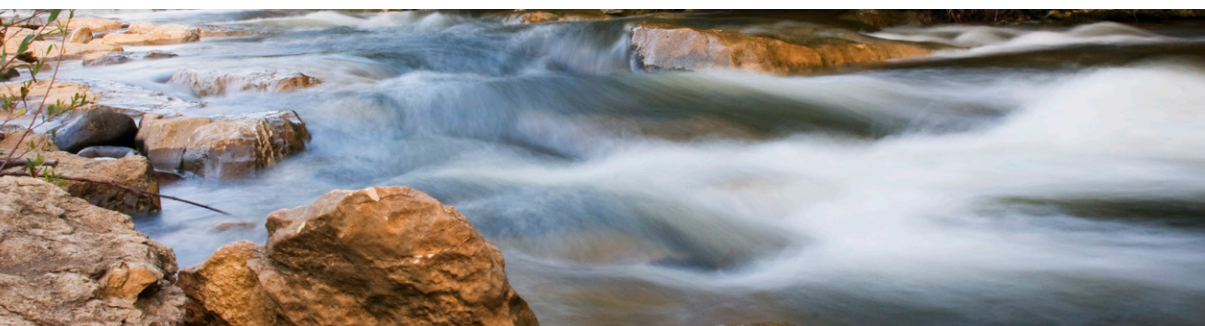
Brigid Landy and Cliff Rothenstein

The Flint Water Crisis raised awareness across the country about the dangers of lead leaching into public water supplies from aging infrastructure. It also highlighted holes in the Environmental Protection Agency's ("EPA") Lead and Copper Rule, as implemented by state environmental agencies, which exacerbated the crisis.

In a report released in June 2016, the National Resources Defense Council found that nearly 5,400 water systems had violations of the Lead and Copper Rule in 2015, and estimated that 18 million Americans are served by those systems. The issue of aging lead service lines is widespread and the cost to repair or replace the lead water lines, both public and private, would be immense.

Capital Hill is responding through an update to the Water Resources Development Act and includes provisions that aim to assist public water systems with the expensive task of ensuring their systems are safe. The House and Senate passed different versions of the bill in September and those differences will need to be worked out in conference committee before it is sent to the President. Both versions of the bill contain language authorizing assistance to Flint, making it likely the provisions will make it to the President's desk.

On October 26, 2016, the EPA released a White Paper explaining the options the agency is considering as part of its revisions to the Lead and Copper Rule. Among EPA's potential revisions is



mandatory, proactive, lead service line replacement, which has an estimated cost of \$2500 to \$8000 per line, suggesting the cost to replace all lead service lines nationwide could range between \$16 and \$80 billion dollars.

The House's bill includes an appropriation of \$170,000,000 for communities for which the President has declared an emergency due to chemical, physical, or biological constituents, including lead, for the repair or replacement of public and private infrastructure.

The Senate's version of the bill includes a \$300,000,000 appropriation and contains the following specific provisions not found in the House's version:

Report on Flint, Michigan Water Crisis

- Orders the U.S. Attorney General and EPA's Inspector General to submit a report on the status of any ongoing investigations into the Federal and State response to the contamination of Flint's drinking water supply.
- Orders the review of any issues not addressed by these ongoing investigations, including the adequacy of the response by the State of Michigan, the City of Flint, and Region 5 of the EPA, including timeliness and transparency of the response.
- Requires the Attorney General and Inspector General to examine the capacity of Michigan and the City

of Flint to manage the drinking water system.

- Requires a report including recommendations for Congress and the President to take any actions to prevent similar situations in the future and to protect public health.

Increased Funding

- Amends the Safe Drinking Water Act to allow the Environmental Protection Agency's capitalization grants for state drinking water revolving funds to be used to provide loans to public water systems for planning, design, siting, and associated preconstruction activities.
- Permits public water systems to use revolving funds as a source of revenue (restricted solely to interest earnings of the applicable State loan fund) or security for payment of the principal and interest on revenue or general obligation bonds issued by the State to provide matching funds, if the proceeds of the sale of the bonds will be deposited in the State loan fund.
- Requires states to prioritize projects that (1) address the most serious human health risks, (2) ensure compliance with safe drinking water requirements, (3) assist systems most in need on a per-household basis according to state affordability criteria, and (4) improve system sustainability.

