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Three Years After— Where Does Implementation of the Lautenberg Act Stand?

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On June 22, 2016, President Barack Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Lautenberg Act made substantial revisions to the forty-year-old Toxic Substances Control Act (TSCA), passed by Congress and enacted into law in 1976. It passed both houses of Congress with overwhelming support—in the House of Representatives by a vote of 403-12 and the Senate by an uncontested voice vote.[1] Republicans and Democrats alike, including both Senator James Inhofe, the Republican Chairman of the Senate Environment and Public Works Committee, and Senator Barbara Boxer, the Ranking Democrat on the same Committee, hailed its passage.

At the signing ceremony, President Obama stated:

> For the first time in 20 years, we are updating a national environmental statute. For the first time in our history, we'll actually be able to regulate chemicals effectively. And we're doing it in the same, overwhelmingly bipartisan fashion as happened with those pillars of legislation to protect our air, and our water, and our wildlife—the initiatives where Democrats and Republicans first came together to pass laws more than four decades ago. And that doesn't happen very often these days. So this is a really significant piece of business.
>
> The Frank R. Lautenberg Chemical Safety Act for the 21st Century will make it easier for the EPA to review chemicals already on the market, as well as the new chemicals our scientists and our businesses design. It will do away with an outdated bureaucratic formula to evaluate safety, and instead focus solely on the risks to our health. And it will finally grant our scientists and our public servants at the EPA the funding they need to get the job done and keep us safe.
>
> So this is a big deal. This is a good law. It is an important law. Here in America, folks should have the confidence to know that the laundry detergent we buy isn't going to make us sick, the mattresses our babies sleep on aren't going to harm them. And just like in the 1970s, when we decided to do something about smog that was choking our cities and our auto industry was able to innovate to make our cars cleaner, just like in the 1990s, when we had the problems with acid rain and our businesses figured out a way to do something about it and still keep growing and thriving, I'm absolutely confident that we can regulate toxic chemicals in a way that's both good for our families and ultimately good for business and our economy—because nobody can innovate better than folks here in this country and our businesses.
>
> In fact, we've got a lot of industry leaders here today who've pushed hard for this law, and I

1 Roll no. 238 (May 24, 2016), http://clerk.house.gov/evs/2016/roll238.xml; 162 Cong. Rec. S3523 (June 7, 2016) (voice vote in Senate).

> want to give them credit—from the American Chemistry Council to S.C. Johnson—because they know that it gives them the certainty they need to keep out-innovating and out-competing companies from other parts of the world. And the public health and environmental leaders who are [here] today—from March of Dimes to the Environmental Defense Fund—know that this law will help protect Americans, especially those who are particularly vulnerable to chemicals—and that includes children, and pregnant women, and the elderly, and poorer communities.[2]

This article will explore significant aspects of the history and implementation of the original TSCA, the revisions made to TSCA in 2016 by the Lautenberg Act, and EPA's experience in implementing the Lautenberg Act after its passage in June 2016. It will highlight certain facets of the legislative history of the original TSCA and some elements of EPA's experience implementing TSCA over the following decades. It will not attempt to lay out a comprehensive legislative history of TSCA or its subsequent revisions, but will highlight portions of the background of the original TSCA that indicate the nature of the problems—both in terms of environmental issues and legal issues—that Congress was attempting to deal with in the early 1970s as they are relevant to the scope and nature of current TSCA as revised by the Lautenberg Act.

With respect to EPA's recent experience under the Lautenberg Act, this article will point out some of the more significant issues EPA has faced and actions it has taken. While EPA has made significant progress in implementing the Lautenberg Act revisions, recent approaches to implementation may undercut some of the protectiveness written into revised risk standards.

I. The First Forty Years of TSCA

TSCA was one of the core environmental statutes enacted in the 1970s. The Nixon Administration first proposed legislation in a 1971 report by the Council on Environmental Quality (CEQ) entitled *Toxic Substances*.[3] Over five years later, on October 11, 1976, President Ford signed it into law.[4] In between the publication of the CEQ report and enactment lay a long legislative path filled with multiple bills and disputes.

2 Office of the Press Secretary, *Remarks by the President at Bill Signing of the Frank R. Lautenberg Chemical Safety for the 21st Century Act* (June 22, 2016), https://obamawhitehouse.archives.gov/the-press-office/2016/06/22/remarks-president-bill-signing-frank-r-lautenberg-chemical-safety-2st.

3 U.S. Council on Environmental Quality, *Toxic Substances* (Apr. 1971), *reprinted in* Environmental and Natural Resources Policy Division, Legislative History of the Toxic Substances Control Act 757 (1976) (hereafter cited as "CEQ Report").

4 Linda-Jo Schierow, Congressional Research Service Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements* 2 (Apr. 1, 2013), https://fas.org/sgp/crs/misc/RL31905.pdf.

A. The CEQ Report: A Call to Action

Written almost 50 years ago, the 1971 CEQ Report laid out the concerns that led to the enactment of TSCA. Russell Train, then the head of CEQ, became the second EPA Administrator in 1973. CEQ's 1971 report pointed out the health and environmental problems arising from chemical substances, noting that particular concerns existed with respect to the increasing numbers and use of synthetic organic chemicals, metals, and metallic compounds.[5]

> "CEQ underscored the shortcomings of media-based statutory authority and emphasized the need for new authority that focused on "the total human exposure to a substance and its total effect on the environment" and the need to be able to control pollutants before emissions or effluents are produced."

The CEQ described the inadequacies of existing federal legal authorities. It grouped existing authorities into two categories. The first was statutes such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and laws regarding drugs and food additives, which controlled the initial production and distribution of substances. CEQ commented that, "[a]lthough this control technique can be very effective, current authorities cover only a small portion of the total number of potentially toxic substances and do not deal with all uses of a substance which may produce toxic effects."[6] The second category of legal authorities included media-oriented laws aimed at water and air pollution from a variety of sources. In reading the 1971 report, it should be borne in mind that significant revisions to such laws occurred after the passage of TSCA in 1976 (e.g., the Clean Air Act amendments of 1990). The CEQ report analyzed the problematic issues with such legislation perceptively, pointing out several concerns. The concerns included difficulties under those laws in dealing with small quantities of dangerous substances, the disposal of consumer products, and the total exposure to substances that occurs from multiple pathways (e.g., air, water, and industrial and consumer products).

Later in its report, CEQ underscored the shortcomings of media-based statutory authority and emphasized the need for new authority that focused on "the *total* human exposure to a substance and its *total* effect on the environment"[7] and the need to be able to control pollutants before emissions or effluents are produced. The 1971 report stated that the "obvious limitation of controls over effluents is that they generally deal with a problem

5 CEQ Report, *supra* note 3, at iv.

6 *Id.* at v.

7 *Id.* at 20 (emphasis in original).

only *after* it is manifest. They do not provide for obtaining information on potential pollutants before widespread damage has occurred."[8]

"CEQ explained how the toxic substances legislative proposal differed from previously-existing legislation such as the Clean Air Act."

CEQ argued strongly for the need for new legal authority to protect people proactively. "Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capability to monitor and predict, although inadequate, are sufficiently developed that we need no longer remain in a purely reactive posture with respect to toxic substances. We should no longer be limited to repairing the damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory."[9]

The Nixon Administration proposed legislation in February 1971 to address the issues outlined by CEQ in a way that did not handicap innovation or impair interstate commerce. That legislation empowered EPA to protect health or the environment by restricting or prohibiting the use or distribution of a chemical substance. Notably, the benefits of each substance would need to be weighed against the adverse effects from it. The legislative proposal also authorized EPA to require testing of substances, to request information from manufacturers, and go to court to restrain immediately the use or distribution of a chemical substance if it were creating an imminent hazard. The proposal charged CEQ with creating a uniform system for classifying substances.[10]

In its report, CEQ explained how the toxic substances legislative proposal differed from existing legislation such as the Clean Air Act. It emphasized the legislation's systematic comprehensive approach to dealing with the environmental and health impacts of toxic chemicals, as opposed to focusing on problems present in individual media such as air or water:

The approach called for in TSCA is a new way of looking at environmental problems. Rather than dealing with pollutants as they appear in air, in water, and on land, it represents a systematic and comprehensive approach to the problem. It relies on understanding the flow of potentially toxic substances throughout the entire range of activity—from extraction to production to consumer use and to disposal. Only through such a comprehensive approach can we provide protection to man and his environment.[11]

Clearly, the proposal that kicked off the legislative process that led to the passage of TSCA five years later represented a fundamental change in approach

8 *Id*.

9 *Id*. at v.

10 *Id*. at vi.

11 *Id. See also id*. at 21–22.

from earlier statutes. Those rules generally focused on specific media such as air or water, and on either effluent limitations or controls on production and distribution. The new toxic substances legislation embodied a multi-media approach that focused on all the health and environmental effects of particular chemicals and provided comprehensive authority over the full range of activities in which a toxic chemical substance was present. The legislative proposal also moved in the direction of pollution prevention, rather than focusing solely on efforts to reduce discharges into air and water.

B. Senate Consideration of TSCA

Congress underscored the importance of the approaches laid out in the CEQ Report as the underpinnings for the new legislation as it closed in on the passage of TSCA. In March of 1976, the Senate Commerce Committee Report emphasized the pollution prevention aspects of TSCA:

> While these other authorities [e.g., clean air and water laws that focus on discharges and emissions] will in many cases be sufficient to adequately protect health and the environment, the alternative of preventing or regulating the use of the chemical in the first instance may be a far more effective way of dealing with the hazards. If expensive sewage treatment facilities can be avoided, for example, through removing dangerous materials from household and industrial wastes, the authority to do so ought to be provided.[12]

It also pointed to the lack of comprehensive regulatory authority under other laws as an issue the new legislation would tackle by giving EPA the authority to look at all the hazards of a chemical. The Commerce Committee Report noted that "there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant the Environmental Protection Agency the authority to look at the hazards in total."[13] In addition, the Senate Commerce Committee affirmed the importance of the provisions of the bill that would provide for pre-market review of chemicals, something lacking in most other environmental statutes.[14]

The Senate Commerce Committee reported that the proposed toxic chemicals legislation would close gaps in existing legal authorities for dealing with adverse health and environmental effects of chemicals before their manufacture commenced.[15] Closing these gaps would lead to a more efficient and effective approach than establishing limitations only after production when the costs of regulation are higher. Referring to a February 1976 speech by EPA Administrator Train, the Senate Commerce Committee listed numerous chemicals responsible for significant health and environmental problems

12 S. Rep. No. 94-698 (Mar. 16, 1976), section 2 of Purpose and Brief Description.

13 *Id.* at section 3 of Purpose and Brief Description.

14 *Id.* at section 1 of Purpose and Brief Description.

15 *Id.* at section on Background and Needs.

that had not been addressed under existing law and reiterated the importance of dealing with the risks posed by chemicals before their production. The Senate Commerce Committee Report agreed with Administrator Train regarding the growth in the number of widely-used chemicals that posed significant health and environmental dangers. These chemicals included fluorocarbons that deplete the ozone layer and lead to increases in skin cancer, carcinogens such as PCBs, vinyl chloride, arsenic, and asbestos, and heavy metals such as mercury and lead.

The partial list of chemicals in the Senate Commerce Committee Report included chemicals that contributed to global environmental problems (e.g., fluorocarbons) and chemicals (such as mercury and lead) subject to regulation under other laws like the Clean Air Act. On the eve of its passage by Congress, Senators viewed TSCA as a mechanism to address environmental problems presented by chemical substances more comprehensively and effectively than existing laws.

The Senate Commerce Committee further examined the relationship of the new legislation to other environmental and health legislation, whether administered by EPA or by some other agency. The Committee's report displayed an understanding that the new law would deal with overlapping legal authorities by allowing TSCA to advance more efficient and effective means of control even for chemicals regulated in other ways, e.g., emission standards established under the Clean Air Act. For example, the report explained that section 9 of TSCA "requires the Administrator of EPA to utilize other Federal laws which he administers unless he determines that the risk may be more appropriately protected against by utilizing this authority." [16] It went on to emphasize the importance of the availability of TSCA's authority, noting TSCA would allow EPA to "regulate a dangerous chemical substance contained within a consumer product, rather than being required to control it later through an effluent standard or emissions standard, which may be a far more inefficient and expensive method of regulation."[17] The Committee also pointed to procedures in the bill that accounted for overlapping jurisdiction of other agencies under certain laws by providing a mechanism for the other agency to make a risk determination and take action under its authority before allowing EPA to move forward under TSCA.[18]

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16 *Id.* at section 3.

17 *Id.*

18 *Id.*

These aspects of the legislative background of the original TSCA show that the proponents of the legislation in both the Executive Branch and Congress saw TSCA as necessary to grapple with environmental problems, including those of global significance, that may well have been subject to other environmental statutes such as the Clean Air Act or Clean Water Act. They saw limitations in how the other statutes addressed environmental issues. Most existing rules focused on controlling emissions or discharges of the pollutants instead of altering production processes to avoid generating pollutants in the first place. The existing statutes did not focus on total risk from or exposure to chemicals. Unlike the new toxic chemicals legislation, they did not provide a mechanism capable of dealing with environmental problems from chemicals in a comprehensive manner, e.g., taking into account all the ways exposure to a chemical might occur. Both Congress and the Executive Branch intended TSCA to do all of that.

