Bloomberg Environment Insights

New Chemicals Under New TSCA—Stalled Commercialization

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This article was originally published as a three part series analyzing the impact of new TSCA Section 5 and EPA's implementation of it on chemical innovation.

Bergeson & Campbell has written extensively about the U.S. Environmental Protection Agency's implementation of the 2016 Amendments to the Toxic Substances Control Act occasioned by enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). On the whole, EPA implementation efforts have been timely, balanced, and defensible. Implementation of Section 5 (new chemicals) revisions has been less successful. To date, the EPA's approach has impeded the commercialization of more sustainable new chemical technologies and thus has, ironically, extended the market presence of often less- sustainable legacy chemicals.

The EPA's release in late July 2018 of a TSCA Section 5 "not likely" determination for a new polymer, P-16-0510, represents a significant positive shift in the agency's approach to reviewing new chemicals. The EPA concluded that the new chemical at issue is "not likely" to pose unreasonable risk despite the fact that health endpoints and ecological hazards were identified. In nearly all prior post-Lautenberg cases, EPA only made a "not likely" determination if it identified a low hazard for both health and ecological effects. We support and applaud the EPA's determination and believe, as discussed in our blog post, "EPA Adds Clarity to Interpretation of 'Reasonably Foreseeable Conditions of Use,'" that this revised approach better implements the law as written and more accurately expresses the national policy, articulated in TSCA Section 2 and unchanged since 1976, to review new chemicals "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation …." TSCA Section 2(b)(3) reads, in pertinent part: "[i]t is the policy of the United States that … authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act." This article makes the case for the urgent need for other changes in new chemical policy to ensure the realization of a more balanced and measured regulatory process that supports and promotes new chemical innovation and commercialization in a way that aligns with TSCA's stated goals and requirements.

Out With the Old and In With the New

Under both old and new TSCA, chemicals listed on the TSCA Inventory are considered existing chemicals. Chemicals that are not listed on the Inventory are considered new chemicals, and chemical manufacturers must notify the EPA under Section 5 prior to manufacturing, processing, or importing new chemicals, or qualify for an exemption from doing so. Section 5 notices include premanufacture notifications (PMN) and various exemption notifications.

Under TSCA pre-Lautenberg, the EPA conducted its scientific and regulatory analysis and, if the EPA did not identify an issue to a PMN submitter and take action within the 90-day statutory review period, EPA would "drop" the case from further review and the submitter was permitted to submit a notice of commencement (NOC) and begin manufacture, processing, or import of the chemical substance for which the notification was submitted. Although not required by old TSCA, the EPA paid close attention to completing any needed actions within the 90-day timeframe for review. Based on our experience, there were only

{00502.035 / 111 / 00251156.DOCX}This is a reprint of an article series published in *Bloomberg Environment Insights*, September 11-13, 2018.

a few instances where EPA missed the deadline due to error. In most of these cases, the EPA and the submitter were able to agree on an approach that kept the case within the PMN regulatory framework. The submission of the NOC was the act that placed the chemicals substance on the chemical Inventory, converting the legal status of the substance to that of an existing chemical.

The efficiency of the pre-Lautenberg Section 5 process was under-appreciated. The EPA's new chemical review process was effective and well-run, did an excellent job of assessing the potential risk of and regulatory issues with new chemicals through various internal working groups which consisted of scientists, risk assessors, regulators, and managers from across program offices, and relied upon sophisticated computational tools to evaluate the new chemical substance. This process included the Chemical Review and Search Strategy (CRSS) team meeting that reviews the chemistry profile of the new chemical substance (*i.e.*, chemical identity and structure, physicochemical properties, and analogs); the Structure Activity Team (SAT) team meeting that reviews and establishes a rating for the likely hazards each new chemical substance may present to health or the environment as well as the substance's expected environmental fate; evaluation of the degree of the new chemical substance's potential human exposures (worker and general public) and environmental releases; a "Focus" meeting, where the EPA characterizes the risk and decides whether the new chemical substance would, might, or was not likely to present risk to health or the environment; and if at the Focus meeting, the EPA decides that a PMN chemical substance may present risks, but those risks are not adequately characterized, an in-depth "standard review" would compile a more complete risk characterization to inform the EPA's risk determination and the most appropriate risk management option. Questions may arise in any of these review stages; if so, the EPA would contact the submitter (or the submitter's agent) to seek additional information. The EPA routinely reviewed risks to workers and other potentially exposed populations and ecological risks. When regulatory issues were identified, the EPA and the submitter negotiated and agreed on the terms of a consent order under Section 5(e) and/or the EPA implemented a Significant New Use Rule (SNUR) to require advance notification to the EPA of any "significant new uses" that the agency foresaw might lead to an unreasonable risk.