- Requires the EPA to establish a grant program for projects that reduce the level of lead in water for human consumption through replacement of service lines, testing, planning, corrosion control, and education. Low-income homeowners can use the grant money to carry out lead-reduction projects.
- If an entity uses grant funds to replace lead service lines, it must: (1) notify customers of the replacement of any publicly owned portion of the line; (2) inform each customer that it will replace the public portions only if the customer agrees to simultaneously replace the privately owned portions; and (3) demonstrate that it has considered multiple options for reducing lead in drinking water, including an evaluation of options for corrosion control.
- The EPA and the USDA must: (1) update their programs that provide drinking water technical assistance to include information on cost-effective, innovative, and alternative drinking water delivery systems; and (2) disseminate information on the cost effectiveness of alternative drinking water delivery systems, including wells, to communities and nonprofit organizations seeking federal funding for drinking water systems

serving 500 or fewer persons.

Applicants for funding for drinking water systems serving 500 or fewer persons must consider drinking water delivery systems sourced by publicly owned individual, shared, and community wells.

Notification requirements

- Public water systems must notify their customers of lead concentration levels in drinking water that exceed lead limits under national primary drinking water regulations.
- The EPA: (1) must notify the public within 15 days of the lead levels exceeding those limits if the public water system or the state does not notify the public, and (2) may notify the public or the local or state health department of the result of lead monitoring conducted by a public water system.
- If a violation has the potential to have serious adverse effects on human health as a result of short-term exposure, notice must be provided to the Centers for Disease Control and Prevention and state and county health agencies.

Compliance Monitoring

- The EPA must require electronic submission of available compliance monitoring data by public water systems and states.

Lead in Schools

- The EPA must establish a voluntary school and child care lead testing program of grants to states to assist local educational agencies in voluntary testing for lead contamination in drinking water at schools and child care programs. The bill repeals the current program of federal assistance for state programs regarding lead contamination in school drinking water.

With the Senate and House both passing their own versions of the Water Resources Development Act (“WRDA”) bills in September, congressional aides are now working feverishly to bridge the differences between the two bills in an informal conference. However, the clock is ticking and a narrower House WRDA bill must be reconciled with the Senate’s much broader measure, which includes significant differences on Flint funding and sweeping changes to the country’s water and wastewater programs. Nonetheless, congressional aids hope to have a negotiated package ready for swift approval when lawmakers return after the November 8th election.

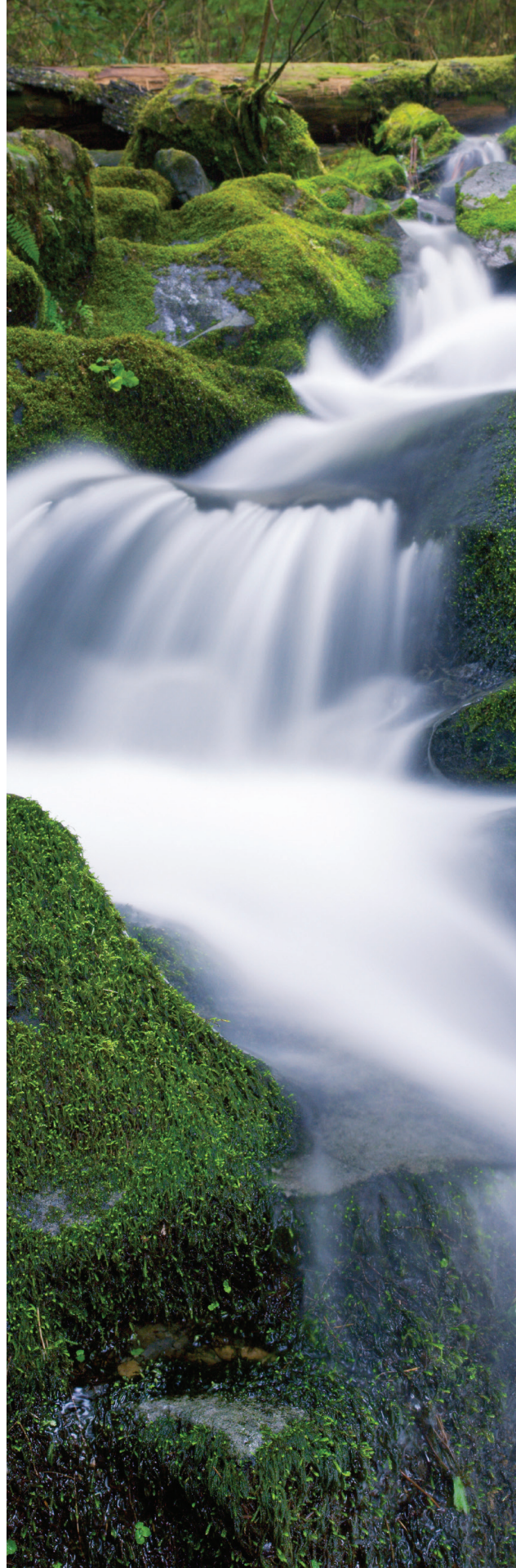
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THE NEW TOXIC SUBSTANCES CONTROL ACT REGIME

