Testing, Testing

Conducting more chemical exposure studies is laudable in theory—and perilous in practice. Stakeholders agree more data are necessary. So why is analysis of new substances so difficult and fraught with legal, regulatory, and commercial challenges?



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A KEY FORCE propelling reform of the Toxic Substances Control Act through Congress in 2016 was a bipartisan belief, shared by the business and environmental communities alike, that the Environmental Protection Agency needs more information to do its job of protecting the American public from adverse effects caused by chemical exposures. After all, it has been domestic policy under TSCA for almost a half-century that "adequate information should be developed . . . and that the development of such information should be the responsibility of those who manufacture and those who process such chemicals." Most stakeholders would agree more chemical information is better than less. So why is generating chemical data so difficult and fraught with legal, regulatory, and commercial challenges? This article provides the answers.

According to EPA, there are 42,377 chemicals listed on the TSCA Inventory that are "active" chemicals in commerce in the United States. Most of these substances are used in relatively discrete commercial chemical applications with few exposure opportunities, or are polymers that meet the definitional criteria for "polymers of low concern" because they are chemically inert. Within this large universe of chemicals and product applications, both private and public information drives innovation and regulation within the chemical sector.

Commercial entities including chemical producers, processors, distributors, and manufacturers of finished products that contain chemicals (known as "articles" under TSCA), particularly those marketed to consumers, develop chemical data for a variety of reasons.

First, regulatory authorities around the world demand chemical data as a condition of initial commercialization. Since its enactment in 1976, TSCA authorized EPA to require, by rule or consent agreement, chemical manufacturers (including importers) and processors to develop information on chemicals and submit the information to the agency. EPA's modest efforts over the first four decades of TSCA, however, elicited little new data. Test rules were often judicially challenged, the agency did not prioritize testing initiatives, and, absent a regulatory imperative, there was no real incentive to generate new data. Some submitters of new chemical notifications generate data voluntarily. Whether and what data were generated depended on business considerations, often because of the need to inform safety practices on the part of the manufacturer for downstream users.

In addition, a vast amount of new data were being generated under the European Union's REACH regulation, implemented in 2006. The acronym stands for Registration, Evaluation, Authorisation, and Restriction of Chemicals. REACH's "registration" component mandates data generation and/or surrogate data evaluation to register a product as a prerequisite to market access. U.S. chemical producers selling these chemicals in the EU fully intended at the time to leverage these

European data for global registration purposes, at least to the extent permitted by law.

Drilling down a bit, there are over 9,400 substances listed on the TSCA Inventory that are also registered under REACH. If you exclude intermediate registrations (chemicals that have a lesser testing requirement), there are over 7,600 substances in commerce in the United States that have been tested, even if they have not been tested under TSCA authority. The important point to appreciate is chemical data of all sorts exist in many global governance programs. The chemical industry chafes at the assertion that many chemicals in commerce "lack data." They may lack data compelled by TSCA, but most active commercial chemicals globally are well supported by exposure and hazard information.

As amended in 2016, Congress strengthened EPA's authority to obtain chemical data by giving it the power to issue unilateral test orders. The agency was initially slow to exercise that authority but has since picked up the pace. EPA has gained significant administrative experience with issuing TSCA orders over the past few years and is working more closely with industry stakeholders to identify more precisely the scope of the information the agency's regulatory efforts need.

The most frequent application of EPA's test order authority has been to require the development of information necessary to conduct a Section 6 risk evaluation. Section 4(a)(2) authorizes the agency to issue a test order to "perform a risk evaluation under Section [6(b)]." Under its Section 4(a)(1) test order language, EPA is authorized to require the development of information on the health and environmental effects of a substance to determine "unreasonable risk," the safety standard under the statute. EPA has prioritized testing under its PFAS National Testing Strategy and its "all of agency" focus on regulating persistent chemicals.

In addition, EPA has, of late, used its TSCA Section 8(d) authority more efficiently in meshing with programs under other sections. For example, EPA is more routinely seeking health and safety data under Section 8(d) from regulated entities who are manufacturing "high priority" chemicals under consideration for Section 6 risk evaluation, doing so in advance of issuing Section 4 test orders. Determining what data exist in company files before ordering the generation of more data is a more sensible way to proceed and ensures test animals are not needlessly sacrificed. The 2016 amendments expressed a congressional goal for EPA to "reduce and replace" the use of vertebrate animals in testing "to the extent practicable." The agency has made strides to do so.