C. Early Implementation Challenges

Despite the many hurdles EPA faced when first applying TSCA, it was able to move forward with its implementation efforts. The challenges encompassed both new and existing chemicals, and the implementation of the inventory requirements needed to establish the status of chemicals.[19]

Over the years EPA explored the use of TSCA for various environmental problems, including its use to deal with chlorofluorocarbons and aerosols that impaired the protection provided by the stratospheric ozone layer (one of the issues flagged as a concern leading to the passage of TSCA).[20] EPA chronicled its implementation efforts in annual reports that laid out its priorities and the implementation steps it was taking.[21] Citizen groups and others, with varying

19 Section 2(2) of TSCA (15 U.S.C. § 2602(2)) defines chemical substance very broadly as meaning "any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical." It does provide for certain specific exceptions such as mixtures, pesticides, tobacco or tobacco products, nuclear materials, firearms subject to certain taxes and components of firearms including shot shells and cartridges, and foods, food additives, drugs, and cosmetics as defined in the Food, Drug and Cosmetic Act. TSCA then divides chemical substances into new and existing chemical substances. New chemical substances (and significant new uses of chemical substances) are subject to regulation under Section 5. Existing chemical substances are subject to regulation under Section 6. Section 2(11) (15 U.S.C. § 2602(11)) defines "new chemical substance" as "any chemical substance which is not included in the chemical substance list compiled and published under" section 8(b), which is the inventory. The inventory was first published in 1979 and is "a list of each chemical substance which is manufactured or processed in the United States." Section 8(b)(1) (15 U.S.C. § 2607(b)(1)). The chemical substance inventory is periodically updated. New chemicals subject to section 5 become existing chemicals subject to section 6 once the manufacturer submits a Notice of Commencement of Manufacture or Import (NOC) to EPA and the chemical is added to the inventory. *See* EPA, "How are chemicals added to the Inventory?," https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory#howare (accessed June 19, 2019). There are now about 85,000 chemicals on the TSCA inventory. *See* EPA, "What is the TSCA Chemical Substances Control Inventory?," https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory (accessed June 19, 2019).

20 42 Fed. Reg. 24,536 (May 13, 1977) (proposal to eliminate CFCs used as aerosol propellants); 43 Fed. Reg. 11,318 (Mar. 17, 1978) (final rule banning CFCs used as propellants under section 6 of TSCA); 45 Fed. Reg. 66,726 (Oct. 7, 1980) (ANPR regarding broader regulation of CFCs).

21 *See, e.g.,* EPA, *Administration of the Toxic Substances Control Act (1979)* (July 1980), https://nepis.epa.gov.

degrees of success, also filed petitions under section 21 of TSCA to push EPA to act on various issues from dioxin to water pollution coming across the border with Mexico.[22]

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D. The *Corrosion Proof Fittings* Case and its Aftermath

EPA's efforts to deal with significant problems arising from existing chemicals essentially came to a halt in the early 1990s after the US Court of Appeals for the Fifth Circuit struck down EPA's regulation banning the use and manufacture of asbestos products in *Corrosion Proof Fittings v. EPA*.[23] EPA undertook a 10-year effort to regulate asbestos under TSCA. It began in 1979 with the issuance of an Advance Notice of Proposed Rulemaking and ended with the promulgation of the asbestos ban in 1989.

After reviewing a multitude of studies and taking public comment at various stages in the process, EPA issued a rule that phased in a ban of the manufacture, processing, import, and distribution of most asbestos-containing products.[24] Petitioners successfully challenged the rule based on both procedural and substantive grounds.

Perhaps most significantly, the Fifth Circuit struck down the rule because it found that EPA failed to meet the TSCA requirement of using "the least burdensome regulation to achieve its goal of minimum reasonable risk."[25] In doing so, the court melded the least burdensome requirement for regulations with the benefit-cost balancing nature of TSCA's unreasonable risk standard. The court explained: "This statutory requirement can create problems in evaluating just what is a 'reasonable risk.' Congress's rejection of a no-risk policy, however, also means that in certain cases, the least burdensome yet still adequate solution may entail somewhat more risk than would other, known regulations that are far more burdensome on the industry and the economy. The very language of TSCA requires that the EPA, once it has determined what an acceptable level of non-zero risk is, choose the least burdensome method of reaching that level."[26]

The court faulted EPA's analysis of the alternatives, finding it did not fulfill TSCA's requirements. The court noted first that "TSCA requires the EPA to

22 *See* 50 Fed. Reg. 4,426, 4,431 (Jan. 30, 1985) (granting petition regarding testing of dioxin and furans); 59 Fed. Reg. 13,721 (Mar. 23, 1994) (response to petition concerning cross-boundary water pollution submitted by Board of Supervisors of Imperial County, California).

23 947 F.2d 1201 (5th Cir. 1991).

24 54 Fed. Reg. 28,460 (1989).

25 947 F.2d at 1215.

26 *Id.*

consider, along with the effects of toxic substances on human health and the environment, 'the benefits of such substance[s] of mixture[s] for various uses and the availability of substances for such uses,' as well as 'the reasonably ascertainable economic consequences of the rule, after consideration for the effect on the national economy, small business, technological innovation, the environment, and public health.'"[27] Stating that EPA's record presented just two possibilities—"a world with no further regulation under TSCA, and a world in which no manufacture of asbestos takes place"—the court faulted EPA for not examining the costs and benefits of intermediate levels of regulation (e.g., new labeling or use restrictions short of a complete ban). In the court's view, EPA needed to analyze these potential actions "to show that there is not some intermediate state of regulation that would be superior to both the currently-regulated and the completely-banned world. Without showing that asbestos regulation would be ineffective, the EPA cannot discharge its TSCA burden of showing that its regulation is the least burdensome available to it."[28] According to the court, EPA rejected options other than a ban in an offhand fashion. Moreover, the court stated that by not analyzing the costs and benefits of other options EPA made it "impossible, both for the EPA and for this court on review, to know that none of these alternatives was less burdensome than the ban in fact chosen by the agency."[29]

Interestingly, the court agreed with EPA's decision to utilize TSCA to deal with asbestos notwithstanding the existence of other possible legal authorities. The court explained that EPA had decided that it was not appropriate to defer to the regulation of workplace and consumer exposures of asbestos by other agencies (e.g., OSHA and the CPSC) "because no one other authority could address all the risks posed 'throughout the life cycle' by asbestos, and any action by one or more of the other agencies still would leave an unacceptable residual risk."[30] Finding much of EPA's analysis correct, the court explicitly upheld EPA's "basic decision to use TSCA as a comprehensive statute to fight a multi-industry problem."[31]

After faulting EPA for not satisfying TSCA's "least burdensome" requirement, the court engaged in a detailed evaluation of EPA's cost-benefit analysis and determined that serious flaws existed. These flaws primarily concerned EPA's reliance on the "unquantified benefits" of lives saved after the year 2000 to offset costs, and what the court viewed as double counting of the costs of asbestos use.[32]

The Fifth Circuit determined that EPA lacked a reasonable basis for the asbestos ban on the basis of flaws other than the ones it found in EPA's analysis of the "least burdensome" requirement and cost-benefit analysis methodology. The court found fault with EPA's ban of certain uses of asbestos for which substitutes did not exist. While the court agreed

27 *Id.* at 1216 (quoting TSCA section 6).

28 *Id.* at 1217.

29 *Id.*

30 *Id.* at 1216.

31 *Id.*

32 *Id.* at 1218–19.

with EPA that a ban could lead to innovation and the development of substitutes, the court criticized EPA for not considering the lack of substitutes. The court stated EPA could ban products that did not have adequate substitutes, but faced a heavier burden when doing so. Perhaps more significantly, the court also found that EPA's failure to consider potential harms from substitute products (which included some that contained known carcinogens) fatal to its conclusions that alternative products posed less risk. While stating that EPA did not have a burden under TSCA of seeking out and testing every possible substitute, the court opined that EPA must consider the comparative risk of substitutes if a party brought credible evidence of such risks to the agency's attention. In light of EPA's concession that many substitutes for asbestos were themselves carcinogenic, the court concluded that "EPA not only cannot assure this court that it has taken the least burdensome alternative, but cannot even prove that its regulations will increase workplace safety. Eager to douse the dangers of asbestos, the agency inadvertently actually may increase the risk of injury Americans face."[33]

The court further found that the agency's overall evaluation of costs and benefits was "meaningless."[34] The high cost per life saved of the ban—as high as $74 million per life according to the court—underlay the Fifth Circuit's conclusion. The court stated with some level of incredulity that "EPA would have this court believe that Congress, when it enacted its requirement that the EPA consider the economic impacts of its regulations, thought that spending $200-300 million to save approximately seven lives (approximately $30-40 million per life) over thirteen years is reasonable."[35]

Finally, the court reviewed EPA's findings with respect to each category of products covered by the ban and found all but one set of determinations flawed. While the court's discussions of each product category generally mirrored its overall analysis of EPA's decisions, it particularly critiqued the agency for not evaluating the potential of non-asbestos replacement brakes for vehicles to lead to greater highway deaths and the potentially toxic nature of asbestos alternatives.[36] The one product category determination upheld by the court concerned products that had been, but were no longer being produced in the US. The court clearly determined EPA had the authority to ban such products to avoid the prospect of their being produced again in the US. The court found little merit to the petitioners' arguments to the contrary, noting EPA had the statutory authority to ban a product that "presents or will present" a significant risk. The court also agreed that EPA could promulgate a "clean up ban" of unknown future uses or products. The court reasoned that even though the costs and benefits of unknown products could not possibly be evaluated, "the nebulousness of these future products, combined with TSCA's language authorizing the EPA to ban products that 'will' create a public risk, allows the EPA to ban future uses of asbestos even in products

33 *Id.* at 1221.

34 *Id.* at 1223.

35 *Id.* at 1222–23.

36 *Id.* at 1225.

not yet on the market."[37]

After the *Corrosion Proof* decision invalidated the results of a decade of effort to deal with a chemical of great concern, EPA stepped back from regulating existing chemicals due to the perceived very high burdens of meeting TSCA's cost-benefit balancing requirement and showing that it was promulgating the "least burdensome" regulatory requirements needed to address any identified unreasonable risk.[38] EPA did not issue another final risk management rule regulating an existing chemical under section 6 of TSCA until 2019 when the agency took final action on a rule proposed on the last day of the Obama Administration.[39] EPA instead focused its implementation efforts on the new chemical aspects of the law by reviewing premanufacture notifications (PMNs) and issuing Significant New Use Rules (SNURs) to restrain new uses of chemicals for which it had concerns.

37 *Id.* at 1229.

38 *See* Linda-Jo Schierow, Congressional Research Service Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges* 17 (July 28, 2009).

39 The EPA took final action regulating consumer uses of methylene chloride for stripping paints and other coatings but did not take final action on the proposed regulations regarding commercial uses. 84 Fed. Reg. 11,420 (Mar. 27, 2019) (codified at 40 C.F.R. pt. 751); 82 Fed. Reg. 7,464 (Jan. 19, 2017) (proposal).

II. Major Changes Made by the Lautenberg Act

The 2016 Lautenberg Act[40] made fundamental changes to TSCA. For example, it eliminated the role of costs and economic factors in evaluating whether chemical substances present an unreasonable risk by redefining the standard to no longer consider such factors. The Lautenberg Act established deadlines and a schedule for EPA to review existing chemicals and a new process for conducting such reviews. With respect to new chemicals, the Lautenberg Act introduced a requirement for EPA to affirmatively approve chemicals before they enter the marketplace. In addition, the Lautenberg Act modified the provisions of TSCA governing the disclosure of information and the preemptive effects of TSCA on state laws and regulatory or administrative actions.

A. Revision of the Unreasonable Risk Standard

Perhaps the most significant change to TSCA wrought by the Lautenberg Act was its express elimination of the consideration of costs and economic factors from EPA evaluations of whether a chemical substance presents an unreasonable risk to health or the environment. In a statement included in the Congressional Record at the time of the Lautenberg's Act passage by the Senate, the

40 The act's full name is The Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Senate Democratic negotiators explained that TSCA, as it stood before the Lautenberg Act, "authorized EPA to regulate chemical substances if it determines that the chemical substance 'presents or will present an unreasonable risk of injury to health or the environment'" and that such an evaluation required EPA "to consider the costs of any proposed actions."[41] The statement went on to explain the differing approach of the new amendments, specifically noting,

> The [Lautenberg Act] clearly rejects that approach to determining what "unreasonable risk of injury to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors" and, if they do, to promulgate a rule that ensures "that the chemical substance no longer presents such risk." In this manner, Congress has ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment and regulates the chemical if it does, the Agency may not apply the sort of "balancing test" described above.[42]

To make this change to TSCA's unreasonable risk approach, Congress added statutory language in a variety of contexts that expressly precludes EPA's consideration of "costs or other nonrisk factors" from the analysis of what constitutes unreasonable risk. For example, in section 6(b)(4)(F)(iii), Congress provided that EPA "may not consider costs or other nonrisk factors" when conducting risk evaluations. With respect to new chemicals, which are subject to the provisions of section 5 of TSCA concerning pre-manufacture notifications, Congress required in section 5(a)(3)(A) that EPA review the pre-manufacture notice and determine "that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors ...."[43] For existing chemicals, section 6(b)(4)(A) requires that the "Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."[44] EPA followed this statutory command in its risk evaluation rule, published on July 20, 2017, by stating simply that the "risk evaluation must not consider costs or other non-risk factors."[45]

41 162 Cong. Rec. S3516 (June 7, 2016).

42 *Id. See also* 162 Cong. Rec. S3513 (June 7, 2016) (statement of Sen. Udall) ("Today, the old law requires that the EPA consider the costs and benefits of regulation when studying the safety of chemicals. Very soon, EPA will have to consider only the health and environmental impacts of a chemical. If they demonstrate a risk, EPA will have to regulate."); 162 Cong. Rec. S3512 (June 7, 2016) (statement of Sen. Boxer) ("The bill requires EPA to evaluate chemicals based on risks ... not costs, ...").

43 Section 5(a)(3)(A) (15 U.S.C. § 2604(a)(3)(A)).

44 *See also* section 5(a)(3)(B); section 5(a)(3)(C); section 5(e)(1)(A); section 5(f); section 6(b)(1)(B) (15 U.S.C. §§ 2604(a)(3)(B)–(C), (e)(1)(A), (f), 2605(b)(1)(B).