EPA review of new chemicals often resulted in the imposition of workplace or environmental release limitations and other restrictions on the notifier, downstream processors, and users of the new chemical under Section 5(e) orders. Alternatively, or in addition, the EPA would promulgate SNURs to ensure notification of significant new uses from these same types of entities. A "significant new use" frequently does not involve a use *per se* but concerns some chemical-specific restriction or regulation which, if exceeded, triggers the notification (for example, use above a certain volume or in a different physical form). A SNUR establishes a requirement to notify the EPA 90 days before commencing any activity that the SNUR defines as a "significant new use." In response to a Significant New Use Notification (SNUN), the EPA will review the proposed use using the same paradigm the agency uses for new chemicals and would issue a Section 5(e) order to require testing, control potential unreasonable risks presented by the significant new use, modify the existing SNUR, or some combination of all three. As part of this process under old TSCA, as the EPA acknowledges, it also routinely identified "potential new uses of the chemical (other than those reviewed as part of the PMN)" (EPA, *Statistics for the New Chemicals Review Program under TSCA, 01/19/17 Snapshot*), as such reviews provided the basis for the 1,557 non-5(e) SNURs the EPA issued under TSCA prior to Lautenberg (EPA, *Statistics for the New Chemicals Review Program under TSCA*). Pre-Lautenberg, some 40,000 new chemicals were

reviewed by the EPA and regulatory action was taken on approximately 10 percent to 15 percent of new chemicals, meaning that between 85 percent to 90 percent could proceed without restriction to commencement of manufacture and commercialization. A Notice of Commencement (NOC) of manufacture or import must be submitted to the EPA within 30 days of first manufacture or import. Based on our prior experience with the EPA, NOCs were typically received on 50 percent or somewhat less of the submitted PMNs.

The EPA's approach under old Section 5 was considered by many to be successful. The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) analyzed TSCA Section 8(e) (notices of substantial risk) notices and PMNs received in 1999 and 2000. Based on that analysis, the Chair of the NPPTAC Broader Issues Work Group concluded in 2004 that the PMN review was "robust." *See* Minutes of NPPTAC meeting, dated July 13-14, 2004. This is one metric by which to assess the success of the PMN review program. Another is a 2003 analysis jointly conducted by the EPA and the European Union that favorably compared Section 5 new chemicals review and the deployment of Structure Activity Relationship (SAR) models against actual measured values for 144 chemicals that were notified in the EU. The House of Representatives passed a version of the Lautenberg bill that did not amend Section 5 at all. H.R. 2576, 114th Cong. (as passed by House, June 23, 2015). Of note, page 13 of the Committee Report on H.R. 2576, when reported on June 23, 2015, stated:

Oversight by the Committee yielded two conclusions about TSCA modernization. First, *not every part of TSCA needs to be rewritten -- and those that do are places where there is widespread agreement*. Second, *not every problem with TSCA is a statutory problem. EPA may, if it chooses, use existing authority to remedy these concerns*.

In light of these conclusions, the Committee on Energy and Commerce focused on providing EPA more direct tools to obtain testing information on chemical substances, restructuring the way existing chemicals are evaluated and regulated, clarifying the treatment and availability of trade secrets submitted to EPA, updating the collection of fees needed to support EPA implementation of TSCA, assuring high quality science is used by the Agency, and organizing the Federal-State regulatory relationship in a way that makes sense for promoting interstate and global commerce, but also recognizes non-conflicting efforts taken by several States." *H.R. Rep. No. 114-176, at 13 (2015) (emphasis added).*

The following statements, taken from a colloquy between Sens. Inhofe and Vitter in the Congressional Record on June 7, 2016, following passage of Lautenberg, captures and reflects the views of many stakeholders:

Mr. INHOFE. … the bill also makes changes to TSCA in the new chemicals program under section 5 which has been largely viewed as one of the major strengths of existing law. It has been credited with spurring innovation in chemistry used for new products and technologies throughout the value chain. … Mr. VITTER. Protecting innovation and not materially altering the new chemicals process was a critical part of the final compromise. Every effort was made to ensure EPA has the right tools to review new chemical substances but the amendments to this section were intended to conform closely with EPA's current practice and maintain the Agency's timely reviews that allow substances to market within the statutory deadlines. … The compromise is very clear: EPA should not stop or slow its review of new chemicals while it develops any needed new policies procedures or guidance for Section 5. 162 Cong. Rec. S3511, S3520 (daily ed. June 7, 2016) (statements of Senators James Inhofe and David Vitter).

Indeed, in the run-up to Lautenberg, unlike risk management under Section 6, testing under

Section 4, state preemption under Section 18, and other TSCA sections, the Section 5 program was seldom noted as a key driver of the TSCA reform effort. Reflecting the measured level of concern evidenced in the legislative process, Congress retained much of old TSCA Section 5 with targeted changes that strengthened the general approach. Most notably, new Section 5 requires the EPA to make one of three determinations in reviewing PMNs, and to take the appropriate action depending upon the determination, rather than defaulting to commercialization if EPA took no action. In our view, Lautenberg did not change the criteria that EPA would use. Instead, it codified the existing process.

Now, EPA review may not consider costs or other non-risk factors in determining whether the new chemical presents an unreasonable risk. New TSCA also now explicitly requires the EPA to consider unreasonable risks to "potentially exposed or susceptible subpopulations" (including workers, infants, children, and others) identified as relevant by the EPA under the "conditions of use" in making certain of the determinations under Sections 5, although EPA arguably routinely did so under old TSCA.

The first of the determinations (TSCA Section 5(a)(3)(A), 15 U.S.C. § 2604(a)(3)(A)) that EPA can make is that the new chemical "presents" an unreasonable risk of injury to health or the environment, in which case EPA must then regulate the new chemical under Section 5(f) "to the extent necessary to protect against such risk" and promulgate a significant new use rule (SNUR), or publish a statement explaining why it is not initiating such a rulemaking. TSCA Section 5(f)(4), 15 U.S.C. § 2604(f)(4).