The agency has interpreted the scope of its test order authority under Section 4 broadly to include manufacturers and processors that have ceased production of the chemical, and disallowed exceptions based on production volume. While companies can anticipate the issuance of an order based on whether a chemical substance is slated for risk evaluation or is part of an EPA testing strategy, test order recipients will find that responding demands significant time and resources. Studies need to be designed by qualified laboratories and contract research organizations, lawyers need to be engaged to ensure the test order negotiation with the agency adheres to TSCA and that the terms of the test order are satisfied by EPA and the order recipients. Data generated by testing consortia need to be managed to reflect group ownership and generation.

International chemical governance frameworks are even more data-centered and often are more prescriptive. Typically, data requirements are codified in legislation that tiers data demands according to potential exposures, as defined by annual production and/or import tonnage levels. Under the REACH program, for example, the higher the volume of chemical production or import, the more chemical data are required as a predicate to registration and access to one of the world's largest markets. Information requirements escalate dramatically as production volume increases. REACH-like statutes emerging around the globe in the United Kingdom, Turkey, South Korea, China, Latin America, and elsewhere are similarly structured.

The second factor driving new data is the fact that, in the absence of data, TSCA imposes conservative (more protective) risk assumptions that are considerably stricter than may be warranted if data on the substance were available. These risk assumptions result in use restrictions that can greatly diminish the commercial applications of a chemical in Section 5 (new chemical) evaluations and Section 6 (existing chemical) risk evaluations. Just as nature abhors a vacuum, EPA abhors a data gap. That gap is filled by applying multiple risk factors on existing data, leading to extremely conservative, and often unreasonable, risk values that can end the commercial promise of a novel and potentially more sustainable chemical, or that eliminate unnecessarily conditions of use of existing chemicals undergoing risk evaluation. As many new chemical innovators and existing chemical producers are learning, risk evaluations under TSCA end badly for those who lack data to rebut the results of EPA's otherwise conservative risk calculations.

The final factor driving increased data generation is emerging product stewardship principles, includ-

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Why Aren't Animal Tests on the Way Out?

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"Although there has been some progress, there are indications that EPA has deprioritized Congress's mandates that it move away from animal experiments"

The Environmental Protection Agency doesn't track the number of animals used each year in U.S. toxicology experiments, but the agency estimates that it's somewhere between 20,000 and 100,000 vertebrates—mostly mice and rats, who lack even the minimal protections of the Animal Welfare Act. Advocacy groups have exposed some of these experiments—animals forced to inhale diesel exhaust, force-fed lard, electro-shocked.

Reflecting growing public concern about animals and an increasingly undeniable understanding of the inadequacy of expensively testing massive doses of chemicals on rats to ascertain the effects of much smaller doses in humans, Congress, in the 2016 TSCA amendments, sought to reduce outmoded experiments on animals and increase state-of-the art, more efficient, and more reliable and human-relevant studies.

Has it worked? Is EPA using our taxpayer dollars to require and conduct human-relevant experiments? Or is it business as usual, with continued reliance on costly, cruel, decades-old animal experiments? Although there has been some progress, there are indications that EPA has deprioritized Congress's mandates that it move away from animal experiments.

As amended, TSCA directs EPA to reduce and replace animal experiments and to promote new approach methodologies, or NAMs. In a 2019 memo about implementing these amendments, then EPA Administrator Andrew Wheeler noted that NAMs could result in the evaluation of a broader range of effects, of more chemicals, in a shorter timeframe, with fewer resources, and pledged that the agency would reduce its requests for and funding of mammal studies by 30 percent by 2025 and entirely eliminate such requests and funding by 2035. A statutorily required 2020 EPA work plan reiterated these commitments. The following year, after the new administration replaced him, the agency quietly removed these commitments. Wheeler lamented that, without deadlines, "We're not going to move away from animal testing, because it's just too easy to continue to do business as usual."

Reinstatement of deadlines could go a long way toward finally forcing a move away from deeply entrenched yet unreliable animal experimentation. For example, a September 2024 EPA report identified numerous outdated regulations that require animal testing even when the statutes they implement do not. Updates to these regulations to bring them into compliance with Congress's intent should be prioritized and expedited.