B. David Naidu, Molly E. Nixon¹

Forty years after it was first enacted, the Toxic Substances Control Act (“TSCA”) was substantially changed with the passage and enactment of The Frank R. Lautenberg Chemical Safety for the 21st Century Act (the “Lautenberg Act”). The new law, enacted on June 22, 2016, affects companies across a wide range of industries and gives the Environmental Protection Agency (“EPA”) new and expanded authority to regulate chemicals.

BACKGROUND

The original version of TSCA gave EPA the authority to regulate chemicals, requiring reporting, record keeping, testing, and restrictions on the production, importation, and use of chemicals that pose an unreasonable risk. Critics argued that the law was too burdensome and had impermeable barriers that severely constrained what EPA could do to regulate harmful chemicals. Despite being in effect for over 40 years, EPA ordered testing of only a few hundred of the more than 80,000 chemicals in use and restricted only a handful. In response, state governments tried to fill the void by enacting their own chemical laws. As a result, a patchwork of chemical regulations creating inconsistent and uneven requirements emerged, and regulatory uncertainty started to develop. The confluence of these factors created

a tidal wave of support for a long overdue major rewrite of TSCA. Some of the most salient changes ushered in by the Lautenberg Act are described below.

NEW CHEMICALS AND SIGNIFICANT NEW USES

Under both the original TSCA and the amended statute, manufacturers must submit notice of new chemicals, or significant new uses of existing chemicals, 90 days before manufacture or processing. Under the new statute, EPA must, within 90 days, review the notice and make an affirmative determination:

- a. that the chemical or new use presents an unreasonable risk of injury to health or the environment;
- b. that EPA has insufficient information or that the chemical or use may present an unreasonable risk; or
- c. that the chemical or use is likely not to present an unreasonable risk.

¹ With thanks and acknowledgement to our colleagues who also contributed to this and our other efforts on this topic: David L. Rieser, Edward P. Sangster, Stanford D. Baird, Barry M. Hartman, Cliff L. Rothenstein, Scott Aliferis, Kathleen L. Nicholas, Maureen O’Dea Brill, and Theresa A. Roozen.

It should be noted that while the new statute uses the term “unreasonable risk,” it does not define “unreasonable risk.” The statute does, however, articulate what can, and what does not need to be considered, in evaluating “unreasonable risk.” EPA, for instance, is no longer required to consider the monetary costs of an action when evaluating what is unreasonable or conduct a formal analysis showing that any restriction on the use of a chemical is the “least burdensome.” Instead, EPA is

directed to determine if an unreasonable risk exists without consideration of costs or other non-risk factors. The Lautenberg Act also removes the requirement to select the “least burdensome” option and instead now requires EPA to evaluate the costs and benefits and cost-effectiveness of options using reasonably available information. If EPA determines that a chemical presents an unreasonable risk, EPA’s options include banning the chemical, creating labeling requirements, or establishing use restrictions.





EPA also was given significant authority to require the development of new information relating to a chemical substance or mixture by rule, order, or consent agreement. EPA can request this information both in the context of evaluating whether the chemical poses an unreasonable risk and in the context of imposing restrictions or labeling requirements on the chemical. While the original statute allowed EPA to require testing to evaluate if a chemical presents an unreasonable risk, it could do so only after making a series of onerous findings. The Lautenberg Act authorizes EPA to act by rule, order, or consent agreement without making such findings.

EXISTING CHEMICALS

The Lautenberg Act also requires EPA to prioritize its review of existing chemicals based on certain identified risks and the EPA is moving forward with that process.

EPA must prioritize its review of chemicals listed on a work plan it has developed having persistence and bioaccumulation scores of 3 (the highest score) and those that are known human carcinogens

and have high acute and chronic toxicity. Alternatively, manufacturers may request that a specific chemical be evaluated. In deciding whether to grant such requests, the EPA will consider whether state restrictions on that chemical have the potential to have a significant impact on interstate commerce, health, or the environment. Chemical manufacturers and other parties will also have an opportunity to submit draft risk evaluations of their own to the EPA.