45 82 Fed. Reg. 33,726, 33,727 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

While Congress did preserve a limited role for costs and economic considerations in the regulation of existing chemical substances under section 6, it imposed the fundamental obligation on EPA to regulate a chemical substance or mixture that poses an unreasonable risk "to the extent necessary so that the chemical substance or mixture no longer presents such risk."[46] Thus, the Lautenberg Act requires EPA to eliminate the unreasonable risk posed by an existing chemical substance or mixture, which EPA must determine without any consideration of costs or other nonrisk factors.

1. SECTION 6 PROVIDES LIMITED CONSIDERATION OF COSTS AND ECONOMIC FACTORS

Nonrisk factors may arise as part of EPA's regulatory activities regarding existing chemicals in any of three different ways. First, in utilizing its section 6(a) authority, EPA must publish a statement covering the "reasonably ascertainable economic consequences of the rule," including factors such as

i. the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

ii. the costs and benefits of the proposed and final regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator; and

iii. the cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator.[47]

While this provision directs EPA to consider economic factors and the costs and benefits of a rule, such consideration occurs in the context of EPA's decision of which regulatory path to take, all of which must eliminate the unreasonable risk posed by the chemical substance. Thus, these factors may affect the manner in which EPA decides to achieve the elimination of the risk, but they do not affect the objective of that regulatory path—i.e., the elimination of an unreasonable risk to health or the environment determined without regard to costs or other nonrisk factors.

> "[T]he Lautenberg Act requires EPA to eliminate the unreasonable risk posed by an existing chemical substance or mixture, which EPA must determine without any consideration of costs or other nonrisk factors."

First, Congress authorized EPA to consider economic factors when deciding to prohibit a specific condition of use for a chemical or a apply a restriction that "substantially prevents a specific condition of use of

46 Section 6(a) (15 U.S.C. § 2605(a)).

47 Section 6(c)(2)(A) (15 U.S.C. § 2605(c)(2)(A)).

a chemical."[48] In such an instance, and when EPA is determining the length of an appropriate transition period for such a regulation to take effect, the Lautenberg Act directs EPA to "consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."[49]

Second, Congress also called for EPA to consider nonrisk factors when it relies on section 6(g) to create narrow exemptions to section 6(a) requirements governing existing chemicals. As revised in 2016, TSCA authorizes EPA to create exemptions from a requirement "for a specific condition of use of a chemical substance or mixture"—i.e., not an entire chemical, just specified conditions of use—if EPA finds that:

A. the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

B. compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

C. the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.[50]

The Lautenberg Act limits such exemptions to a reasonable time period but authorizes EPA to extend the time period.[51]

The establishment of the explicit authority for EPA to create these exemptions as part of a rulemaking under section 6(a) demonstrates the sweeping nature of the changes to the concept of unreasonable risk wrought by the Lautenberg Act. This exemption authority confirms that Congress meant what it said when it provided that cost or other nonrisk factors were not to play a role in the determination of unreasonable risk to health or the environment. If Congress had not excluded those factors or considerations from the unreasonable risk determination itself, there would have been no need to include explicit statutory language providing EPA with the authority to create limited exemptions from section 6 requirements premised on economic and other nonrisk factors. For example, it would not have been necessary for Congress to grant EPA authority to exempt conditions of use from the requirements due to significant disruptions to the national economy, critical infrastructure, or national security, if EPA could have taken into account economic or other nonrisk factors in the underlying unreasonable risk determination (as it could have under pre-Lautenberg Act TSCA). Moreover, the narrow scope

48 Section 6(c)(2)(C) (15 U.S.C. § 2605(c)(2)(C)).

49 *Id.*

50 Section 6(g)(1) (15 U.S.C. § 2605(g)(1)).

51 Section 6(g)(3) (15 U.S.C. § 2605(g)(3)).

of this exemption authority ("significantly disrupt") shows that lesser disruptions, even of national security, critical infrastructure, and the national economy, do not justify an exemption, thereby confirming that the provision in no way suggests that costs or other nonrisk factors may be considered more broadly.

2. IMPACT OF NEW UNREASONABLE RISK STANDARD ON TSCA SECTIONS 9 AND 21

Other provisions of TSCA have had their import changed significantly due to the changes in the concept of unreasonable risk. These provisions include section 9, which addresses the relationship of TSCA to other federal statutes, and section 21, which authorizes citizens to petition EPA to take action under TSCA.

> "Section 21, a citizen petition provision unique to TSCA, establishes 'unusually powerful procedures for citizens to force EPA's hand.'"

Section 9 speaks to the interaction between TSCA and other statutes, whether administered by EPA or by other agencies. A key criterion that affects how actions under the Lautenberg Act are coordinated with other statutes is whether "a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws."[52]

As cost and nonrisk considerations have now been eliminated from TSCA's unreasonable risk standard, how actions taken under other statutes compare with the risk reduction that would be achieved directly under TSCA has also changed. An action that may have reduced a pre-Lautenberg Act unreasonable risk by a "sufficient extent" may not necessarily do so under the revised concept of unreasonable risk. While "sufficient extent" leaves some room for interpretation (e.g., section 9 does not say the risk must be reduced under the other statute to the "same extent" as under TSCA), what is a sufficient reduction is likely affected by the nature of the pollution reductions required under different statutes. For example, another statute may require reductions reflecting practicability or economic considerations. Those reductions may have reduced risk to a "sufficient extent" when compared to TSCA prior to June 22, 2016, but they may no longer do so in light of the revised concept of unreasonable risk put in place by the Lautenberg Act.

Section 21, a citizen petition provision unique to TSCA, establishes "unusually powerful procedures for citizens to force EPA's hand."[53] Section 21(a) provides that any person may petition "the Administrator to initiate a proceeding for the

52 Section 9(b)(1) (15 U.S.C. § 2608(b)(1)) (concerning laws administered by EPA). *See also* section 9(a)(1) (15 U.S.C. § 2608(a)(1)) (using the phrase "risk may be prevented or reduced to a sufficient extent" with respect to laws administered by other agencies).

53 *Trumpeter Swan Soc'y v. EPA*, 774 F.3d 1037, 1039 (D.C. Cir. 2014). *See also EDF v. Reilly,* 909 F.2d 1497, 1503 (D.C. Cir. 1990) (describing section 21 as "a comprehensive as well as an unusual remedy open to petitioners denied promulgation of new rules").

issuance, amendment, or repeal of a rule" or order under several sections of TSCA. It further provides that EPA must either grant or deny the petition within 90 days of its submission. If EPA fails to act within the 90-day period, the agency's inaction is treated as a denial. In the event of either an express denial or a constructive denial through inaction, section 21(b)(4)(A) authorizes the petitioner to seek review in federal district court within 60 days of the denial. If EPA grants a petition, section 21(b)(3) provides that EPA is to "promptly commence an appropriate proceeding."

"De novo review pursuant to Section 21 appears advantageous to plaintiffs challenging a denial of a petition when compared with more typical judicial review of agency actions."

Section 21 differs from many other statutory provisions that provide for citizen petitions to EPA. Instead of establishing a deadline for the agency to act that may lead to a suit to enforce the deadline in the absence of agency action, section 21 treats the agency's failure to act as a denial of the petition that is reviewable in district court. In the event of a denial of a petition to initiate a rulemaking, section 21(b)(4)(B) provides for de novo review in the district court. Such a proceeding could lead directly to a court order finding a chemical substance presents an unreasonable risk and requiring EPA to take action with respect to the substance at issue (rather than a remand to the agency for further proceedings). Pursuant to section 21(b)(4)(B), if a petitioner seeks judicial review of EPA's express or constructive denial of a petition, the court must consider the petition in a "de novo proceeding" and "shall order" EPA to take the requested action if "the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that … the chemical substance or mixture … presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors."[54]

De novo review pursuant to section 21 appears advantageous to plaintiffs challenging a denial of a petition when compared with more typical judicial review of agency actions, which relies on review of a record and reflects principles of judicial deference. As the DC Circuit explained in *EDF v. Reilly*:[55]

> The plaintiff in a Section 21 proceeding is entitled to de novo consideration of his petition for issuance of a new rule, but APA review, save in rare instances, must be conducted on an administrative record. The Section 21 plaintiff must demonstrate, by a preponderance of the evidence, a risk affecting health or the environment; on APA review, the agency's action must be evaluated on the record. *While the Section 21 court, proceeding de novo, is free to disregard EPA's reasoning and decision, APA review is restricted and highly deferential. If the Section 21 plaintiff carries*

54 Section 21(b)(4)(B) (15 U.S.C. § 2620(b)(4)(B)).

55 909 F.2d at 1506.

> *his burden* and the court makes any one of the statutorily-specified determinations, *the court itself directs the disposition to be made of the petition. On the other hand should a district court on APA review find agency action defective, either substantively or procedurally, it ordinarily must remand to the agency for further proceedings.*[56]

The Lautenberg Act may well have effectively changed the import of section 21 due to the fundamental change it made to the definition of unreasonable risk. Eliminating costs and other non-risk considerations from the determination may make the task for section 21 petitioners easier than it was prior to the Lautenberg Act. Before the 2016 revisions, petitioners seeking regulatory action to control a chemical substance needed to make a case to EPA regarding both (1) the health and environmental effects of a chemical substance and (2) the costs and benefits of regulating it. EPA often relied on the difficulties facing petitioners, especially those concerning the cost and benefit issues, at least in part, to deny petitions.[57] Now however, a petitioner need only make a case on the health or environmental impacts under the revised standard to petition EPA to regulate a chemical substance that it believes poses an unreasonable risk to health or the environment.

B. Affirmative Risk Determination for New Chemicals

The Lautenberg Act changed section 5 of TSCA, which establishes the program for EPA to deal with new chemicals, in a number of important ways. Perhaps most significantly, it established a new requirement that EPA make affirmative risk determinations before new chemical substances may be introduced into commerce or significant new uses of chemical substances can commence.

Section 5 requires manufacturers and processors of chemical substances to submit a pre-manufacture notification (PMN) to EPA for review prior to the manufacture of a new chemical substance or processing of a chemical substance for a significant new use. Under pre-Lautenberg Act TSCA, if EPA did not issue an unreasonable risk determination by the end of the statutory review period, the manufacturer or processor could nevertheless move forward with production. The Lautenberg Act modified this process by requiring that EPA make an express decision regarding the safety of a chemical before it may be introduced into commerce or a significant new use commenced. As revised by the Lautenberg Act, a person may only undertake the manufacture of a new chemical substance or manufacture or processing of a chemical substance for a significant new use if it submits a notice to EPA at least 90 days prior to the commencement of manufacture or processing, and EPA

I. conducts a review of the notice; and

II. makes a determination under [section

56 *Id.* at 1505–06 (emphasis added; footnotes and citations omitted).

57 *See, e.g.,* 80 Fed. Reg. 60,577 (Oct. 7, 2015) (denying section 21 petition seeking a determination that anthropogenic emissions of carbon dioxide posed an unreasonable risk to health or the environment and to control carbon dioxide emissions); 79 Fed. Reg. 64,722 (Oct. 31, 2014) (denying section 21 petition seeking regulation of polyvinyl chloride, vinyl chloride, and phthalates used as plasticizers).

> 5(a)(3)] and takes the actions required in association with that determination under such subparagraph within the applicable review period.[58]

Congress provided EPA with the authority to extend the initial 90-day review period up to another 90 days for "good cause."[59]

Section 5(a)(3) requires EPA to make one of three determinations within the applicable review period. Which determination section 5(a)(3) calls for depends on whether sufficient information exists for EPA to evaluate properly the risk presented by a new chemical substance or significant new use or the nature of the risk EPA determines exists. Consistent with the Lautenberg Act's elimination of cost-benefit balancing from TSCA, section 5(a)(3) requires that the unreasonable risk determinations under it be made without consideration of costs or other nonrisk factors.

If EPA determines under section 5(a)(3)(A) that the "chemical substance or significant new use *presents* an unreasonable risk of injury to health or the environment," the administrator shall take the actions required under section 5(f) to prevent the unreasonable risk by imposing requirements on the chemical or use or by issuing an order prohibiting or limiting the manufacturing, processing, or distribution of the chemical substance.[60]

Section 5(a)(3)(B) concerns instances of insufficient information to evaluate a chemical substance. It provides that if the administrator determines that the information available to him or her is "insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use … or … in the absence of sufficient information to permit the administrator to make such an evaluation, [the chemical] substance *may present* an unreasonable risk of injury to health or the environment … or … such substance is or may be produced in substantial quantities, and such substance either *enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance*" the administrator must take the actions required under section 5(e).[61]

Section 5(a)(3)(C) controls what happens if EPA determines that the chemical substance or significant new use "is not likely to present an unreasonable risk of injury to health or the

58 Section 5(a)(1)(B)(ii) (15 U.S.C. § 2604(a)(1)(B)(ii)).

59 Section 5(c) (15 U.S.C. § 2604(c)).

60 Subsection 5(f) (15 U.S.C. § 2604(f)) provides that if EPA determines that the new chemical substance or significant new use presents an unreasonable risk then EPA "shall, before the expiration of the applicable review period … to the extent necessary to protect against such risk" either (1) issue a proposed rule effective upon publication in the Federal Register to impose requirements on the chemical substance or new use or (2) issue an order prohibiting or limiting the manufacture, processing or distribution of the chemical substance.

61 Section 5(a)(3)(B) (emphasis added) (15 U.S.C. § 2604(a)(3)(B)). Section 5(e) (15 U.S.C. § 2604(e)) provides that if EPA makes one of the possible determinations under section 5(a)(3)(B), it shall issue an order "to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment …."

environment."[62] In such a case, the submitter of the notice to EPA may commence manufacture or processing of the chemical substance.

"While many apparently believed that these changes would not significantly alter the way TSCA's new chemicals program was being implemented by EPA, the requirement that EPA make affirmative determinations regarding the risks of new chemical substances or significant new uses has led to substantial issues."