But it's not all bad news. For example, EPA has taken steps—albeit not binding ones—to move away from more than 100-year-old skin and eye irritation tests in animals that have been shown to be reproduceable less than half of the time. And a recent D.C. Circuit decision makes clear that at least one aspect of the 2016 amendments has teeth. TSCA now mandates that the agency, before requiring any animal experiments, explain the basis for such a requirement after considering all reasonably available existing information, including information about NAMs. In ordering chemical manufacturers to test a product on animals, EPA cursorily asserted that it hadn't identified any approved or readily available NAMs.

The court overturned the agency's order, explaining that such conclusory statements don't fulfill the statutory mandates that the agency explain why it is requiring animal testing and adequately demonstrate its consideration of NAMs. This decision should incentivize the agency to take Congress's mandates seriously—and it provides a solid basis for challenge should it not do so.

Nearly a decade since Congress amended TSCA, we're not nearly as far along as we could be in reducing animal experiments and increasing faster, cheaper, and more reliable NAMs. Progress has been made, but it's been slow, and the cost of that sluggishness has been born by the tens of thousands of animals subjected to experiments every year—and by the humans who deserve studies that accurately convey the likely effects of chemicals in people, not in rats who've been exposed to levels that can exceed those a human would normally be exposed to by 100 or even 1,000 times.

ing reducing the environmental and health impacts of chemicals and proactively understanding a chemical's effects on human health and the environment, that are resulting in more chemical testing. These principles require manufacturers of industrial chemicals and articles (finished goods) alike to understand the toxicological, environmental, and exposure implications, as well as demonstrated efficacy of their products. Incomplete product profiles translate into product liability claims, commercially adverse inferences regarding risk potential, and mistrust among significant constituencies like consumers, workers, regulators, and residents around facilities. Savvy chemical producers are increasingly conducting data gap analyses for both critical products and the key chemical components in them, and voluntarily generating defensive data. This information fortifies advocacy opportunities in product liability disputes, fulfills product stewardship commitments, and holds entities accountable to answer questions that key stakeholders can be expected to ask if things go south. While juries may not always be won over by facts, defendants have a much stronger case when their arguments are supported by sound science, which fundamentally depends upon reliable data.

AFTER an entity determines testing is necessary or otherwise recommended, the issue arises of how to conduct such testing. While companies should consider ensuring data are suitable for all potential purposes, for data intended for use on a global scale, the question of how becomes increasingly complex. Global harmonization of testing guidelines has fallen under the oversight of the intergovernmental Organization for Economic Co-operation and Development. OECD aims to develop evidence-based international standards across a variety of economic, social, and environmental issues. In the area of science policy, the international standard is set by the OECD Guidelines for the Testing of Chemicals. The multilateral OECD Mutual Acceptance of Data agreement establishes criteria under which member countries (the United States included) and other adherents are obliged to share and accept results from non-clinical testing. This reduces duplication of data, saving industry and governments time and money, and reduces the use of animals in testing. Adhering to OECD testing guidelines, however, is not enough to ensure data can be used across borders.

Most regulatory frameworks employ multi-step, systematic review processes that rely on the principal objectives described by the Institute of Medicine in 2011 to identify, select, critically assess, and synthesize data from published and unpublished studies. Effective systematic review reduces bias while enhancing transparency, objectivity, and consistency. Ultimately, these processes should result in regulatory decisions and policy informed by reliable findings. Many systematic review protocols fall short of this goal and instead are unnecessarily cumbersome, remain subject to reviewers' interpretations and implicit biases, and vary greatly across jurisdictions. This results in what may feel like a frustratingly elusive target for those aiming to meet the data requirements across a global regulatory landscape.

Clearing the bar of any systematic review depends upon not only reliability-scoring metrics, but also relevant data and compliance with universal best practices and established quality standards. Standard methods, guidelines, and norms provide harmonized approaches for study conduct. Quality assurance and quality control measures allow for the assessing and documenting of data integrity. Independent quality assurance, not unlike peer review for scientific literature, is essential for regulatory testing conducted in accordance with rigorous, internationally recognized standards for quality management, e.g., Good Laboratory Practice Standards, the International Organization for Standardization's ISO 9001:2015, or American Industrial Hygiene Association Laboratory Accreditation Programs. Oversight by an institutional animal care and use committee or review board, which serve to protect the rights and welfare of animal and human research subjects, may be supplemented by other governing bodies, such as EPA's Human Studies Review Board or licensing bodies in other jurisdictions, to ensure compliance with regulations, ethical standards, and institutional policies.