The second determination (TSCA Section 5(a)(3)(B), 15 U.S.C. § 2604(a)(3)(B)) that the EPA can make is that the information available is insufficient for a reasoned evaluation of the health and environmental effects; or that in the absence of sufficient information for an evaluation, the manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; or that the new chemical is or will be produced in substantial quantities, and 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 new chemical. Because this alternative consists of a series of "or" statements, if any of these determinations is satisfied, the EPA must then issue an order to regulate the new chemical under Section 5(e) to the extent necessary to protect against an unreasonable risk of injury, without consideration of costs or other non-risk factors, including unreasonable risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use. The EPA must also then either promulgate a SNUR or explain why it is not initiating such a rulemaking. TSCA Section 5(f)(4), 15 U.S.C. § 2604(f)(4).

The third determination (TSCA Section 5(a)(3)(C), 15 U.S.C. § 2604(a)(3)(C)) that the EPA can make is that the new chemical is not likely to present an unreasonable risk of injury to health or the environment. In such cases, the PMN submitter may immediately commence manufacture, import, or processing. New TSCA requires the EPA to publish a statement of its finding (TSCA Section 5(g), 15 U.S.C. § 2604(g)), which EPA publishes on its website and in the *Federal Register*. TSCA Section 5(h), which concerns exemptions from PMN notification, has been retained with generally conforming changes in new TSCA. They include test market exemptions (TME) and low volume exemptions (LVE). 15 U.S.C. § 2604(h).

Despite EPA's best efforts, its implementation of the Section 5 revisions has been rocky and uneven. The reasons for this are many. The EPA in its early implementation initially embraced an overly broad interpretation of "reasonably foreseen" (a term embedded in the definition of "conditions of use" (TSCA Section 3(4), 15

U.S.C. § 2602(4)) to include virtually any imaginable set of conditions, including those based on mere speculation, as opposed to what we believe Congress intended, namely a plausible (*i.e.*, "reasonably foreseen") extension of or addition to the conditions of use as described in the PMN. Based on our experience, particularly at the outset of implementation of Lautenberg, EPA decisions also often simply conflated assessment of hazard (toxicity) and risk (a function of both hazard and exposure) with the result that virtually any new chemical with an identified "potential hazard" was regulated as if it presented an unreasonable risk. That is, if the EPA identified a potential hazard, the agency then assumed that some condition of use could exist that would lead to an exceedance of a concern level, without considering whether such condition of use was plausible or likely as defined by Lautenberg.

In other instances, based on our experience, the EPA overlooked the factual hazard and exposure data and information contained in the PMN and instead used modeled results from SAR analysis and/or chemical analogs to assess hazards and EPA-preferred exposure "assumptions" that yielded unreasonably conservative or simply incorrect hazard, exposure, and risk assessments that compelled the application of limitations that, not infrequently, represented commercially devastating overreach. The EPA would only use a submitter's estimate for releases or exposures if those values were more conservative (*i.e.*, higher exposures and greater releases) than EPA's conservative assumptions. In this paradigm, there was essentially no reason for a submitter to include measured exposure or other information relating to conditions of use. This outcome is not aligned with the EPA's frequently made recommendation to include as much information about the conditions of use as possible in a PMN, a recommendation now included in the EPA's Points to Consider document.

The result has been implementation of a new chemicals program characterized by lengthy delays (delays of more than a year are common) and over-regulation. Table 1 presents information on the outcomes from PMN review that were seen under old TSCA, and Table 2 provides outcome information for post-Lautenberg PMN cases. As can be seen in Table 2, the EPA under the new law has made "not likely" determinations for less than 10% of the PMNs submitted since TSCA was amended and the other 90% of cases have been regulated, are poised for regulation, or have been withdrawn. The table also shows that while the EPA has completed Section 5(a)(3) determinations on 1,545 (77 percent) of the 2,018 new TSCA PMNs, this is only the first part of the process and 1,374 or a disturbing 68 percent of these PMNs remain uncompleted. Under old TSCA, approximately 13% of PMNs were regulated or withdrawn and the remainder, following EPA's review, could enter commerce without restriction. Our point is not that regulatory outcomes under new TSCA should track the pattern seen in old TSCA. Our point is that a better balance needs to be struck between these poles. The result of EPA implementation of the new law is a "perfect storm" of delay and over-regulation that has greatly reduced the new chemical innovation spigot that existed under old TSCA. As discussed below, this is tangibly seen in the small number of post-Lautenberg PMN chemicals that have commenced manufacture since the new law entered into effect in June 2016. Our purpose in this article is to make clearer the impact of the EPA's early implementation of new TSCA and focus on the potential consequences of the delays and regulatory overreach.

Chemical Innovation in the 21st Century

For those of us who have been laboring in the TSCA vineyard for decades, the extent of the disruption caused by the EPA's early implementation of new TSCA was quite surprising. As noted, EPA review of new chemicals under old TSCA worked well and, while Congress made measured changes to the law, the seismic changes in EPA implementation since June 2016 were unexpected and have not advanced TSCA's goals of increased chemical safety. Some respected members of the TSCA stakeholder community will disagree with this statement, but the truth is that it did. That TSCA needed revision in other key areas was indisputable and this firm supported TSCA reform long before it was embraced by the industrial chemical community. Nonetheless, the great difficulty that EPA has had in implementing the law in a way that recognizes and values innovation in the 21st century is puzzling. These aspects are discussed below.

The TSCA revisions and EPA implementation of them inexplicably fail to appreciate and value innovation and the fact that industrial chemical innovation is not the same as it was when TSCA was enacted in 1976.