As discussed more fully below in section III.B, the provisions of the Lautenberg Act requiring EPA determinations prior to the introduction into commerce of a new chemical substance or the manufacture or processing of a chemical substance for a significant new use, have led to controversy and significant implementation issues. While many apparently believed that these changes would not significantly alter the way TSCA's new chemicals program was being implemented by EPA, the requirement that EPA make affirmative determinations regarding the risks of new chemical substances or significant new uses has led to substantial issues. When a government agency is required to make a decision on the risks of a chemical on the basis of a record in a limited period of time rather than simply allowing the manufacture or processing of a chemical to proceed without a documented decision, it should not be a surprise that implementation issues will arise. As the agency now faces the possibility of judicial review of its decisions, it likely needs a more rigorous mechanism for making them.

C. Strengthening of the Existing Chemicals Program by Mandating Action

The Lautenberg Act made substantial reforms in the existing chemicals program established under section 6 of TSCA. The new law created a prioritization scheme under which EPA must review chemical substances and identify them as high or low priority. It required EPA, within a year after its enactment, to

> establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at this time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially

62 Section 5(a)(3)(C) (emphasis added) (15 U.S.C. § 2604(a)(3)(C)).

> exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.[63]

The Lautenberg Act, however, obligated EPA to begin the process of undertaking risk evaluations prior to the promulgation of the prioritization rule. Section 6(b)(2) required that, not later than 180 days after the June 22, 2016 enactment of the Lautenberg Act, EPA "ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period."[64]

The Lautenberg Act established a multitude of requirements related to the risk evaluation process. First, section 6(b)(4) required EPA to promulgate a rule, again within one year of enactment, to establish the process for conducting risk evaluations for chemical substances (1) identified as high priority under the prioritization rule, (2) identified under section 6(b)(2), or (3) for which a risk evaluation had been requested by a manufacturer. Second, it established timelines for the conduct of risk evaluations. Section 6(b)(3) provides requires a risk evaluation to be initiated '[u]pon designating a chemical substance as a high-priority substance." Then section 6(b)(4)(D) directs EPA, within six months of initiation of a risk evaluation, to publish "the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations [EPA] expects to consider …." Third, section 6(b)(4)(G) requires EPA to complete risk evaluations as soon as practicable but not later than three years after their initiation, although the agency may extend that period by up to six months.

"The Lautenberg Act established a multitude of requirements related to the risk evaluation process."

The Lautenberg Act also revised section 6 to establish minimum throughput requirements for the pace of Agency's conduct of risk evaluations. In addition to the initial ten chemical substances to be selected by EPA from the 2014 Work Plan, section 6(b)(2)(B) requires that no later than three and a half years after June 22, 2016, EPA must ensure that it is conducting risk evaluations on at least 20 high priority substances and 20 low priority substances. It also requires that chemicals drawn from the 2014 Work Plan account for at least 50 percent of risk evaluations underway. Moreover, section 6(b)(4)(E)(i) establishes minimum and maximum limits on the percentage of risk evaluations that EPA may conduct in response to industry requests. Assuming there have been sufficient industry requests, industry-requested evaluations must constitute between 25 and 50 percent of the risk evaluations EPA conducts.

Thus, EPA must keep moving forward on risk

63 Section 6(b)(1)(A) (15 U.S.C. § 2605(b)(1)(A)).

64 Section 6(b)(2)(A) (15 U.S.C. § 2605(b)(2)(A)).

evaluations over time—pushed forward by the throughput requirements in conjunction with the mandatory deadlines for completion. Moreover, the Lautenberg Act struck a balance by potentially making manufacturer-requested risk evaluations 25-50 percent of the risk evaluations undertaken by EPA at any point in time.

D. Changes to Preemption Provisions

Largely negotiated at the end of legislative process by Senators Inhofe and Boxer,[65] the overhaul of the preemption provisions in section 18 of TSCA was one of the major legislative compromises that underlay the passage of the Lautenberg Act. The new preemption provisions restrict state activities to a greater extent than pre-Lautenberg Act TSCA. However, the new preemption language preserves state authority through a series of complicated provisions, achieving a balance that allowed both chemical industry supporters such as Senators Inhofe and Vitter and environmental advocates such as Senator Boxer to support the final bill.

Section 18(a) establishes the general principle that, subject to some exceptions, TSCA preempts states from taking certain actions. Section 18(a)(1) preempts states from

a. developing information about chemical substances that is "reasonably likely to produce the same information required under" section 4, 5, or 6 of TSCA by a rule, consent agreement, or order;

b. establishing or implementing a "statute, criminal penalty or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance" for which EPA has made a determination under section 6(i)(1) that a chemical substance does not present an unreasonable risk or for which EPA promulgates a final rule under section 6 regulating an existing chemical; or

c. establishing or enforcing a statute or administrative action that requires a notification of a use of a chemical substance if EPA has specified the use as a significant new use and required notification through a rule issued under section 5 of TSCA.

Section 18(a)(2) further provides that the federal preemption does not occur until the effective date of the listed federal actions.

Section 18(b) addresses the preemption of new statutes, criminal penalties and administrative actions during the time EPA undertakes certain activities under section 6 with respect to existing chemicals. Again subject to some exceptions, section 18(b)(1) preempts states from establishing a statute, criminal penalty, or administrative action that prohibits or restricts the manufacture, processing, distribution in commerce, or use of the high-priority chemical substance at issue from the date EPA

65 *See* Andy Igrejas, Safer Chemicals, Healthy Families, *UPDATED: The Near-Final TSCA Reform Legislation—A Rundown* (May 21, 2016), https://saferchemicals.org/2016/05/21/e-near-final-tsca-reform-legislation-a-rundown.

defines the scope of a risk evaluation pursuant to section 6(b)(4)(D) until the earlier of either the date of EPA's publication of a risk evaluation or the deadline established under section 6 for the completion of the risk evaluation. Section 18(b)(2) says explicitly that this preemption does not prevent states from continuing to enforce "any statute enacted, criminal penalty assessed, or administrative action taken," prior to the date EPA defines and publishes the scope of a risk evaluation under section 6(b)(4)(D).

Section 18(c) defines the scope of preemption differently for each of the different species of preemption identified in section 18(a) and (b).[66] In each case, however, section 18(c) limits preemption to matters or issues considered by EPA in the pertinent federal action, e.g., it limits preemption with respect to chemical substances that EPA finds do not present an unreasonable risk to the hazards, exposures, uses, or conditions of use considered by EPA in its final action.

"[S]ection 18(c) limits preemption to matters or issues considered by EPA in the pertinent federal action."

Subsections (d) and (e) of section 18 lay out several broad exceptions to preemption by either subsection (a) or (b). Section 18(d) exempts from preemption several categories of state actions, including rules adopted to satisfy or obtain approval or authorization under other federal laws. It also exempts rules adopted by states or their political subdivisions pursuant to environmental laws unless they restrict manufacturing, processing, use or distribution in commerce of a chemical substance (which most presumably would) and either address the "same hazards and exposures, with respect to the same conditions of use, as are included in the scope of a risk evaluation published pursuant to" section 6(b)(4)(D) or cause a violation of an EPA action taken pursuant to section 5 or section 6.[67]

66 Section 18(c) (15 U.S.C. § 2617(c)) provides that preemption "shall apply only to—

(1) with respect to [the development of information], the chemical substances subject to a rule, order, or consent agreement under [section 4, 5, or 6];

(2) with respect to [pause preemption for risk evaluations under section 6], the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to [section 6(b)(4)(D)];

(3) with respect to [chemical substances found not to present an unreasonable risk or restricted under section 6] the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action [EPA] takes pursuant to [section 6(a) or 6(i)(1)];

(4) with respect to [significant new uses], the uses of such chemical substances that [EPA] has specified as significant new uses and for which [EPA] has required notification pursuant to a rule promulgated under [section 5]."

67 Section 18(d)(1)(A) (15 U.S.C. § 2617(d)(1)(A)) provides that nothing in the Lautenberg Act, "nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to [the Lautenberg Act], shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that—

Section 18(e) spells out further exceptions. Notably, it expressly provides that nothing in TSCA shall "be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003." Section 18(e) also explicitly states that the Act does not preempt or affect the authority of states or political subdivisions to continue to enforce actions taken or requirements adopted before April 22, 2016, with respect to a particular chemical substance, "under the authority of a law

(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

(ii) implements a reporting, monitoring, or other information obligation for the chemical substance not otherwise required by [EPA under the Lautenberg Act] or required under any other Federal law;

(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

(II) (aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation published pursuant to [section 6(b)(4)(D)], but is inconsistent with the action of [EPA]; or

(bb) would cause a violation of the applicable action by [EPA taken under section 5 or 6]; or

(iv) subject to [section 18(d)(1)(B)], is identical to a requirement prescribed by [EPA].

of the State or political subdivision of the State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance."

In addition, section 18(f) provides EPA authority to grant both "discretionary" and "required" waivers from preemption upon application from a state in accordance with certain procedures. These provisions establish timeframes for EPA action on applications by states and provide for judicial review of EPA decisions.[68]

"[S]ection 18(f) provides EPA authority to grant both 'discretionary' and 'required' waivers from preemption upon application from a state in accordance with certain procedures."

The Administrator "may" grant a discretionary waiver of 18(a) preemption if he or she finds that it satisfies four criteria. These criteria are that (1) "compelling conditions [that] warrant granting the waiver to protect health or the environment"; (2) that compliance with the state requirement would not unduly burden interstate commerce; (3) that compliance with the proposed state requirement would not cause a violation of another federal

68 *See* Section 18(f)(3), (6) (15 U.S.C. §§ 2617(f)(3), (6)).

law, rule or order; and that (4) "in the judgment of the Administrator, the proposed requirement … is designed to address a risk of a chemical substance … that was identified" and is consistent with the best available science, using supporting studies in accordance "with sound and objective scientific practices [and] based on the weight of the scientific evidence."[69]

Even the "required exemptions" in section 18(f)(2), which concerns preemption created by section 18(b), reflect a significant amount of EPA discretion. While the statute states that the administrator "shall" grant the exemption, it premises the command "shall" on determinations that involve the exercise of discretion. Section 18(f)(2)(A) provides that the administrator of EPA shall grant the requested exemption from preemption if he or she determines that the state's concern about a chemical substance is based on peer-reviewed science and that compliance with the state requirement would neither unduly burden interstate commerce nor cause a violation of federal law, rules or orders.[70] Plainly, this exemption from preemption rests on what EPA views as an undue burden on interstate commerce, a determination that involves a significant degree of discretion. It also provides room for EPA to determine what it means for the state or political subdivision to have a concern "based in peer-reviewed science."

"Even the 'required exemptions' in section 18(f)(2), which concerns preemption created by section 18(b), reflect a significant amount of EPA discretion."

Section 18(f)(2)(B)'s exemption from preemption differs substantially from the section 18(f)(2)(A) exemption. It establishes an exemption for a chemical substance subject to EPA risk evaluation for state action that occurs within a specified window of time. Section 18(f)(2)(B) provides that EPA shall grant an exemption from section 18(b) preemption for proposed or final administrative action taken by a state (or political subdivision of a state) that prohibits or otherwise restricts a chemical substance's manufacture, processing, use, or distribution in commerce by a specified date. The state action must occur no later than the earlier of the date on which EPA publishes the scope of the risk evaluation concerning the chemical or the date 18 months after the commencement of the prioritization process

69 Section 18(f)(1) (15 U.S.C. § 2617(f)(1)).

70 Section 18(f)(2) (15 U.S.C. § 2617(f)(2)) provides that EPA "shall exempt from subsection (b) a statute or administrative action … that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that –

(A)(i) compliance with the proposed requirement … would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(ii) compliance with the proposed requirement … would not cause a violation of any applicable Federal law, rule, or order; and

(iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science ….

concerning the chemical at issue.[71] Assuming the time limitations are satisfied, there appears to be far less room for the agency to utilize discretion to not grant an exemption. Moreover, section 18(f)(9) provides for automatic approval of applications for section 18(f)(2)(B) waivers if EPA fails to act within its 110-day response period.[72]

While the Lautenberg Act's preemption provisions are both more preemptive and more complicated than the previous ones, they contain significant exceptions that preserve state authority. The scope of these exceptions is not necessarily clear, however.

In particular, section 18(d)(1)(A)(iii) does not delineate precisely the contours of the exemption for state actions taken pursuant to other environmental laws. It does not exempt from preemption actions that both (1) impose restrictions on manufacturing, processing, distribution in commerce, or use and (2) address "the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation" if the actions are inconsistent with or would cause a violation of EPA's action under either section 5 or section 6.

Most regulatory actions taken by states pursuant to environmental laws to control a chemical substance would presumably restrict manufacturing, processing, distribution in commerce, or use.[73] However, for preemption to apply, those state actions must address the *same* hazards, exposures, and conditions of use as EPA considered within the scope of a risk evaluation pursuant to section 6(b)(4)(D). This would exempt from preemption state actions based on analyses of hazards, exposures, and conditions of use that differ from those included within the scope of a section 6(b)(4)(D) risk evaluation.[74] Moreover, EPA may regulate existing chemicals without undertaking a risk evaluation under section 6(b)(4)(D) in certain circumstances (e.g., under the provisions of section 6(h) authorizing action regarding chemical substances that are persistent, bioaccumulative, and toxic or after the submission of a petition under section 21). TSCA would not preempt state actions taken pursuant to environmental laws if they address chemicals subject to such regulation.

Finally, even if the state action addresses the same hazards, exposures, and conditions of use included in the scope of a section 6(b)(4)(D) risk evaluation, the exemption from preemption would still apply unless the state action is "inconsistent with the action of the Administrator." It is not clear what that

71 Section 18(f)(2)(B) (15 U.S.C. § 2617(f)(2)(B)) requires EPA to grant a state's application for an exemption from preemption if EPA determines that "no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to [section 6(b)(1)(A)], or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under [section 6(B)(4)(D)], whichever is sooner, the State or political subdivision of the State has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance."

72 Section 18(f)(9) (15 U.S.C. § 2617(f)(9)).

73 Congress did not refer to disposal in this list, apparently leaving disposal requirements exempted without qualification.