Before embarking on any testing, a registrant or "study sponsor" must consider the role that the resulting data are expected to play in current and unforeseen future regulatory and advocacy contexts. Where and how the testing is performed influences the longevity and thus the utility of the investment. Scientific considerations and/or technical limitations may be key drivers, especially for challenging chemistries that may require novel methods or that may not be compatible with validated test systems and procedures. Key endpoints and guideline modifications required by one regulatory authority may not satisfy another regulatory authority or objective. For example, some regulatory authorities require that testing be conducted locally, with test organisms indigenous to that region, or under conditions representative of where and how the substance or final product is intended for use. Stud-

SIDEBAR

Make More Sense of Required Test Orders

"To make future PFAS test orders impactful, EPA should reconsider the categories and testing requirements and focus its future orders on substances actually found in the environment"

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In 2016, the Lautenberg Chemical Safety Act passed with bipartisan support, changing how EPA regulates chemicals in commerce by expanding its authority under TSCA Section 6 risk management and chemical testing under Section 4. While much of the testing required under the new act has been specific to chemicals undergoing Section 6, test orders on PFAS substances were issued that have raised many of the same old industry concerns on testing, as well as introduced new complexities.

In 2021, EPA issued its National PFAS Testing Strategy to help identify and select substances for testing based on similar features and consideration of what existing data are available for each chemical category. While well intentioned, the testing strategy has several flaws that should be considered to meet the intended goal.

Testing initially focused on 24 substances representing structurally similar categories. Manufacturers performed impact analyses and collated data. The first three test orders were among the 24. However, without specific knowledge of what substances were in each category, industry's ability to identify other relevant data was limited.

The initial three PFAS test orders highlighted significant deficiencies in the program. First, EPA's mandate for Section 4 is based on production in large quantities that may cause substantial or significant exposure. However, only the first chemical selected presented a current non-manufacturing potential exposure concern. The other two initial orders required extensive animal and non-animal testing on substances that are used in the manufacturing of other products and are handled such that potential exposure and environmental releases have been identified as negligible.

EPA's selection of tier 1 tests for the initial three test orders was also problematic. The agency mandated non-guideline tests, including a procedure using specialized inhalation apparatus and methodology published in the mid-1980s and not currently offered by commercial labs, making it nearly impossible to comply with the mandated testing.

Guidelines typically list the requirements for conducting a study, including acceptance criteria. This level of detail enables laboratories and companies to clarify the scope of work, cost, and timing. When non-guideline study details are not standardized, it becomes difficult to directly compare studies, particularly if they were performed by different laboratories. It was also unclear how the mandated testing would be used by EPA in a category approach.

In 2023, the testing strategy was modified, expanding the scope to 15,000-plus substances, further increasing the complexities and challenges of the program. PFAS test orders were issued in 2023 and 2024 for substances not included in the original list of 24, and without industry input or discussion. Furthermore, throughout the expansion, EPA declined to share details on the substance categorization, preventing companies from effectively collating relevant data that could be utilized instead of conducting animal testing.

In a landmark ruling, last July, the D.C. Circuit in *Vinyl Institute, Inc. v. EPA* vacated a 2022 non-PFAS test order after finding that EPA failed to explain its basis for requiring certain vertebrate testing, failed to demonstrate consideration of relative testing costs and the availability of appropriate testing facilities and personnel, and failed to explain that it adequately assessed existing available information.

In considering future test orders and the overall program, EPA should clearly identify criteria for selecting a substance and disclose the other substances within each category. It should be incumbent upon the agency to utilize testing guidelines and check the European Chemicals Agency database for existing data prior to issuing a test order.

To make future PFAS test orders impactful, EPA should reconsider the categories and testing requirements and focus its future orders on substances actually found in the environment. Doing so would be a step in the right direction of better optimizing EPA's limited resources and protecting human health and the biosphere.

ies conducted according to harmonized guidelines that are subsequently amended, cancelled, or replaced may have limited the utility in the future.