Risk evaluations, whether initiated by EPA or based on a request, must be completed no later than three years after initiation. If EPA finds that a chemical presents an unreasonable risk, it must propose a rule for the chemical no more than one year after the final risk evaluation for that chemical is published, and a final rule no more than two years after the final risk evaluation for that chemical is published. EPA will provide deadlines for compliance in each rule promulgated.

Finally, in order to create an inventory of active and inactive chemicals, EPA will require industries to report chemicals manufactured or processed in the previous ten years.

ARTICLES

The Lautenberg Act imposes new limits on EPA's ability to require significant new use notifications for articles (manufactured goods) or categories of articles that contain a chemical. These amendments are likely to result in more certainty and less delay in connection with the use of chemicals in manufactured goods and should provide industry with increased transparency with respect to the TSCA's application to articles. Under the new law, EPA may require notification of the importation or processing of a chemical substance as part of an article only if EPA has made an affirmative finding in a significant new use rule that the reasonable potential for exposure to a chemical through an article justifies notification. EPA can regulate such articles "only to the extent necessary to address the identified risks from exposure" to the chemical, so that the chemical does not present an unreasonable risk identified in EPA's risk evaluation. Although EPA has had the authority to regulate manufactured goods containing chemicals, the agency has generally not regulated articles, until recently.

Additionally, EPA may exempt articles (and chemicals) from requirements for specific conditions of use that are deemed critical and for which no technical and economically feasible alternative is available; where compliance would significantly disrupt the national economy, national security, or critical infrastructure; or when the specific use exempted provides a substantial benefit to health, the environment, or public safety.

STATE PREEMPTION

In the years leading up to enactment of the Lautenberg Act, chemical manufacturers, chemical distributors, and product retailers grew increasingly concerned by this growing patchwork of state chemical regulations. On the other hand, environmental and consumer groups did not want strong state statutes watered down. In 2016, legislators reached a preemption compromise that ultimately paved the way for passage of the bill that became the Lautenberg Act.

The Lautenberg Act includes two significant new preemption provisions. First and foremost, TSCA now precludes state action on a chemical if EPA determines through a risk evaluation that such chemical does not present an unreasonable risk or if EPA promulgates a rule to address the identified risks posed by the chemical. The scope of federal preemption matches the scope of the hazards, exposures, risks, and uses or conditions of use of a given chemical included in EPA's final action on such chemical. For example, if EPA were to conduct a risk assessment limited to a particular use of a chemical and did not evaluate or take final action related to other uses of the chemical, then preemption would not apply to such other uses. Importantly, preemption only occurs when EPA takes final action (whether by a determination of no unreasonable risk or a final rule addressing chemical risks).

Second, the law creates the new concept of "pause preemption." Under this

concept, a state is temporarily preempted from imposing any new restrictions on a given chemical from the time that EPA defines the scope of a risk evaluation for a high-priority chemical until EPA publishes its final risk evaluation or when the deadline for completing the evaluation expires, whichever is earlier. The scope of the preemption matches the scope of EPA's risk evaluation, so if certain risks or chemical uses are not included in the scope of EPA's risk evaluation, the "pause preemption" does not apply, and a state could take new action on such chemical related to risks or uses that are outside that scope.

Under the amended law, states maintain significant regulatory authority. For example, states can act on any chemical or particular use of a chemical that EPA has not yet addressed and can implement reporting, monitoring, or disclosure requirements not imposed under federal law. States also can adopt and enforce chemical regulations that are identical to the federal regulations.² As a practical matter, this empowers states to adopt parallel regulations and then to interpret and enforce them independently of EPA. One unresolved question is whether activist state regulatory authorities will interpret their parallel regulations differently from, or enforce them more aggressively than, EPA.

Perhaps most important, however, the Lautenberg Act includes two significant grandfathering provisions:

1. States may continue to enforce any actions taken or requirements imposed regarding specific chemicals prior to April 22, 2016; and
2. States may continue to enforce and take new regulatory actions regarding chemicals pursuant to state laws that were in effect on August 31, 2003.

The grandfathering provisions were a critical part of the compromise reached by legislators on preemption. In particular, the August 31, 2003 date preserves California's Proposition 65 law and regulations and Massachusetts' Toxics Use Reduction Act. There also is no preemption on state "right to know" or other laws requiring disclosure of the presence of, or exposures to, a chemical; nor does preemption apply to common law rights of action, laws granting remedies for civil relief, including damages, or penalties for criminal conduct.