74 As described below at III.A.2, EPA has adopted approaches pursuant to which it carves out certain conditions of use and exposure pathways from its risk evaluations. Presumably, by narrowing the scope of its risk evaluations, EPA is leaving more room for states to take their own actions with respect to those chemical substances.

means, as a state action that is more protective of health or the environment would not necessarily be "inconsistent" with the EPA action. This is clear on the face of Section 209 of the Clean Air Act, which establishes the waiver program by which California is able to have more stringent mobile source standards than those established by EPA under the Clean Air Act. If California's "standards and enforcement procedures are not consistent with" section 202, EPA should not issue California a waiver from preemption. Plainly, as the whole point of section 209 is to establish a mechanism for allowing California to have more stringent motor vehicle standards, it is clearly possible for its standards to be both more environmentally protective than federal standards and not be inconsistent with federal standards.

III. EPA's Implementation of the Lautenberg Act

Upon enactment, EPA confronted major issues regarding the implementation of the Lautenberg Act. The Act became effective immediately upon signature by the President on June 22, 2016, thereby kicking off the timelines for implementation and requiring changes in approach. Not only did EPA face deadlines for major rulemakings such as the ones to establish the prioritization and risk evaluation processes under section 6, but it also needed to immediately apply the new provisions of section 5 regarding unreasonable risk determinations. Furthermore, EPA had to deal with a variety of issues of interpretation under the new law, and to issue guidance on various matters.

A. Existing Chemicals Program

With respect to existing chemicals, EPA had several statutory deadlines to meet. Section 6(b)(2)(A) obligated EPA to undertake risk evaluations on ten chemical substances selected from the 2014 TSCA Work Plan and publish the list of those ten substances within 180 days of enactment. Section 6 also required EPA to promulgate two significant rules—the prioritization process rule and the risk evaluation process rule by June 22, 2017 — one year after enactment.[75]

In addition, by the end of that first year, EPA had to update the inventory of existing chemicals by requiring manufacturers (and possibly processors) to notify EPA of chemical substances manufactured or processed for commercial purposes within the 10-year period prior to the enactment of the Lautenberg Act.[76] EPA needed the information to determine which substances were active and which were inactive, information that could be factored into the prioritization and risk evaluation processes.[77]

75 Section 6(b)(1)(A), 6(b)(4)(B) (15 U.S.C. §§ 2605 (b)(1)(A), (4)(B)).

76 Section 8(b)(4)(A) (15 U.S.C. § 2607(b)(4)(A)).

77 EPA Press Office, *EPA Releases First Major Update to Chemicals List in 40 Years* (Feb. 19, 2019) https://www.epa.gov/newsreleases/epa-releases-first-major-update-chemicals-list-40-years.

EPA met these statutory deadlines for the major rules underpinning the existing chemicals program, albeit with subsequent litigation.

1. FIRST TEN CHEMICALS

EPA announced the first ten chemicals selected for risk evaluations under section 6 on November 29, 2016. The ten selected were: 1,4-dioxane; 1-bromopropane; trichloroethylene (TCE); carbon tetrachloride; hexabromocyclododecane (HBCD); methylene chloride; Pigment Violet 29; perchloroethylene (PERC); N-methylpyrrolidone (NMP); and asbestos.[78] EPA then took public comments regarding various issues related to the ten chemicals, including uses, products containing these chemicals, exposed populations, and alternatives to each of these chemicals.[79]

Seven months later, on June 22, 2017, the first anniversary of the signing of the Lautenberg Act, EPA released the scoping documents for the risk evaluations for the ten chemicals. The scoping documents outlined the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expected to consider in conducting the risk evaluations on the chemicals.[80]

a. Problem Formulation Documents

On June 11, 2018, EPA published for public comment the problem formulation documents for the first ten chemicals, which refined the scope of the risk evaluations. These documents raise some significant legal issues.

> "EPA met these statutory deadlines for the major rules underpinning the existing chemicals program, albeit with subsequent litigation."

For example, EPA stated in its TCE problem formulation that it "removed from the risk evaluation any activities and exposure pathways that EPA has concluded do not warrant inclusion."[81] First, EPA referenced "conditions of use" that were listed in the scope document, but for which EPA determined it did not have sufficient information to find qualified as conditions of use.[82] Second, EPA asserted that it intended to use discretion to exclude from the risk evaluation certain exposure pathways that "fall under the jurisdiction of other EPA-administered statutes" because such pathways present a lesser concern to

78 81 Fed. Reg. 91,927 (Dec. 19, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0718-0001; https://www.govinfo.gov/content/pkg/FR-2016-12-19/pdf/2016-30468.pdf

79 Memorandum to Open a Docket, EPA-HQ-OPPT-2016-0736 (Dec. 12, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0001.

80 82 Fed. Reg 31,592 (July 7, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0327-0001; https://www.govinfo.gov/content/pkg/FR-2017-07-07/pdf/2017-14321.pdf.

81 *See* EPA, *Problem Formulation of the Risk Evaluation for Trichloroethylene (CASRN: 79-01-6)* 13 (May 2018) (hereafter cited as "*TCE problem formulation*"), https://www.epa.gov/sites/production/files/2018-06/documents/tce_problem_formulation_05-31-31.pdf.

82 *Id*. at 12–13.

EPA under TSCA.[83]

EPA argues it can focus on this smaller group of exposure pathways due to both resource concerns and the agency's belief that those statutes and their regulations "represent the judgment" of Congress and the administrator as to what "is sufficient under the various environmental statutes."[84] EPA explained that:

> As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes. EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

EPA's assertion of authority to exclude such exposure pathways in a risk evaluation seems inconsistent with the language of section 9 of TSCA, which lays out how to coordinate TSCA with other statutes, on both substantive and procedural grounds. Section 9(b)(1) states: "If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under [TSCA]."[85]

Section 9(b)(1) explicitly states that the coordination with other laws occurs "[i]f the Administrator determines" there is a risk that could be eliminated. However, in the problem formulation documents EPA removes consideration of exposure pathways that may be subject to other regulatory programs at the outset, thus preventing an analysis under TSCA of the risks from those pathways. EPA's approach

83 *Id.* at 13. *See also id.* at 46 ("EPA believes that the TSCA risk evaluation should focus on those exposure pathways associated with TSCA uses that are not subject to the regulatory regimes discuss above because these pathways are likely to represent the greatest areas of concern to EPA.") Similar or identical statements were made in other problem formulation documents. *See, e.g.,* EPA, *Problem Formulation of the Risk Evaluation for 1-Bromopropane (CASRN: 106-94-5)* 13 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/1bp_problem_formulation_05-31-18.pdf.

84 *TCE problem formulation, supra* note 83, at 13.

85 Section 9(b)(2) (15 U.S.C. § 2608(b)(2)) provides a road map for how the administrator is to make the public interest determination referred to in section 9(b)(1).

undermines the language of section 9 by affecting the risk evaluation itself, rather than waiting to determine the appropriate coordination of statutes until the determination of unreasonable risk on the basis of an evaluation of exposure pathways that includes ones that may be affected by other statutes.

EPA's assertion that the existence of a regulatory program under another statute that has "jurisdiction" over an exposure pathway for a chemical substance is sufficient to avoid TSCA regulation of that route of exposure is flawed. When Congress first passed TSCA in 1976, it intended TSCA to be an overarching statute that allowed for controls that other statutes did not authorize. As discussed above, one of the main moving theories behind TSCA was that regulatory regimes like the Clean Air Act and Clean Water Act that tended to focus on emission or discharge controls were inadequate. Congress did not think that the mere fact that a chemical substance was in some way regulated under another statute meant that TSCA had no role.

The expansive nature of TSCA's overlapping authority apparently underlay then Judge Kavanaugh's reasoning in a 2017 D.C. Circuit decision, *Mexichem Fluor, Inc. V. EPA*.[86] That decision vacated and remanded in part a rule promulgated by EPA under section 612 of the Clean Air Act regulating the use of certain HFCs. In doing so, Judge Kavanaugh stated that not only did EPA have other authority under section 612(c) of the Clean Air Act to regulate HFCs, but also that "EPA possesses other statutory authorities, including the Toxic Substances Control Act, to directly regulate non-ozone-depleting substances that are causing harm to the environment. Our decision today does not in any way cabin those expansive EPA authorities."[87] Thus, Judge Kavanaugh recognized that even though the Clean Air Act established a regulatory regime applicable to HFCs, EPA still had authority to regulate them under TSCA; EPA's assertions in its TCE problem formulation run counter to that recognition.

"Congress did not think that the mere fact that a chemical substance was in some way regulated under another statute meant that TSCA had no role."

EPA's explanation that the "provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator"[88] about the level of risk reduction needed begs the question of what purpose section 9 of TSCA would hold if that were the case. With respect to the coordination of TSCA with other laws administered by EPA, section 9(b)(1) states:

> The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the

86 866 F.3d 451 (D.C. Cir. 2017).

87 866 F.3d at 460 (citations omitted).

88 *TCE problem formulation, supra* note 83, at 13.

> Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

EPA's position appears to be that the amount of risk reduction achieved under environmental statutes other than TSCA is "sufficient" to avoid TSCA regulation because it represents the amount of risk reduction Congress intended under those statutes. Of course, the amount of risk reduction achieved under another statute is presumably the amount of risk reduction Congress intended to achieve under that statute (at least assuming the Agency implemented that statute appropriately). However, if that were the test Congress intended to apply under TSCA to the question of whether reductions achieved under other statutes were "sufficient" to rely on it would not have written section 9 the way it did; rather, it could simply have stated that if a source of pollution were subject to another statute, that would be the end of the inquiry. There would be no point in evaluating the "sufficiency" of the risk reduction achieved under the other statute or its regulatory regime if the test were whether the other regulatory regime met Congress' goals for that statute. The inquiry into sufficiency under section 9 is an inquiry into the sufficiency of the other statute compared with TSCA's elimination of the unreasonable risk as defined in and identified under TSCA.

EPA's reasoning erroneously suggests that Congress intended whatever amount of risk reduction the other environmental statutes achieved would be sufficient for purposes of determining that further regulation under TSCA was not appropriate. That suggestion runs counter to both the language and intention of section 9 of TSCA.

"EPA's position appears to be that the amount of risk reduction achieved under environmental statutes other than TSCA is 'sufficient' to avoid TSCA regulation because it represents the amount of risk reduction Congress intended under those statutes."

EPA can only assess properly whether another statute reduces risk to a sufficient extent after it has applied TSCA to determine the unreasonable risk level. This has even more force after the enactment of the Lautenberg Act as it fundamentally changed TSCA's unreasonable risk standard from a cost-benefit balancing one to a standard that requires the elimination of an unreasonable risk determined without consideration of costs or other non-risk factors. Now, if another statute requires controls on the basis of non-risk criteria (e.g., cost or technology),

rather than risk, the reductions that other statute would bring about may well be insufficient when compared with what TSCA requires. EPA's approach of excluding exposure pathways at the outset of the risk evaluation simply on the basis that another statute provides for some regulatory authority is both procedurally and substantively flawed.

b. Draft Risk Evaluations

At the same time it released the problem formulation documents, EPA released for public comment a document titled "Application of Systematic Review in TSCA Risk Evaluations." The systematic review document delineates a structured process of identifying, evaluating, and integrating evidence for the hazard and exposure assessments.[89]

"EPA's approach of excluding exposure pathways at the outset of the risk evaluation simply on the basis that another statute provides for some regulatory authority is both procedurally and substantively flawed."

EPA released the first draft risk evaluation for one of the first ten chemicals in November 2018 for Colour Index (C.I.) Pigment Violet 29 (PV29), a pigment used in inks, paints, coatings, and plastics.[90] In that risk evaluation, EPA preliminarily concluded that PV29 does not present an unreasonable risk.[91] Commenters raised numerous concerns, including the extent of the data and information EPA did and did not rely upon or seek to obtain, EPA's determinations regarding what should be considered conditions of use, alleged deficiencies in EPA's evaluation of worker risks and the manner in which EPA analyzed hazard and exposure.[92] Commenters' major underlying concerns included whether EPA had utilized tools available to it under TSCA to gather the necessary information to conduct a risk evaluation with minimal uncertainty.[93]

During the summer of 2019, EPA released three additional draft risk evaluations for public comment. In June 2019, EPA issued its draft risk evaluations for 1,4-Dioxane[94] and for Cyclic Aliphatic Bromide Cluster

89 83 Fed. Reg. 26,998 (June 11, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0070; https://www.govinfo.gov/content/pkg/FR-2018-06-11/pdf/2018-12520.pdf.

90 EPA, *Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline1,3,8,10(2H,9H)-tetrone) (CASRN: 81-33-4)* (Nov. 2018), https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf.

91 *Id.* at 5.

92 Environmental Defense Fund Comments on Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone) Docket ID: EPA-HQ-OPPT-2018-0604 (submitted Jan. 14, 2019); Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council, and the undersigned groups on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29 under the Amended Toxic Substances Control Act, (submitted Jan. 14, 2019).

93 *Id.*

94 EPA, *Draft Risk Evaluation for 1,4-Dioxane (CASRN: 123-91-1)* (June 2019), https://www.epa.gov/sites/production/files/2019-06/documents/1_14-dioxane_draft_risk_evaluation_06-27-2019.pdf.

(HBCD).[95] The comment period on both of those draft risk evaluations closed on August 30, 2019.[96]

1,4-dioxane is primarily used as a solvent in industrial and commercial settings. Preliminarily EPA found that 1,4-dioxane posed no unreasonable risks to the environment and no unreasonable risks to occupational non-users, but that it did pose an unreasonable risk to workers under a variety of circumstances (including certain manufacturing, processing and industrial uses).[97]

"EPA's Scientific Advisory Committee on Chemicals (SACC) has criticized EPA's approach to the draft risk revaluations of PV29, 1,4-dioxane and HBCD in its peer reviews of the draft risk evaluations."