An argument can also be made that the language that appears in new TSCA Section 5(e)(1)(A) that tells the EPA to regulate new chemicals for which it has made a Section 5(a)(3)(B) determination "to the extent necessary to protect against an unreasonable risk of injury to health or the environment, *without consideration of costs or other nonrisk factors…*" (emphasis added) was completely unexpected and may have contributed to the early implementation problems and to confusion about what Congress intended. The language is incongruous relative to the rest of new TSCA's text and was unexpected for several reasons. Little or nothing in the legislative history of hearings, testimony, and congressional statements prior to the passage of Lautenberg sets the stage for an approach wherein cost-benefit aspects should not be considered by EPA in taking action to control new chemical risks. On the contrary, there are instances where statements noted the importance of recognizing the health and environmental and performance benefits of new chemicals (*see*, for example, written testimony of Craig Morrison, Momentive Performance Materials Holding, LLC:

"Innovation is critical to the survival and growth of our industry and the downstream industries that we supply. To remain a market leader, our process of research, development, product testing and introduction is nearly constant. That is why an efficient, effective process to evaluate and approve new chemical innovations is vitally important to the chemical industry and why I will be focusing my comments on Section 5 of the Toxic Substances Control Act, known as the New Chemicals Program. … TSCA Section 5 established a rigorous process to evaluate and approve new chemistries in a way that protects health and the environment, enables continuous innovation, and allows new transformative products to come to market. Ensuring that this remains the case as part of any new effort or reform to modernize TSCA should be a top priority." *Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation*: *Hearing Before the Subcomm. on Environment and the Economy of the H. Comm. on Energy and Commerce*, 113th Cong. (2013), Serial No. 113-68.

Section 5(e) as amended stands alone as the only control provision in new or old TSCA that does not consider cost or cost-benefit aspects in taking regulatory actions. Such considerations are part of Section 5(f) and Sections 6(a) and (c), and requirements to consider cost aspects in taking regulatory action to require testing under Section 4 (subsection 4(b)(1)(C) states that the considerations in requiring testing "shall include the relative costs of the various test protocols") and reporting under Section 8(a) (subsection 8(a)(5)(B) requires that EPA "minimize the cost

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of compliance with this section"). Regarding this issue, during questioning by Sen. David Vitter, Linda Fisher, then vice president and chief sustainability officer, DuPont, stated the following: "I think that is a big step forward from the current law, and I think you have made it clear that the cost benefit analysis really goes to the risk management decision piece, not the safety standard and the safety determination piece." *Strengthening Public Health Protections by Addressing Toxic Chemical Threats: Hearing Before the S. Comm. on Environment and Public Works*, 113th Cong. (2013), *available at* https://www.gpo.gov/fdsys/pkg/CHRG-113shrg96018/pdf/CHRG-113shrg96018.pdf.

This provision in Section 5(e) is also in considerable tension with the overarching policy guidance found in TSCA Section 2(b)(3) that EPA should exercise its regulatory authority "in such a manner as not to impede or create unnecessary economic barriers to technological innovation." It is also inconsistent with the policy guidance embodied in the Pollution Prevention Act.

Perhaps the best that can be said about this problematic language in Section 5(e) is that it illustrates well the unintended consequences of hurried decision-making that lacked transparency and, apparently, first-hand knowledge of the chemical industry and how and why new chemicals are created. Nonetheless, it has had real world consequences in that EPA, unlike under old TSCA, no longer gives value to improvements in new chemicals that, relative to the existing chemical competitors, indicate they have pollution prevention benefits or are more energy or process efficient or possess other non-risk attributes that can greatly benefit society and the environment.

The profound impact of chemical exposures to human and environmental health is well-understood today by all stakeholders as well as by the general public, and more is learned daily. The twin concepts of environmental protection and pollution prevention are deeply ingrained in our collective consciousness and the vast majority of chemical innovators and manufacturers are committed to these goals.

Most new chemicals are largely products intended to achieve a particular, and often discrete, market need. Many are not intended for continuous production. They are often high value, low-volume products that are often batch produced. Most "new chemical" products are not entirely new but are chiefly intended to improve on the functionality and performance of existing chemicals by commercializing new chemicals that are more efficient, with better processing options, better performance, and less toxic. Based on our experience, most of the time the improvements seen with new chemicals are incremental. New chemicals also frequently have only a limited time-period of commercial success as, over time, "new and improved" substances replace their new chemical predecessors. In this regard, it would be useful to have a clearer understanding of the typical commercial life of new chemicals to understand better how long and at what volumes they remain in the market. The reporting under the Chemical Data Reporting (CDR) rule should provide an excellent data set for such an analysis which, insofar as it has access to both confidential and non-confidential reporting, could be undertaken by EPA.

The net result of these factors is a strong continuous improvement and "creative destruction" effect. Increased product efficiency also translates into less material being used, and less material being released into the environment, which is the very essence of pollution prevention. The availability of better processing options, including equal or improved performance at lower temperatures, leads to reduced energy usage and potentially safer work environments. These are goals TSCA was intended to achieve.