LET'S assume a chemical manufacturing or processing company, or a formulator, identifies a data gap and decides to fill it. In taking a stepwise approach, the first question should be whether new data are needed or if there are other ways to fill the gap. Understanding the reason for the data requirement(s) is a pre-requisite to assessing the options to address a data gap. There may be opportunities to repurpose existing data developed in another jurisdiction or to use "other scientifically relevant information" for the specific substance or product. The properties and (eco)toxicological profile of the substance may make it a good candidate for bridging data developed for other structurally similar analogue substances. Knowing what data exist and how to access them may require some savvy sleuthing, but it is often worthwhile, if not required.

It is important for industry stakeholders to consider the benefits of testing consortia to facilitate the sharing of any existing information or developing new information

Data-sharing agreements are a mechanism for negotiating the scope and terms of accessing another data owner's studies. These agreements may be guided by established procedures written into legislation, as is the case under REACH, and enhance a company's return on investment for prior testing through compensation negotiated with other stakeholders. Absent existing empirical data, models that may rely on other computational tools that predict toxicity and fate can provide reasonable estimations directly to address the gap, validate or refine assumptions, or inform next steps. These alternative approaches to testing are efficient, cost-effective solutions, and ensure that global mandates to reduce vertebrate animal testing are met.

If after exploring other means to fill the gap it is decided that new data must be developed, the next critically important step is developing a strategy for study conduct. This test plan should serve as a basis for the entity sponsoring a study (or "study sponsor") to communicate with the laboratory (or "testing facility") about the methodology and sequence of the proposed testing. This commences with first understanding the nature of the substance being tested, including its identity and physical-chemical properties; developing and validating methods for quantitation of the substance in relevant test systems and matrices if none exist; and establishing baseline toxicology and fate data to inform whether and how to approach more complex, higher-tiered studies. Throughout a test plan, new information should be fed back into the prior data gap analysis to refine the testing strategy going forward. Employing a more haphazard approach can result in unnecessary or repeat testing.

As a company contemplates engaging a candidate laboratory for proposed testing, it may be well-advised, if not required, also to consult with the relevant regulatory authority(ies) to ensure that the proposed testing strategy is acceptable and that any assigned deadlines can be met. This may include, but is not limited to, agency review and approval of the study plan prior to initiating study conduct, as required by EPA in Section 4 test orders and select data requirements under the Federal Insecticide, Fungicide, and Rodenticide Act. This process can become inordinately protracted, and requires effective and continuous communication with all stakeholders—the labs, regulatory authorities, and, in the case of testing consortia, the co-sponsoring members—to ensure that the testing progresses timely, in a manner that is compliant with the relevant regulations and that meets the overall regulatory, scientific, and business objectives of all involved.

It is important for industry stakeholders to consider the opportunities and potential benefits of forming a testing consortium to facilitate the sharing of any existing information or developing new information. The benefits of such coalitions, which include forming temporary or continuing trade associations, are amplified when joint testing is required by a Section 4 order or when preparing joint submissions under REACH. Forethought and early action are crucial for test order recipients or co-registrants that are compelled to pool resources to address common data requirements. The terms of engagement require significant up-front administrative and legal resources.

This all may seem daunting, but the net savings of multi-stakeholder testing and data sharing, in terms of time, money, sweat equity, and mitigated enforcement and legal risk, is worthy of consideration. The key to utilizing effectively pooled resources in a testing program is to start this process as early as possible, leveraging expertise and engaging multi-disciplinary skill sets among stakeholders. If deadlines are not achievable or testing challenges arise, this should be communicated timely to any regulatory authorities according to the appropriate channels and legal frameworks. This also affords opportunities for the regulators to reassess data needs and due process.

Good Laboratory Practice Standards were first established by the U.S. government in 1979 and later

adopted and adapted in other countries. GLP provide a basic guide for ensuring reliable and reproducible data that are necessary to inform regulatory decisions and risk mitigation. These standards clearly define the roles and responsibilities within a testing program; the constraints of each role are sometimes more difficult to interpret, which is where supplemental guidance documents, such as those published by OECD, are often beneficial. Prior to study initiation, a sponsor must make several critical decisions regarding objectives, scope, and placement. Throughout study conduct, reporting, auditing, archiving, and the registration process itself, the sponsor may have discrete functions to ensure the timely progress of a study, assess its validity, and assure compliance. GLP make clear, however, that it is the "study director," as the single point of control in a GLP study, who is responsible for the overall conduct, compliance, and data interpretation of the study.