HBCD (hexabromocyclododecane) is primarily used as a flame retardant in expanded and extruded polystyrene, but EPA identified other uses as well, including in solder and automobile replacement parts. HBCD is subject to a ban on production, import and export under the Stockholm Convention. While the US is not a party to the convention, EPA found that domestic manufacture of HBCD came to an end in the US as of 2018, and EPA also believes that it would be cost prohibitive for small manufacturers to produce small quantities of HBCD. Imports into the US could still occur, although none did during 2018.[98]

EPA preliminarily found that HBCD does not present any unreasonable risk to the environment under the conditions of use that it identified. With respect to health risks, EPA found that HBCD does not present an unreasonable risk to the health of workers, occupational non-users, consumers, and the general population under the conditions of use included in the scope of the risk evaluation.[99]

EPA's Scientific Advisory Committee on Chemicals (SACC) has criticized EPA's approach to the draft risk revaluations of PV29, 1,4-dioxane and HBCD in its peer reviews of the draft risk evaluations. The SACC released its report on the PV29 draft risk evaluation in September and followed that with reports on 1,4-dioxane and HBCD at the end of October.

With respect to PV29, the SACC agreed with EPA's draft on many points, but stated that "[i]n general, significantly more detail needs to be provided to better support the risk evaluation conclusions and improve transparency of the decision-making."[100] The

95 EPA, *Draft Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD)* (June 2019), https://www.epa.gov/sites/production/files/2019-07/documents/hbcd_draft_risk_evaluation_062719_hero_link_0.pdf.

96 84 Fed. Reg. 31,315 (July 1, 2019).

97 *Draft Risk Evaluation for 1,4-Dioxane, supra* note 96, at 21–22.

98 *Draft Risk Evaluation for HBCD, supra* note 97, at 23–24.

99 *Id*. at 27–28.

100 TSCA Science Advisory Committee on Chemicals, Meeting

SACC issued several recommendations concerning the PV29 risk assessment, including the need to perform quality assessments of exposure data for occupational exposures provided to EPA through personal communications from a manufacturer, and a better discussion of why available study data supported EPA's conclusions of "no unreasonable risk" and justify why additional testing was not necessary to verify that conclusion.[101] Among its criticisms of EPA's consideration of occupational exposures, environmental releases, potential exposures and susceptible subpopulations, as well as conclusions regarding aggregate exposures, was the statement that EPA should "refrain from making sweeping generalizations especially when based on limited and/or uncertain information regarding physical chemical properties or toxicological testing."[102] The SACC faulted EPA's analysis of occupation exposures, noting that EPA should acknowledge there was little data to support conclusions that workers would not be exposed through dermal or inhalation routes.[103] Notably, the SACC stated that its members "were in general agreement that the information presented to support the conclusions outlined in the draft **risk characterization** was not sufficiently robust for this purpose."[104]

On October 31, 2019, the SACC released its reports on the draft risk evaluations regarding 1,4-dioxane and HBCD.[105] The SACC had some criticisms of the agency regarding HBCD but was more supportive of that analysis than EPA's analysis of either PV29 or 1,4-dioxane.[106] With respect to 1,4-dioxane, the SACC's report supported EPA on some issues but contained strong criticisms of the agency's methodology and conclusions, finding that EPA had overlooked routes of exposure, used overly optimistic exposure estimates, and departed from its own guidance and basic risk assessment principles. For example, the SACC commented that it "generally agreed that the **environmental fate, exposure and effects** assessment was inadequate."[107] The SACC criticized EPA for not adequately evaluating human exposures and stated that its process does not follow the agency's own guidance for risk assessment and that the problem formulation for 1,4-dioxane "strayed from basic risk assessment principles by omitting well known exposure routes such as water consumption by all occupationally and non-occupationally-exposed humans as well as similar exposure to other biological receptors.

Minutes and Final Report, No. 2019-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Peer Review for EPA Draft Risk Evaluation of C.I. Pigment Violet 29, June 18-21, 2019, TSCA Science Advisory Committee on Chemicals Meeting, dated Sept. 18, 2019, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0088, at 14.

101 *Id.* at 15.

102 *Id.* at 16.

103 *Id.* at 18.

104 *Id.* at 19 (bold face in original).

105 TSCA Science Advisory Committee on Chemicals, Meeting Minutes and Final Report, No. 2019-02, Peer Review for EPA Draft Risk Evaluations of 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD), July 29-August 2, 2019, TSCA Science Advisory Committee on Chemicals Meeting, dated Oct. 31, 2019, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063.

106 *Id.* at 85.

107 *Id.* at 18 (bold face in original).

The Committee noted that it is inappropriate to use optimistic inhalation estimates rather than realistic or near-worst-case conditions."[108] With respect to occupational inhalation exposures, the SACC commented that the agency's finding such exposures do not present an unreasonable risk of injury to health "is not adequately supported in this draft Evaluation."[109] Furthermore, many SACC members did not think that the agency's deferral of concerns regarding consumer or public exposures to 1,4-dioxane on the basis of other environmental statutes was acceptable.[110]

In August 2019, EPA released its draft risk evaluation for 1-bromopropane.[111] The comment period regarding the 1-bromopropane draft risk evaluation closed on October 11.[112] While there are other uses, 1-bromopropane is primarily used as a solvent for cleaning and degreasing.[113] EPA initially determined in the draft that 1-bromopropane does not present an unreasonable risk to the environment under the conditions of use that it identified. As for health risks, EPA initially determined that some uses presented unreasonable risks to workers, consumers, or bystanders (e.g., industrial and commercial use as a solvent for degreasing and cleaning), while other uses did not present unreasonable risks to human health (e.g., manufacturing and certain processing activities).[114] In evaluating the risks to workers, EPA assumed that "workers are properly trained and fitted on respirator use, and that they wear respirators for the entire duration of the work activity where there is potential exposure."[115]

"[M]any SACC members did not think that the agency's deferral of concerns regarding consumer or public exposures to 1,4-dioxane on the basis of other environmental statutes was acceptable."

2. PRIORITIZATION AND RISK EVALUATION RULES

EPA proposed both the prioritization and risk evaluation rules in January 2017, just under seven months after the enactment of the Lautenberg Act.[116] The proposal outlined the processes for identifying potential chemicals for prioritization, screening them against certain criteria, formally initiating the prioritization process, providing opportunities for

108 *Id.*

109 *Id.* at 19.

110 *Id.*

111 EPA, *Draft Risk Evaluation for 1-Bromopropane (n-Propyl Bromide) (CASRN: 106-94-5)* (Aug. 2019), https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OPPT&dirEntryId=347140.

112 84 Fed. Reg. 39,830 (Aug. 12, 2019).

113 *Draft Risk Evaluation for 1-Bromopropane, supra* note 102, at 19.

114 *Id.* at 23–26.

115 *Id.* at 24.

116 82 Fed. Reg. 4,825 (Jan. 17, 2017) (proposed rule), https://www.govinfo.gov/content/pkg/FR-2017-01-17/pdf/2017-00051.pdf; 82 Fed. Reg. 7,562 (Jan. 19, 2017) (proposed rule), https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01224.pdf.

public comment, as well as proposing and finalizing designations of priority. This proposed rule identified the steps of a risk evaluation process, including scope, hazard assessment, exposure assessment, risk characterization, and risk determination, which excluded considerations of costs or other non-risk factors.

Just over six months later, on June 22, 2017, the first anniversary of the Lautenberg Act's signing, the administrator signed both final rules. This represented a significant achievement in terms of meeting the statutory deadlines, particularly due to the disruption caused by a change of administrations with its attendant turnover in senior-level management.

The prioritization rule underwent significant changes between the proposal and the final rule. While the final rule preserved many aspects of the proposal,[117] it dropped the proposed pre-prioritization process for EPA to gather information and fill data gaps on potential chemicals for prioritization before making decisions. It also dropped a default mechanism pursuant to which a chemical that failed to qualify as low priority would automatically be designated as high priority. The final rule also added explicit references to EPA following the scientific standards listed in section 26(h) of TSCA related to best available science.[118]

In addition, the risk evaluation rule also underwent significant changes between its proposal and finalization. Although the final rule contained many provisions found in the proposal, the agency made a number of important revisions.

"Just over six months later, on June 22, 2017, the first anniversary of the Lautenberg Act's signing, the administrator signed both final rules."

First, EPA substantially altered its approach to evaluating the conditions of use of a chemical substance when undertaking risk evaluations by dropping an interpretation requiring it to examine all conditions of use. Section 6(b)(4)(A) of TSCA provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], *under the conditions of use*." (Emphasis added.)

In the proposal, EPA interpreted this language as requiring it to examine all conditions of use when

117 These included the codification of the policy objective, the timeframes for action, the designation of a chemical substance as a whole, provisions regarding EPA's authority to take action concerning categories of chemical substances, the chemicals subject to prioritization, and many of the definitions. 82 Fed. Reg. 33,753, 33,754–57 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

118 *Id*. at 33,756–58.

evaluating a chemical substance.[119] In the final risk evaluation rule, however, EPA changed its interpretation, in response to industry comments, to assert that EPA had the discretion to limit a risk evaluation to certain conditions of use. In doing so, EPA pointed to the definition of conditions of use in section 2 of TSCA, which provides that the "term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

EPA stated it "intends this to primarily be a case-by-case determination" but outlined certain activities that it identified on the basis of "legislative history, statutory structure and other evidence of Congressional intent … that may generally not be considered conditions of use."[120] Furthermore, EPA argued that because it must publish the scope of a risk evaluation under section 6(b)(4)(D), *inter alia,* and identify the conditions of use it expects to consider, it "is not required to consider all conditions of use."[121] Pointing to resource concerns and other factors, EPA concluded that it

> may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures [such as uses in a closed system or as an intermediate]. During the scoping phase, EPA may also exclude a condition of use that has been adequately addressed by another regulatory authority, particularly where the other agency has effectively managed the risks.[122]

Elaborating, EPA explained that TSCA was "ambiguous as to whether the conditions of use identified by EPA should include the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution, which EPA will refer to as 'legacy uses.' The statute is also ambiguous as to disposals from such uses …."[123]

Although EPA interpreted "the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal states of their lifecycle" EPA also said that "in a particular risk evaluation, [it] may

119 "Overall, the statutory text and purpose are best effectuated through a more encompassing reading. TSCA section 6(b)(4)(A) (15 U.S.C. § 2605(b)(4)(A)) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on '*the* conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use." 82 Fed. Reg. 7,565 (Jan. 19, 2017) (codified at 40 C.F.R. pt. 702).

120 82 Fed. Reg. 33,729 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

121 *Id*.

122 *Id*.

123 *Id*. at 33,729.

consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from legacy uses."[124] Asbestos represents a prime example of such legacy uses and associated or legacy disposals. No longer produced in the US, asbestos is found in building insulation in both homes and commercial buildings and is subject to disposal.[125]

Second, EPA made changes to the provisions governing manufacturer-requested risk evaluations. One change allowed manufacturers to submit a request for a risk evaluation "on only the conditions of use of the chemical substances that are of interest to the manufacturer."[126] EPA explained that it intended to conduct risk evaluations on manufacturer requests in the same way as other risk evaluations and could add other conditions of use it identified.[127] EPA also dropped a proposed requirement that manufacturers who made a request had to submit "any risk assessment or evaluation that they might possess."[128] In doing so, the agency responded to industry concerns that such risk evaluations may have been conducted under other statutes or for other purposes, including in response to litigation. The agency, however, stated it believed all relevant risk assessments on a chemical would need to be provided pursuant to section 8(e) of TSCA or other regulatory provisions requiring the submission of any relevant information.[129]

Third, the agency modified definitions in the rule and the process requirements for risk evaluations. These encompassed numerous issues, including the components of a risk evaluation and the addition to the rule of more definitions than incorporated in the proposal.[130]

Environmental organizations challenged both of these rules in August 2017. The groups, however, filed petitions for review in three different circuits, [131] leading to a transfer and consolidation of the cases involving both the prioritization and risk evaluation rules in the Ninth Circuit.[132] Subsequently, various industry trade associations intervened on behalf of EPA.

The main issues raised by the environmental petitioners focused on the core question of whether EPA has the authority to carve out conditions of use from its evaluation of a chemical substance.[133]

124 *Id*. at 33,730.

125 EPA, *Problem Formulation of the Risk Evaluation for Asbestos* 8–9 (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/asbestos_problem_formulation_05-31-18.pdf.

126 82 Fed. Reg. 33,736 (July 20, 2017) (codified at 40 C.F.R. pt. 702).

127 *Id*.

128 *Id*.

129 *Id.* at 33,736–37.

130 *Id.* at 33,731–38.

131 The petitioners were Environmental Defense Fund (challenging both the prioritization rule and risk evaluation rule), Safer Chemicals, Healthy Families (challenging the risk evaluation rule), and the Alliance of Nurses for Healthy Environments (challenging the prioritization rule).

132 Order, *Alliance of Nurses for Healthy Environments v. US EPA,* No. 17-2040 (4th Cir. Dec. 11, 2017).

133 Opening Brief of Petitioners, *Safer Chem. Healthy Families v. US EPA*, No. 17-72260 (consolidated with Nos. 17-72501, 17-72968, 17-

However, at the oral argument before the Ninth Circuit in May of 2019, the judges focused much of their attention on whether petitioners could properly challenge the procedural framework rules or needed to wait until individual determinations regarding particular chemicals. The court requested additional briefing on the issue of Article III justiciability, which the parties completed in June.[134]

On November 14, 2019, the Ninth Circuit issued its decision in the case dismissing in part, denying in part, and granting in part the petitions for review.[135] While one part of the decision rested on justiciability grounds, as intimated by the oral argument and additional briefing request, the other two parts of the decision reached the merits.