Other commercial and legal drivers reinforce these fundamental goals. Ever-mindful of tort and product liability, evolving and increasingly

stringent stewardship standards, and private codes of conduct that significantly exceed legally enforceable limits, chemical manufacturers are driven to diminish risk at many levels. The glare of an unforgiving stakeholder community that holds companies immediately accountable for missteps (real or perceived) in the court of public opinion through social media, and the relentless pressure on corporate entities to diminish their environmental footprint, chemical innovation today is fundamentally different from what it was four decades ago. Not only is the global commercial context of chemical production completely different today (legislative examples include the European Union's Registration, Evaluation and Authorization of Chemicals (EU REACH) and the Canadian Environmental Protection Act (CEPA), among others), so also is the role new chemicals play in the 21st century. Chemical innovation is essential to achieving sustainable prosperity. New chemicals enable technologies designed to diminish greenhouse gas emissions, achieve significant energy reductions, facilitate the development of new, lighter, and more sustainable materials, contribute to the optimization of renewables, and in countless other ways help to actualize the potential to achieve sustainable prosperity.

These facts of chemical life have taken a distant back seat to a misperception that new chemicals are designed and produced in a factual and experiential vacuum, devoid of the business realities of life in the 21st century. Today, new chemicals are developed and engineered with careful consideration given to the consequences of human and environmental exposure to them, focused on satisfying the increasing demands of a supply chain whose appetite for risk is extremely low, mindful of the high cost of product and tort liability, and cognizant of the tremendous upsides of "green" chemistry. Our concern is there has been too little focus on the consequences of an EPA new chemicals program that seems to approach all new chemicals as needing regulation as a predicate to safe use. While this may be appropriate in the case of a registration program for substances that are known to be biologically active and are intended to be administered (drugs) or applied (pesticides), Congress chose not to go in this direction in constructing new TSCA. In its REACH legislation, the EU employs a third paradigm—testing is required to enter the market. Only a small fraction of registered substances are subject to regulatory restrictions. Nevertheless, we are confronted with a new chemicals program that causes innovators of new chemical technologies that offer considerable societal, health, and environmental promise to experience unpredictable delays of a year or longer in commercialization, delays that may cause them to abandon commercialization efforts altogether. The statistic in Table 2 (see first installment of this series) indicating that withdrawals of PMNs represents 26 percent of the new TSCA completed cases actions is dismaying; this compares to withdrawals of about 5 percent of PMNs under old TSCA. While some increase in withdrawals might be expected during the initial period as the chemical community adjusted to new TSCA, this figure strikes us as excessive.

Congress and most stakeholders could not have wanted this outcome. Yet EPA's overly conservative, if not overtly precautionary, approach to new chemicals reviews, in conjunction with the unexpected effect of the changes made to Section 5 in the new law has yielded exactly this result. If Congress had intended EPA to take such a dramatic and more precautionary approach under TSCA, it would have included language such as "reasonably certainty of no harm" instead of "not likely to present unreasonable risk" or have specified that Section 5(a)(3) determination be hazard-based rather than risk-based. Congress did neither, and we find it difficult to reconcile EPA's practice since Lautenberg's enactment with the statutory language.

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Perhaps the most compelling example of EPA's precautionary approach is the ironic fact that if the substances listed on EPA's Safer Chemical Ingredient List were subject to Section 5 review post-Lautenberg, many would have been heavily regulated with a consent order. Although we have asked several times, EPA has yet to provide a rationale for how a chemical can both be exemplars of "safe" chemicals and yet require full-face respirators and prohibited consumer uses if they had been the subject of post-Lautenberg PMNs.

What Changed?

EPA's departure from its previous practices is due principally to its interpretation of what is "not likely to present unreasonable risk" under the reasonably foreseeable conditions of use. There are several points in this standard that require EPA to make a judgment: How unlikely does a circumstance need to be to be deemed as "not likely," what is an "unreasonable risk," and what is a "reasonably foreseeable" condition of use.

What is "likely" can be addressed by EPA employing its standard conservative models (the Sustainable Futures tools). If the EPA standard conservative estimates do not lead to EPA predicting releases or exposures that lead to a concern, EPA could conclude that such exceedances are "not likely." Based on past experience, regardless of the model outcomes, EPA would seek to impose release or exposure restrictions (or both) based upon EPA's hazard determination.

For example, EPA might identity a surface water concentration of concern (CoC) of 100 parts per billion (ppb). In its review of the PMN, the EPA conservatively predicts a maximum concentration of 28 ppb. Under new TSCA, the EPA has been concluding that there is not an unreasonable risk based on the intended conditions of use, but that "someone might" release an even higher amount to surface water and then proposed a consent order (and/or a SNUR) to limit surface water concentration to 100 ppb, the CoC. In our view, the EPA has not been meeting its obligations under Section 26(h) and optimizing EPA's extensive experience with evaluating whether such an exceedance was likely or not, but merely concluding that it might happen. A more measured approach could be that the EPA compares the conservative, predicted concentration, 28 ppb, and the CoC, 100 ppb, and concludes that there is a sufficient difference between the two that the concentration was not likely to exceed the CoC and decline to regulate that substance for aquatic toxicity risk. EPA might be less sanguine about a predicted concentration of 98 ppb compared to a CoC of 100 ppb. In that case, the EPA might look at other factors in its assessment to determine whether its hazard and exposure predictions were sufficiently conservative to justify a "not likely" determination or if a "may present" finding was indicated.