Further reducing the reach of the federal preemption provisions, the new statute includes substantial state waiver provisions. Specifically, states may seek a mandatory waiver from pause preemption or a discretionary waiver from general preemption where certain criteria are

²States may be able to exert substantial, indirect influence over the use of chemicals through the adoption and enforcement of water quality, air quality, and waste treatment or disposal regulations by addressing different hazards, exposures, uses, and conditions of use.



established. States may also apply to EPA for discretionary waivers from the general preemption provisions. However, such waivers require rulemaking by EPA based on a determination that (i) compelling conditions warrant granting the waiver to protect health or the environment, (ii) compliance with the proposed state requirement would place no undue burden on interstate commerce, and (iii) the proposed state requirement is designed to address a risk that was identified using the best available science.

PROTECTION OF TRADE SECRETS

While continuing to protect trade secrets, the new law provides greater transparency and disclosure of information by tightening and expanding the conditions that companies must demonstrate before the EPA can protect

trade secrets. Critics of the old TSCA law successfully argued that the EPA was obligated to protect virtually any confidential business information (“CBI”) claim that was made and to protect the claims forever. The new law dramatically changes this. It now requires companies seeking protection from disclosure to assert their claims to the EPA concurrent with data that substantiates their claims and places a ten-year time limit on protecting the claims unless they are resubstantiated by the company. Unlike the old law, the new law also obligates the EPA to review all existing CBI claims to determine if the claims are still warranted. The new law also explicitly prohibits protection for certain types of information.

Under the new statute, generally, to obtain protection from disclosure, a nondisclosure claim must be submitted at the time information is submitted to

the EPA. The submitter now must make a statement that he or she has:

- i. taken reasonable measures to protect the confidentiality of the information;
- ii. determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- iii. a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- iv. a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

It also requires that submitters substantiate their claims for nondisclosure in accordance with

rules already promulgated and those promulgated in the future.

Some types of information that cannot obtain confidential protection have expanded, while there has been constriction in other areas. For example, general manufacturing information, such as manufacturing volumes and/or the general description of the processes used, are not afforded protection. If a chemical is banned or phased out, the submitted information in relation to the banned or phased-out chemical is presumed to lose protection. The presumption against protection is limited (thus, protection may be permitted) when the information is related to a critical use chemical, an export chemical (if certain criteria is met), or a specific conditions of use chemical.

Under original TSCA, CBI claims did not expire. However, under the new TSCA, CBI claims generally expire after



ten years. Manufacturers may request an additional ten-year extension. The EPA may grant an unlimited number of extensions. To obtain an extension, one must request an extension, substantiating the need for the extension in the request, no later than 30 days before the expiration of the original 10-year term.

However, for certain types of CBI (such as marketing information, customer data, or manufacturing processes), the 10-year period does not apply. Instead, the information remains protected unless the claimant withdraws the claim or the EPA Administrator learns that the information is no longer eligible for protection.

If a manufacturer's CBI request is denied by the Administrator, he or she may appeal the decision in a court of appeals of the United States. The codification of the right to prevent disclosure affords a little more protection than previously provided under the regulations because the statute now requires that the information not be disclosed while the action is pending (with a few exceptions), effectively removing the EPA's ability to disclose information, after notice, when it appears that the person seeking protection is not acting in an appropriate and expeditious manner.

CONCLUSION

Companies and other stakeholders should not wait to begin assessing the impact of TSCA reform on their operations and should consider taking advantage of opportunities to engage with EPA as it begins the implementation process. EPA will exercise significant discretion in implementing the Lautenberg Act and stakeholders may be able to influence EPA in its interpretation of the Act. Interested entities and individuals will be able to submit comments to EPA at various points over the next few years as EPA develops rules and guidance and may be able to advocate for advantageous interpretations of the law. Engagement with legal and policy professionals with agency experience will be critical to identify the appropriate time and circumstances in which an industry participant should make its views known to the regulator.

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The image features a light blue background with a white silhouette of a world map. In the top left corner, there is a dark blue rectangle containing the text 'K&L GATES' in white. To the right of this rectangle, the text 'GLOBAL LEGAL COUNSEL ACROSS FIVE CONTINENTS' is displayed in a bold, dark blue font. Three purple circles of varying sizes are overlaid on the map, each containing a list of city names in white text. The largest circle is positioned over North America, the medium circle is over Europe, and the smallest circle is over South America.

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