First, the court found that petitioners' challenge concerning whether EPA had to evaluate risks from the uses of a chemical substance collectively, as opposed to the risk from each use individually, was not justiciable at this time because the petitioners' views of EPA's intentions on which it rested and the consequent theory of injury were too speculative.[136] The court found that the text of the Risk Evaluation Rule itself regarding whether risks from individual uses as opposed to all uses holistically was ambiguous and it was therefore not clear how EPA would evaluate risks in its evaluations.[137] The court made clear, however, that it was leaving for the future the resolution of this issue on the merits. Writing for a unanimous panel, Judge Friedland concluded on this issue that: "If EPA *does,* in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA's 'no unreasonable risk' determination."[138] While the petitioners did not lose on the merits of this issue, the Ninth Circuit's ruling that these issues were too speculative to be resolved at this juncture represents a significant setback for environmental NGOs. The challenges will now have to await the completion of potentially years of effort on each individual chemical at issue, leading to significant delays if EPA were then required to reevaluate chemicals under a broader set of conditions of use before rendering another decision on whether the chemical substance presents an unreasonable risk.

Next, the Ninth Circuit ruled against the environmental petitioners on the second issue, albeit in a way that may in fact largely represent a victory for the petitioners. That issue concerned the petitioners' argument that the Risk Evaluation Rule violated TSCA's provisions regarding the scope of a risk evaluation by not requiring that EPA consider all of a chemical substance's conditions of use (whether collectively or individually) as part of the risk evaluation. Petitioners challenged both language in the preamble and language in the regulatory text.

73290, 17-73383, 17-73390) (9th Cir. Apr. 16, 2018).

134 Chemical Watch, *TSCA Litigation: NGOs' legal standing takes centre stage* (May 21, 2019), https://chemicalwatch.com/77765/tsca-litigation-ngos-legal-standing-takes-centre-stage.

135 *Safer Chemicals v. United States EPA,* 2019 U.S. App. LEXIS 33976 (9th Cir. Nov. 14, 2019).

136 *Id.* at 18.

137 *Id.* at 23.

138 *Id.* at 30 (emphasis in original).

The court first rejected the arguments premised on the preamble language on the basis that the preamble language was not final action. Then the court proceeded to examine the claims made regarding the provisions of the regulation itself. The court rejected the petitioners' arguments about the text on the merits "because the provisions that Petitioners point to do not, as Petitioners contend, in fact assert discretion to exclude conditions of use from evaluation."[139] In essence, the court stated that the regulatory text did not provide a basis for EPA to do as the petitioners feared, which was to use discretion to exclude certain conditions of use from its risk evaluations. Judge Friedland explained that the court saw the regulatory provisions as unambiguous on the issue of EPA's discretion to exclude conditions of use that it had identified from the scope of a risk evaluation: "[A] more natural reading is that this refers … simply to the Agency's discretion (and expertise) in determining what constitutes a condition of use for a particular chemical substance. We therefore conclude that the challenged provisions unambiguously do not grant EPA the discretion Petitioners contend."[140] The court also rejected reference to the preamble language that petitioners saw as indicative of EPA's intent to exclude conditions of use from the scope of risk evaluations since reliance on preamble language was improper where regulatory provisions were themselves unambiguous.[141]

Lastly, the court turned to petitioners' challenge to EPA's preamble language excluding from the definition of conditions of use an entire category of activities, referred to as "legacy activities," which consist of "legacy uses," "associated disposals," and "legacy disposals."[142] After dealing with justiciability and standing issues regarding this issue, the court reached the merits. The court viewed the preamble language regarding legacy activities as subject to judicial review since it was "EPA's final, unequivocal interpretation—there is every reason to believe that the agency intended to bind itself, and what is required by this interpretation is, as EPA concedes, sufficiently clear to be reviewable."[143] The Ninth Circuit ruled that EPA's exclusion of legacy uses and associated disposals from the definition of conditions of use was unlawful because it contravened the clear language of TSCA. The court concluded that "TSCA's definition of 'conditions of use' clearly includes uses and future disposals of chemicals even if those chemicals were only historically

139 *Id.* at 32-33.

140 *Id.* at 39-40.

141 *Id.* at 40.

142 *Id.* at 42. The court explained: "EPA defines the term 'legacy uses' in the preamble as 'the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution.' For example, although asbestos is now infrequently used in making new insulation, it remains in place in previously installed insulation. According to EPA's interpretation, the use of asbestos in insulation is a 'legacy use' of that chemical. "Associated disposal[s]' refers to future disposals from legacy uses, such as the removal of asbestos-containing insulation to a landfill during a building's renovation. Finally, 'legacy disposal[s]' are defined as 'disposals that have already occurred,' regardless of whether the substance disposed of is still manufactured for its pre-disposal use. For example, this could refer to the previous placement of asbestos insulation into a landfill or the previous disposal of a chemical substance in a flame retardant that is still used for that purpose." *Id.* at 42-43 (citations omitted).

143 *Id.* at 46-47.

manufactured for those uses."[144] The court, however, rejected petitioners' attempt to wrap "legacy disposals" into the same category as "legacy uses" and "associated disposals." The court found that TSCA's definition of conditions of use unambiguously does not encompass disposals that occurred in the past, the court upheld EPA's exclusion of "legacy disposals" from the universe of conditions of use to be considered in risk evaluations.[145]

"[T]he Ninth Circuit's ruling in favor of the petitioners on the issue of legacy uses and associated disposals on the basis of clear statutory language is a significant win for the environmental NGOs and a rejection of EPA's narrow approach to the scope of TSCA's health and environmental protections."

While the Ninth Circuit's decision in *Safer Chemicals* represents a mixed result in terms of whether EPA or the environmental NGOs prevailed on particular issues it serves as a warning to EPA that the courts will review its interpretations carefully and not hesitate to strike down those that contravene the language of TSCA. Although the ruling regarding justiciability on the issue of collective evaluation of risks is a clear setback for environmental NGOs due to the delay that will result in ultimately raising that issue to the courts, it is obviously not a loss on the merits. The court's ruling on the agency's ability to use discretion to exclude conditions of use from risk evaluations is nominally a loss for the environmental NGOs, but in fact represents a clear victory for them in terms of the courts reading of the regulations that prevents EPA from interpreting them in the way that the NGOs feared. Finally, the Ninth Circuit's ruling in favor of the petitioners on the issue of legacy uses and associated disposals on the basis of clear statutory language is a significant win for the environmental NGOs and a rejection of EPA's narrow approach to the scope of TSCA's health and environmental protections.

3. INVENTORY RULE

At the same time it proposed and took final action on the prioritization and risk evaluation rules, EPA also completed the inventory rule requiring notification to EPA of active and inactive chemicals. As with the other two rules, EPA met the June 22, 2017 statutory deadline.[146]

The Environmental Defense Fund challenged the inventory rule in the DC Circuit as unlawfully protecting information about chemical substances from public disclosure and the court issued its

144 *Id.* at 53.

145 *Id.* 55-56.

146 82 Fed. Reg. 37,520 (Aug. 11, 2017) (codified at 40 C.F.R. pt. 710), https://www.govinfo.gov/content/pkg/FR-2017-08-11/pdf/2017-15736.pdf.

ruling in April of last year.[147] The court's decision represented a mixed verdict for EDF's claims.

First, the court firmly rejected arguments by EPA and chemical industry intervenors that EDF lacked standing. The court found that EDF successfully asserted "a quintessential claim of informational standing," noting that the "law is settled that 'a denial of access to information' qualifies as an injury in fact 'where a statute (on the claimants' reading) requires that the information 'be publicly disclosed' and there 'is no reason to doubt their claim the information would help them.'"[148]

On the merits, the court ruled in favor of EDF on its challenge to EPA's elimination of proposed questions that companies had to answer to keep the chemical identity of a substance confidential. The questions were designed to implement the statutory requirement to substantiate an assertion that the chemical identity "is not readily discoverable through reverse engineering."[149] The court found that EPA acted arbitrarily and capriciously in eliminating the reverse engineering questions. The court ruled that by its complete elimination of the questions, EPA had "effectively excised a statutorily required criterion from the substantiation process" with an "explanation for excising that criterion [that] was, nonsensically, a denial that it had done so."[150]

The court then rejected EDF's challenge to the provisions of the rule that permitted companies that were not the original source of a claim of confidentiality (or its successor in interest) to maintain such a claim. The court found that EPA's allowance of the continued maintenance of confidentiality claims by a broader array of companies than the original one or a successor in interest "fits comfortably within the statutory text."[151]

The court also denied EDF's claim that the Inventory Rule should have contained all of TSCA's procedural requirements. Stating that it is "not necessary" to "duplicate" the statutory requirements "in the rule for duplication's sake," the court noted that if EPA failed to meet the statutory requirements in its future implementation of the Inventory Rule, judicial challenges to those failures could be raised then.[152]

EDF also challenged EPA's failure to incorporate Lautenberg Act requirements to establish a "unique identifier" for each chemical substance that EPA keeps confidential. The court agreed that the Lautenberg Act obligated EPA to develop those requirements, but found that it was not unreasonable for EPA to have moved forward with the Inventory Rule without such requirements since the law did not contain a deadline for the development and implementation of the unique identifier system. Finding that agencies need not address all obligations at the same time, the court determined that it should not second-guess EPA's prioritization of its regulatory tasks.[153]

147 *EDF v. EPA*, 922 F.3d 446 (D.C. Cir. 2019).

148 *Id.* at 452.

149 Section 14(c)(1)(B)(iv) (15 U.S.C. § 2613(c)(1)(B)(iv)).

150 922 F.3d at 454.

151 *Id*. at 455.

152 *Id*. at 457.

153 *Id*. at 458.

Finally, the court rejected EDF's objection to EPA's decision to exclude chemicals produced only for export from the requirement to notify EPA of the manufacture or processing of chemical substances. The court found that the statute was silent on the precise matter at issue and determined that the Inventory Rule's "narrow excision of exports from one reporting requirement passes muster."[154]

"While the court did reject four out of the five substantive claims raised by EDF, its clear rulings in favor of EDF's informational standing are potentially significant for future litigation."

The court ordered a limited remand of the Inventory Rule, without vacatur, for EPA to address its omission of the reverse engineering questions.[155] While the court did reject four out of the five substantive claims raised by EDF, its clear rulings in favor of EDF's informational standing are potentially significant for future litigation.

4. OTHER EXISTING CHEMICALS ACTIVITIES

EPA has taken a number of other significant actions on existing chemicals after the passage of the Lautenberg Act. These include final action on rules proposed under the Obama Administration,[156] and the identification of the first 20 high priority chemical substances and the first 20 low priority substances.

EPA took final action on its January 2017 proposal to ban methylene chloride from paint removers in consumer products in March of 2019 due to its serious human health effects.[157] EPA concluded that methylene chloride in consumer paint and coating removal products posed an unreasonable risk to human health and banned its use in such products. EPA, however, did not follow through with its proposal to ban methylene chloride for commercial use.[158] Instead, EPA deferred taking final action on the unreasonable risk determination regarding commercial uses and its proposed regulation to deal with the unreasonable risk, even though it concluded that the use of methylene chloride in paint and coating removal "presents an unreasonable risk of injury to health in the consumer context due to acute human lethality."[159] In conjunction with that deferral,

154 *Id*. at 458–59.

155 *Id*. at 459.

156 Congress specifically authorized EPA to proceed with these rulemakings without having to pause and redo analysis under the Lautenberg Act. Section 26(l)(4) (15 U.S.C. § 2625(l)(4)) stated that with "respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to June 22, 2016 [among which TCE and NMP were both included], the Administrator may publish proposed and final rules under [section 6(a)] that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of [section 6]."

157 84 Fed. Reg. 11,420 (Mar. 27, 2019). Methylene chloride is both an acute neurotoxicant that can be acutely lethal and a likely human carcinogen.

158 82 Fed. Reg. 7,464 (Jan. 19, 2017).

159 84 Fed. Reg. 11,421 (Mar. 27, 2019).

EPA published an Advance Notice of Proposed Rulemaking seeking additional public comment on a program of certification, training, and limiting access to commercial methylene chloride products.[160]

The Trump EPA has also abandoned or deferred acting on two other proposals to ban chemicals made late in the Obama Administration after the passage of the Lautenberg Act. These actions concerned trichloroethylene (TCE) and N-methylpyrrolidone (NMP), two chemicals that had been placed on the list of the first ten chemicals to be regulated.[161] In December 2016, EPA proposed to ban uses of trichloroethylene (TCE) for aerosol degreasing and for spot cleaning in dry cleaners and then, in January 2017, proposed to ban the use of TCE in vapor degreasing.[162] With respect to NMP, EPA proposed to ban consumer and most types of commercial use of the chemical for paint and coating removal in January 2017.[163] In December 2017, the Trump Administration moved both of these rulemaking proceedings from the category of "active" rulemakings to the category of "long term actions" on its unified regulatory agenda, signaling a long delay in any final action on them.[164] EPA subsequently announced that it would consider the uses of TCE in the December 2016 and January 2017 proposals in its overall TCE risk evaluation as one of the first ten chemicals.[165]

"The Trump EPA has also abandoned or deferred acting on two other proposals to ban chemicals made late in the Obama Administration after the passage of the Lautenberg Act."

EPA has denied five section 21 petitions received since the enactment of the Lautenberg Act, most of which concerned testing or reporting requirements.[166] Petitioners have challenged most

160 84 Fed. Reg. 11,466 (Mar. 27, 2019).

161 81 Fed. Reg. 91,927 (Dec. 19, 2016).

162 81 Fed. Reg. 91,592 (Dec. 16, 2016) (first TCE proposal); 82 Fed. Reg. 7,432 (Jan. 19. 2017)(second TCE proposal).

163 82 Fed. Reg. 7,464 (Jan. 19, 2017).

164 Richard Denison, Environmental Defense Fund, *Systematic slowdown: EPA indefinitely delays virtually all proposed actions to restrict chemicals under TSCA* (Dec. 20, 2017), http://blogs.edf.org/health/2017/12/20/systematic-slowdown-epa-indefinitely-delays-virtually-all-proposed-actions-to-restrict-chemicals-under-tsca/.