"Unreasonable risk" is not a new term in new TSCA, but neither has it been defined or its boundaries tested under old or new TSCA. An example of a hazard EPA identified that it believed presented an unreasonable risk includes mild-to-moderate eye irritation. There are cases in which the EPA identified concerns for eye irritation and then proposed requiring workers to use protective eyewear such as goggles. We question how eye irritation is determined to be an unreasonable risk. Nearly everything is irritating to eyes, even water. This standard would require that the EPA require eye protection for everything that has not been tested and shown to not irritate eyes. In addition, eye irritation is an endpoint against which one would fully expect users to opt to protect themselves. If an activity causes an eye exposure that leads to irritation, it is likely that the user would choose to use eye protection, regardless of whether such protection is required by TSCA, or to use the substance in a manner to minimize the chance for eye exposure. When a person goes swimming, if the water irritates the swimmer's eyes, a decision is made

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either to wear goggles or to close one's eyes. In our view, mild-to-moderate eye irritation is not an unreasonable risk, nor is it a risk that requires a TSCA consent order to mitigate.

"Reasonably foreseeable condition of use" is a new term under Lautenberg, but a similar term has been in use under old TSCA for some time, "reasonably anticipated." In the polymer exemption criteria, "reasonably anticipated" is defined, in relevant part, as what "a knowledgeable person would expect a given physical or chemical composition or characteristic to occur." 40 C.F.R. § 723.250(b). EPA also defined "reasonably foreseeable" as being based on information, knowledge, or experience in its risk evaluation rule. 82 Fed. Reg. 33726 (July 20, 2017). Neither of these definitions aligns with the concept of "any possible" conditions of use. We, on behalf of the New Chemicals Coalition, suggested to EPA that could safely assume that routine PPE (*e.g.*, long sleeves, long pants, closed-toe shoes, gloves, and goggles) are used in workplace settings. EPA challenged us to provide data to support this contention.

After significant effort, we found data in OSHA's database of violations. In data that spans four decades and more than 12 million violations, a tiny fraction of OSHA violations relate to workers not using appropriate gloves (0.5 percent), goggles (0.4 percent), or general dermal protection (one in 12 million). We submit that the extremely low incidence of OSHA violations demonstrates that it is reasonably foreseeable that gloves, goggles, and general dermal protection will be used in a workplace setting when such use is otherwise required by OSHA regulations. A worker may decide otherwise as—workers do occasionally fail to observe workplace rules. On the other hand, it is questionable whether a TSCA consent order requiring glove use was intended to or in fact will prevent such noncompliance when gloves are already required under OSHA workplace standards and the reality that gloves are routinely worn in workplace settings.

Why Are SNURs a Big Deal?

A frequent retort to a submitter's objection to a significant new use rule (SNUR) is, "Why is a SNUR a big deal?" Returning to the previous example, if gloves are routinely worn, why would a submitter object to a SNUR (consent orders under the Toxic Substances Control Act have the same effects) requiring glove use? The fact is that SNURs trigger several new recordkeeping requirements. Even if a SNUR duplicates otherwise applicable Occupational Safety and Health Administration requirements, SNURs impose additional supply chain communication, in addition to standard Safety Data Sheet requirements, and additional explanation to downstream customers, especially when those customers are unfamiliar with TSCA requirements.

Both SNUR and TSCA consent orders also trigger other TSCA obligations, such as a lower reporting threshold for Chemical Data Reporting (CDR) and Section 12(b) export notifications. These obligations may not sound like a big deal, but this example illustrates that they are not inconsequential. Assume you are shopping for a car and looking for a "greener" model. You are deciding between two models: One is a traditional car that gets 35 mpg (combined) and is made from 75 percent recycled material. Cost: $28,000. The other is an innovative new model that gets 45 mpg (combined) and is made from greater than 90 percent recycled or renewable materials. Based on the fuel efficiency, you expect to save $4,000 over the life of the car. Cost $30,000. In addition, the purchase contract requires that you keep records of how many miles you drive each month, to document that you have a procedure to ensure that you and every passenger wears a seatbelt, and to notify EPA within 30 days of the first time you drive the car out of state. If you fail to keep these records, or fail to notify EPA that you drove out of state, and

EPA audits you, you could be subject to thousands of dollars in fines, more than wiping out any potential cost savings.

Under these circumstances, the choice between cars seems self-evident. You may already track your mileage and your state already has a seat belt law, but would you take the risk of an audit and potential fine if you cannot produce the records to EPA's satisfaction? You might accept the regulatory risk if the car were twice as efficient, but for only a marginal improvement, many customers will simply opt for the old, reliable, unregulated standard and forgo the benefits of the new and improved, regulated model.

Consent orders also add additional complications in that such orders permit only one level of distribution, that is, the manufacturer may only distribute to its customer, the customer is prohibited from further distributing the substance unless the substance has somehow been incorporated into something else (embedded in a plastic resin, reacted to form something else, or converted into an article). Some supply chains are that simple: A manufacturer provides a substance to a customer, but in many cases, the customer processes the substance without converting it and sells the processed substance to another customer.

This prohibition on further distribution expires 75 days after the EPA promulgates a SNUR derivative of the consent order, but that is a substantial delay on top of the delay in EPA promulgating the SNUR (no less than 30 days), and the delay associated with EPA proposing SNURs derivative of consent orders. Even at EPA's best, SNURs were proposed many months after the consent order was signed; now EPA is taking more than a year to even propose SNURs. These substantial delays may mean that even with a consent order, a new product may not be able to enter the supply chain until many months (or years) have passed after the manufacturer signs the consent order. A large company with other products on the market may be able to endure (albeit reluctantly) such a delay, but small companies, especially pre-commercial companies, may go out of business as a result of such delays.