165 In the May 2018 Problem Formulation for the Risk Evaluation for Trichloroethylene, EPA stated: "Although EPA indicated in the TCE scope document that EPA did not expect to evaluate the uses assessed in the 2014 risk assessment in the TCE risk evaluation, EPA has decided to evaluate these conditions of use in the risk evaluation as described in this problem formulation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE presents an unreasonable risk 'under the conditions of use,' TSCA 6(b)(4)(A)." *TCE Problem Formulation, supra* note 83, at 24.

166 *See* 84 Fed. Reg. 20,062 (May 8, 2019)(denying petition from 14 state Attorneys General and the Attorney General for the District of Columbia to initiate the process for a new reporting rule for asbestos); 84 Fed. Reg. 3,396 (Feb. 12, 2019)(denying petition from NGO's to amend existing reporting rules regarding asbestos); 82 Fed. Reg. 17,601 (Apr. 12, 2017)(denying petition to require testing of by manufacturers and processors of chlorinated phosphate esters ("CPE")); 82 Fed. Reg. 14,173 (Mar. 17, 2017)(denying petition seeking to require testing by manufacturers and processors on tetrabromobisphenol A ("TBBPA"); 82

of these denials in court. None of the courts has yet issued a final decision resolving any of the challenges.

The denial of a petition seeking to prohibit fluoride additives in water supplies—the only petition seeking control of a chemical, as opposed to reporting or testing of chemicals—has resulted in extended litigation in the Northern District of California, *Food & Water Watch, Inc. v. US EPA.*[167] Plaintiffs asked the court to require that EPA begin a TSCA section 6 process to regulate fluoridation chemicals. While that case is still being litigated, there have been a number of preliminary decisions regarding issues arising under section 21, including one rejecting EPA's motion to limit review to the administrative record, and EPA is currently facing discovery, including depositions of personnel.[168] Trial is currently set for April 2020.[169] This litigation demonstrates the complications that may ensue in the event of future section 21 denials and consequent litigation.

Petitioners challenged two denials of asbestos-related section 21 petitions earlier this year. Both cases are still pending. The Asbestos Disease Awareness Organization and other NGOs filed a challenge on February 18, 2019, to EPA's denial of a section 21 petition seeking an amendment of a rule to require asbestos reporting.[170] Subsequently, on June 28, 2019, the State of California and ten other state attorneys general filed a complaint in the Northern District of California challenging EPA's denial of a petition to initiate rulemaking on a new asbestos-reporting rule.[171]

More recently, on August 7, 2019, Public Employees for Environmental Responsibility (PEER) filed a section 21 petition seeking a ban on the use of hydrofluoric acid at oil refineries. PEER invoked both section 6 of TSCA and provisions of the Clean Air Act, since hydrofluoric acid is listed as a hazardous air pollutant under section 112, as the bases for authority for new regulations to phase out the use of the chemical at oil refineries within two years.[172]

EPA denied the petition on November 4, 2019, finding that the petition did not contain sufficient facts establishing the necessity of issuing a rule under section 6(a) of TSCA.[173] According to EPA, a section 21 petition must provide facts for EPA to be able to "conclude, within 90 days of filing the

Fed. Reg. 11,878 (Feb. 27, 2017)(denying petition seeking to prohibit the addition of fluoride chemicals to water supplies).

167 No. 17-cv-02162-EMC, 2019 U.S. Dist. LEXIS 63656 (N.D. Cal. Apr. 12, 2019).

168 *See id.* (order concerning discovery, including depositions); *Food & Water Watch, Inc. v. US EPA,* 302 F. Supp. 3d 1058 (N.D. Cal. 2018) (rejecting EPA's motion to limit review to the administrative record); *Food & Water Watch, Inc. v. US EPA,* 291 F. Supp. 3d 1033 (N.D. Cal. 2017) (order denying EPA's motion to dismiss).

169 Amended Case Management & Pretrial Order for Trial, *Food & Water Watch, Inc. v. US EPA*, No. 3:17-cv-02161-EMC (N.D. Cal. June 17, 2019).

170 *Asbestos Disease Awareness Organization (ADAO) v. Wheeler*, No. 19-cv-00871-EMC (N.D. Cal. 2019).

171 *State of California v. US EPA*, No. 19-cv-03807 (N.D. Cal. 2019).

172 Public Employees for Environmental Responsibility (PEER), Petition for Rulemaking to the Administrator of the Environmental Protection Agency, *In Re: Ban on Hydrofluoric Acid in Refineries* (Aug. 7, 2019), https://www.epa.gov/sites/production/files/2019-08/documents/hydrofluoric_acid_rulemaking_petition.pdf.

173 84 Fed. Reg. 60986, 60987 (Nov. 12, 2019).

petition, that the chemical presents an unreasonable risk of injury to health or the environment and that issuance of a TSCA section 6(a) rule is the appropriate response to the petition."[174] EPA acknowledged that, due to its hazardous properties, the federal government regulates hydrofluoric acid under various authorities, including Superfund, CERCLA, the Emergency Planning and Community Right-to-Know Act, and the Clean Air Act.[175] Hydrofluoric acid was listed by Congress in 1990 as a hazardous air pollutant and it is subject to the regulations promulgated under section 112(r) regarding the prevention of chemical accidents (generally referred to as the Risk Management Plan (RMP) rule). EPA described the chemicals subject to the RMP rule as "extremely hazardous substances such as hydrofluoric acid" in its denial of the hydrofluoric acid petition.[176] EPA, however, stated that it would need information, including hazard and exposure data, that would allow it to assess the risk of hydrofluoric acid and determine whether that risk is unreasonable. It listed information it would need to assess risk and determine that a section 6(a) rulemaking is necessary, including hazard thresholds recommended and exposure estimates. EPA denied PEER's petition as "facially incomplete" because the petition only made conclusory statements regarding the toxicity of hydrofluoric acid and lacked analysis that would be expected in a TSCA risk evaluation. [177] Thus, notwithstanding its recognition that hydrofluoric acid was an extremely hazardous substance that it regulated under other programs, EPA denied the hydrofluoric acid petition because it reasoned that the petition did not itself provide facts sufficient for EPA to evaluate whether the chemical posed an unreasonable risk during the 90-day section 21 petition review period.

B. New Chemicals Program

EPA's implementation of the new chemicals program under section 5 of TSCA as revised by the Lautenberg Act has generated considerable controversy, particularly as EPA has shifted positions and implementation approaches in response to pressures from different sets of stakeholders. EPA faced significant challenges in implementing the new law. The requirement to make affirmative risk determinations for new chemicals within the short statutory time frames posed particular challenges. The challenges were compounded by the lack of any transition time under the new law, and the need to figure out if and how to apply the new statutory provisions to hundreds of premanufacture notifications ("PMNs") that had been filed prior to the new law.

These issues quickly led to a buildup of hundreds of PMNs awaiting final determinations. Not surprisingly, industry sought to avoid delays in the processing of PMNs and the pace with which it could introduce new chemical substances into commerce. The pressure on EPA to speed up the processing of PMNs for new chemicals and significant new uses increased with the arrival of the Trump Administration.

As a consequence of the difficulties it faced with the

174 *Id.*

175 *Id.* at 60987.

176 *Id*.

177 *Id.* at 60987-88.

new statute, and the impetus to find ways to diminish the time it was taking for EPA to review PMNs, EPA has altered its approaches to reviewing PMNs under section 5, leading to faster processing. These changes, however, have brought their own degree of controversy as they have raised concerns that EPA's approvals are flawed and do not adequately protect health or the environment.

"With respect to the worker protection issue, EPA has recently adopted a practice of assuming that manufacturers and processors will supply workers with adequate personal protective equipment as a way of justifying a finding that a chemical substance or significant new use is not likely to present an unreasonable health risk."

A number of important issues have emerged during the implementation of the new section 5 provisions. A key question is how EPA will determine that a chemical substance or significant new use is "not likely" to present an unreasonable risk under TSCA section 5(B)(3)(C). This includes the degree to which EPA may make assumptions about how manufacturers and processors will protect workers from exposure in determining whether a chemical substance is "not likely" to present an unreasonable risk to health. Another is the meaning under the definition of conditions of use in section 3(4) for circumstances to be "reasonably foreseen." Related to these is the potential role of Significant New Use Rules as a tool that EPA might use to foreclose the possibility of additional uses beyond those identified by the submitter of a PMN.

With respect to the worker protection issue, EPA has recently adopted a practice of assuming that manufacturers and processors will supply workers with adequate personal protective equipment as a way of justifying a finding that a chemical substance or significant new use is not likely to present an unreasonable health risk. Historically, EPA has required manufacturers and processors to provide such equipment to ensure that their workers were not exposed to chemicals that presented health risks. In a series of "not likely" determinations, however, EPA has preliminarily identified health risks, stated that it assumes that employers will provide the necessary equipment, and then determined that the chemical substance is not likely to present an unreasonable risk due to that assumption.[178]

178 *See, e.g., Determination for PMN P-17-0382 (amides, tallow, N,N-bis(2-hydroxypropyl), CASRN 1454803-04-3)* 1, 5 (Nov. 21, 2018), https://www.epa.gov/sites/production/files/2018-11/documents/p-17-0382_determination_non-cbi_final.pdf; *Determination for Premanufacture Notice (PMN) P-18-0212 (generic name: substituted carbomonocycle, polymer with alkyl alkenoate, alkenyl substituted carbomonocycle, substituted alkanediol, heteropolycycle, alklyene glycol and alkenoic acid, compd. with alkylamino alkanol; polymer exemption flag)* 5–6 (Nov. 30, 2018), https://www.epa.gov/sites/production/files/2018-12/documents/p-18-0212_determination_non-cbi_final.pdf; *Determination for PMN P-17-0281 (generic chemical name: poly silo and-polyester polygon carboxylate)* 5 (Dec. 4, 2018), https://www.epa.gov/sites/production/files/2018-12/documents/p-17-0281_

The new chemicals program will continue to be a source of controversy but has yet to generate any significant litigation. As more determinations are made regarding individual chemical substances and significant new uses, it is likely that some of these decisions will lead to litigation.

C. Fees Rule

Another rulemaking of great significance for the implementation of the new law, but not subject to a specific mandatory deadline, is the fees rule authorized by section 26(b). The fees rule provides EPA with the capacity to undertake the work required under the Lautenberg Act by authorizing EPA to collect payments to fund a portion of the costs of implementing sections 4, 5, and 6, and the costs of implementing the information-related provisions of section 14. It also provides a mechanism for EPA to recoup costs related to manufacturer-requested risk evaluations.[179]

In the absence of a statutory deadline, EPA proceeded at a slower pace on the fees rule, and it did not publish the proposal until February 26, 2018.[180] The proposal described the fee categories for fiscal years 2019, 2020, and 2021, and explained the methodology for determining the proposed TSCA user. The final rule, issued on September 27, 2018, included a new process for identifying manufacturers subject to fee obligations for section 4 test rules and section 6 EPA-initiated risk evaluations. It also modified the proposed methodology for calculating charges for manufacturer-requested risk evaluations and made other changes.[181] Unlike the other three framework rules, the fees rule was not challenged in court.

determination_non-cbi_final_0.pdf.

179 EPA explained that section 26(b) (15 U.S.C. § 2625(b)) "authorizes EPA to establish, by rule, fees for activities under TSCA sections 4, 5 and/or 6. In so doing, the Agency must set lower fees for small business concerns and establish the fees at a level such that they'll offset 25% of the Agency's costs to carry out a broader set of activities under sections 4, 5, and 6 and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. In addition, in the case of a manufacturer-requested risk evaluation, the Agency is authorized to establish fees sufficient to defray 50% of the costs associated with conducting a manufacturer-requested risk evaluation on a chemical included in the *TSCA Work Plan for Chemical Assessments: 2014 Update,* and 100% of the costs of conducting a manufacturer-requested risk evaluation for all other chemicals. TSCA now requires fee revenue to be deposited into a new dedicated TSCA fund intended to ensure that resources are made available to the Agency to defray some of the costs that EPA incurs in carrying out activities under sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under TSCA. EPA is also required in TSCA section 26(b)(4)(F) to review and adjust the fees established in this rule every three years, and to consult with parties potentially subject to fees when the fees are reviewed and updated to reflect changes in program costs." 83 Fed. Reg. 52,694, 52,695 (Oct. 17, 2018) (codified at 40 C.F.R. pts. 700, 720, 723, 725, 790, and 791).

180 83 Fed. Reg. 8,212 (Feb. 26, 2018) (codified at 40 C.F.R. pts. 700, 720, 723, 725, 790, and 791).

181 83 Fed. Reg. 52,694 (Oct. 17, 2018) (codified at 40 C.F.R. pts. 700, 720, 723, 725, 790, and 791).

Conclusion

EPA's implementation of the Lautenberg Act shows that the promise of the new law has yet to be fulfilled. EPA has made significant progress in terms of achieving a number of the major milestones, including the issuance of the key framework rules, in a timely fashion. It has begun moving forward on the risk evaluations of the first ten chemicals and selected the first groups of high and low priority chemical substances. EPA has also grappled with issues created by the changes to the new chemicals program brought about by the new law.

How successful EPA's efforts will be in meeting the objectives of both the original TSCA and the Lautenberg Act remain to be seen. Congress intended TSCA to be an overarching law capable of eliminating unreasonable risks from chemicals, even risks presented on a global scale such as those from CFCs or by chemicals that were subject to other environmental laws. The Lautenberg Act undoubtedly increased the protectiveness of TSCA's unreasonable risk standard by eliminating the cost-benefit balancing nature of the original law. But the real impact of the revised unreasonable risk standard is not yet clear. EPA's recent actions may limit the real protectiveness of the new standard. The assumptions EPA makes and approaches it adopts in existing chemical risk evaluations and new chemical determinations may result in a less protective regime than was intended by the drafters of the Lautenberg Act revisions. As the Ninth Circuit's recent decision in *Safer Chemicals* indicates, however, the courts will be weighing in on the choices EPA is making as it proceeds with implementation.

AUTHOR BIO

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AUTHOR NOTES

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