NOCs for New TSCA PMNs Have Shrunk

What does this mean for innovation? We reviewed NOCs received by EPA for the approximately two years before and after new TSCA's entry into force in June 2016.

(Note that the PMN submission year is based on EPA's fiscal year (October-September), while the NOC year is based on the calendar year reported by the submitter for the date of commencement. Because of the 90-day review period, it is very unlikely that the PMN could be commenced before the new calendar year: a PMN submitted on Oct. 1 (the beginning of the fiscal year) could not be commenced until Dec. 30 at the earliest.) As shown in Figures 1 and 2, about 350 PMNs from each of Fiscal Year (FY; Oct. 1 through Sept. 31) 2014 and FY2015 were commenced at some point in the past four year (this represents about 47 percent (359/764) and 50 percent (336/669) of all PMNs submitted during FY2014 and 2015, respectively).

The analysis covers February 2014 through May 2018. Most NOCs are filed within two years of the PMN decision date. Of the 1,414 NOCs submitted in this time frame, 1,173 (83 percent) were for cases submitted in the two years after the corresponding PMN was submitted. For 2016 PMNs, there was a marked drop-off in the number that commenced manufacture to a total of 201. Note that this set includes PMNs submitted under old TSCA that had completed the review process prior to June 22, 2016 ("pre" Lautenberg cases), PMNs that had their "applicable review period" reset after enactment ("reset" cases), and PMNs submitted after June 22, 2016 ("post" Lautenberg cases).

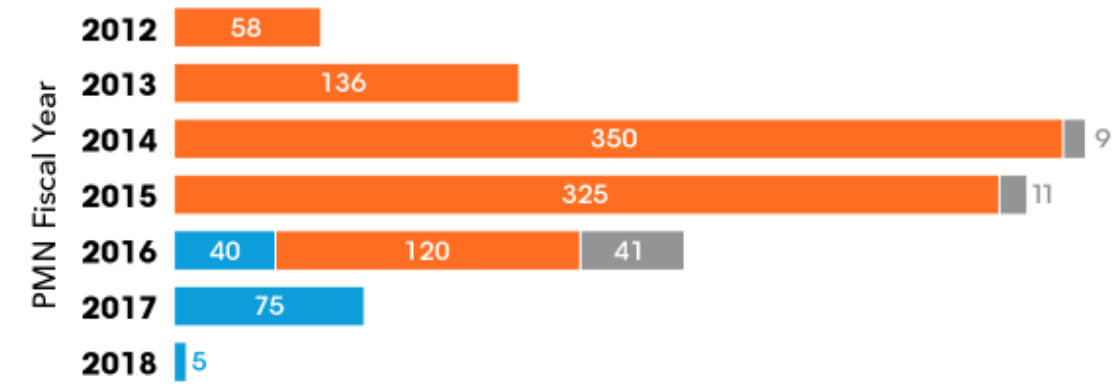
For the FY14 and FY15 "pre" Lautenberg cases, approximately half were commenced by May

2018, following the trend over the last decade that about half of PMNs were commenced. Compare that rate with the percentage of FY14 and FY15 cases that were "reset." Only 33 percent and 21 percent of the reset cases from those years were commenced. Among the FY2016 cases that were completed prior to June 22, 2016, the long-term trend held and about half were commenced, while only 22 percent of the "reset" cases and 22 percent of cases submitted after June 22, 2016, were commenced. The decline in commenced cases continued in FY 2017. Only 21 percent of cases submitted in FY2017 were commenced by May 2018. The very low number of commenced cases in FY2018 reflects the relatively short time period for cases to be submitted, reviewed, and commenced, but even so, we would have expected more to be commenced. Among the FY 2015 cases, 24 were commenced before May 1, 2015, compared to five cases submitted in FY 2018 that were commenced before May 1, 2018.

The significant drop in the rate of commenced cases, from roughly 50 percent under old TSCA, to around 20 percent under new TSCA is evidence that the current new chemicals process is having a decided adverse effect on the commercialization of new chemicals. While it is possible that a large percentage of the cases submitted after June 22, 2016, are, on balance, more "toxic" than the cases submitted in the preceding decades necessitating a greater level of regulatory oversight by EPA, but we find that speculation unlikely and not representative of many cases familiar to the authors. For example, 58 PMNs submitted in FY2012 were commenced in this time period.

For example, 47 percent of PMNs submitted in FY2014 that were completed prior to June 22, 2016 were commenced by May 2018, while only 33 percent of cases submitted in FY 2014 that had the reviews "reset" were commenced by May 2018.

Figure 1:
Number of NOCs submitted between February 2014 and May 2018



"Pre-Lautenberg" cases were submitted and review was completed prior to June 22, 2016.
"Reset" cases were still in their 90-day review period on June 22, 2016.
"Post-Lautenberg" cases were submitted on or after June 22, 2016.

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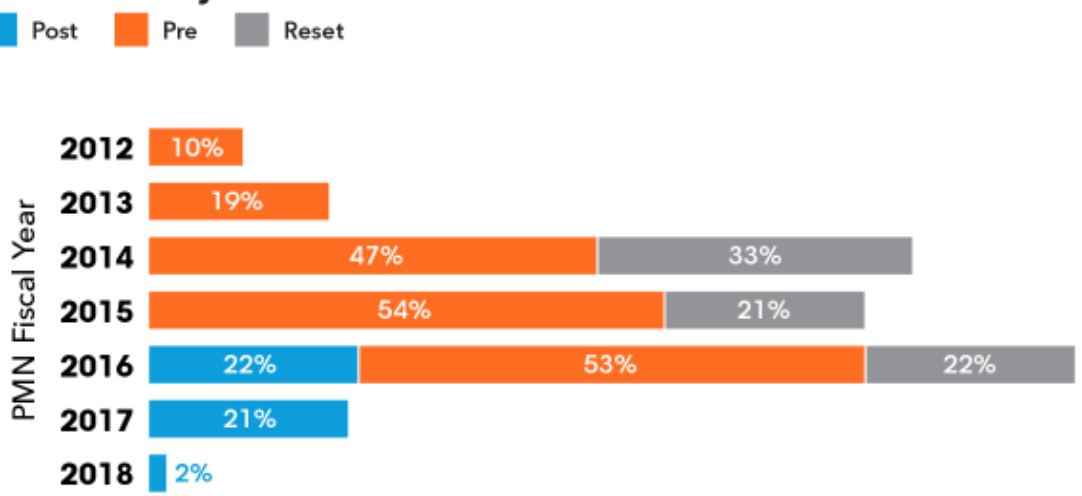
Figure 2:
Percentage of PMNs of each type commenced between February 2014 and May 2018



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These graphs exclude 112 cases that are or are likely to be derivative to enforcement actions or self-audits; in our view, the timing of PMN submissions and NOCs for such cases is not indicative of innovation or planned business activity. An additional 84 cases submitted between 1998 and 2012 were also commenced in this timeframe, but were excluded to simplify the graphs.

Summary and Conclusions

New chemicals tend to be niche products intended to achieve a particular, and often, discrete, market need. Many new products are not entirely novel and are intended to improve the functionality and performance of existing chemicals to make them more efficient, with better processing options, less toxic, and more environmentally sustainable. Their commercial life is often relatively short as they are replaced by "newer and improved" new chemicals. New chemicals thus frequently represent incremental and short term "continuous improvement" enhancements against their existing chemical competitors.

This combination of continuous improvement and "creative destruction" when combined with greater product efficiency, less release to the environment, and better and safer processing options produces a strong innovation impact over time. Other commercial, legal, and public drivers, such as tort and product liability, increasingly stringent stewardship standards and private codes of conduct, greater public accountability due to social media pressures and public sustainability commitments, and the relentless pressure on corporate entities to diminish their environmental footprint, also contribute to a new chemical development and innovation process that is very different from what it was four decades ago.

Stakeholders recognize that new chemical innovation is essential to achieving sustainable prosperity and to enabling technologies that can

help to meet the challenges of the 21st century. For reasons such as these, TSCA stakeholders should be concerned by the precipitous decline in the number of new chemicals that have been introduced into commerce post Lautenberg. EPA's recent efforts to right this situation should be applauded, and concerned groups should urge EPA to expeditiously make similar corrections to support the chemical innovation process.

{00502.035 / 111 / 00251156.DOCX} This is a reprint of an article series published in *Bloomberg Environment Insights*, September 11-13, 2018.

Table 1. PMN Outcomes Under Old TSCA from 1979 - September 30, 2015[1]

Valid PMNs	39,962
Actions:	
§5(e) order	1,710 (4%)
§5(e)/SNUR	739 (2%)
Non §5(e) SNUR	1,457 (4%)
Withdrawn	2,068 (5%)
Voluntary testing	>300 (1%)
PMNs dropped early in review	~80%

[1] EPA, *Statistics for the New Chemicals Review Program under TSCA* (prior to June 22, 2016), available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

Table 2. PMN Case Statistics Under New TSCA from June 22, 2016 - August 14, 2018[1]

	All Valid Cases	Completed PMN Cases
Total valid cases[2]	**2,040**	
§5(a)(3) determinations completed	1,565 (73%)	
§5(a)(3) determinations under review	475 (22%)	
Completed cases[3]	**751 (35%)**	751 (100%)
§5(g) "not likely" determination made	127 (6%)	127 (17%)
§5(e) order allowing commercialization with restriction	420 (21%)	420 (56%)
§5(e) order with testing required before commercialization	6 (<0.1%)	6 (0.8%)
Cases withdrawn by notifier	240 (11%)	198 (26%)
Uncompleted cases[4]	**575 (28%)**	

[1] Based on EPA's *Statistics for the New Chemicals Review Program under TSCA*, available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats. It includes PMN, MCAN, SNUN, LVE, and other exemption notices that were within the 90-day review period as of June 22, 2016 -- cases in which EPA restarted the 90-day clock and re-reviewed regardless of the outcome of its initial review.

[2] Total PMNs received minus invalid or incomplete PMNs.

[3] TSCA Section 5(a)(3) determination and final Section 5(e) or Section 5(g) action, as appropriate, completed; the right-hand column provides the breakdown as a percentage of the completed cases.

[4] Valid PMN cases that remain incomplete (Total valid cases, less withdrawn and completed PMNs and LVEs).

Part 2, the next installment in this series, will run tomorrow and address Chemical Innovation in the 21st Century.

{00502.035 / 111 / 00251110.DOC}This is a reprint of an article series published in *Bloomberg Environment Insights*, September 11-13, 2018.

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{00502.035 / 111 / 00251110.DOC}This is a reprint of an article series published in *Bloomberg Environment Insights*, September 11-13, 2018.