INFORMATION drives global legislation for new and existing chemicals. Investment in the development of information, however, is costly and driven chiefly by commercial interests. When initiating a study voluntarily, the study sponsor controls the timing, approach, resource allocation, and how and when to publish or share proprietary data. When regulatory authorities mandate the development or submission of new information, they control all such decisions. Entities whose activities are regulated under REACH, TSCA, FIFRA, and other chemical legislation must comply with information requirements under penalty of law. Failing to submit requisite information or develop new information as required invites significant commercial and enforcement risk. Data sponsors must be cognizant of any applicable notification requirements and ensure compliance with GLP and other testing mandates. They should also take measures, however, to prevent the disclosure of confidential business information, protect the proprietary value of their data, and respond to potentially unlawful agency actions Though protecting proprietary, commercial, and legal interests is a complex endeavor, it is not without safeguards.

Information drives global legislation for new and existing chemicals. Development of information, however, is costly and driven chiefly by commercial interests

Indeed, developing new information is incentivized when study owners can protect their investment and preserve their data compensation rights, which ensure that when others seek to use the data for their own commercial purposes, they receive fair financial reward and a return on their investment. When information must or should be disclosed, data sharing and compensation agreements are the primary ways to protect the value of proprietary information when granting the right to use, or cite to, existing data to other chemical producers who need to rely on these data for registration purposes. Such agreements may further joint commercial interests and global initiatives to reduce unnecessary animal testing. These agreements may be unavoidable when jointly responding to data submission requirements. While data sharing may have tremendous utility, and regulatory authorities have continuously sought to increase transparency by publishing supporting information online, protecting ownership rights and facilitating equitable data compensation are crucial to ensure continued incentives to invest in testing. Data sharing and data compensation requirements vary by jurisdiction and statute, and it is essential to understand these requirements to leverage a data owner's investment.

Under various REACH frameworks, co-registrants are required to form data sharing agreements. Though the parties have contractual freedom, they must abide by the basic principles of fairness, transparency, and non-discrimination and address actual costs incurred rather than profit-generation for data owners. Data sharing agreements must include elements such as the itemization of the data to be shared, actual costs of the data, administrative costs, and a cost-sharing model that includes a reimbursement mechanism for future data needs.

In the EU, the European Chemicals Agency establishes procedures for dispute resolution if the parties cannot reach an agreement. REACH then ensures that entities that later seek to gain access to the market for a chemical substance share in the costs for data needed to register the substance. In contrast, TSCA does not establish requirements for data sharing or compensation. While stakeholders have the option to form consortia to facilitate submitting information and to enter voluntarily into data sharing agreements, unlike under REACH, they are not obligated to do so. EPA encourages TSCA Section 4 test order recipients to form consortia when jointly developing information, but cost-sharing agreements are reached voluntarily. While Section 4(c) includes terms wherein a test order recipient must provide fair and equitable reimbursement to data owners, this circumstance is limited to exemption requests where equivalent information is currently being developed or already

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submitted to EPA under a Section 4(a) rule, order, or consent agreement.

While both voluntary and mandatory submissions ensure EPA's decisionmaking is informed by the best available science, TSCA codifies protections for confidential business information but does not codify protections for intellectual property rights through mechanisms such as data compensation requirements. First, unlike under REACH, such TSCA data requirements are temporal. This means that manufacturers or processors of a chemical substance at the time EPA conducts a risk evaluation or issues a test order are responsible for submitting existing information or developing new information. There is no mechanism for recompense from future beneficiaries of such data.

For example, suppose EPA issues a test order for a substance undergoing risk evaluation in 2025 that requires all identified manufacturers or processors of the substance in the five years preceding the order to develop new information. Data submitted in response to the test order informs EPA's Section 6 risk evaluation and subsequent risk management rule. A new manufacturer enters the market in 2030, commencing production in accordance with EPA's risk management rule. TSCA does not require this new manufacturer to compensate the 2025 test order recipients for the costs of developing information.

Next, EPA is required to make available information—except as limited by Section 14 confidential business information provisions submitted under Sections 4, 5(b), and 5(e). Under Section 6(c)(3), the agency is required to allow interested persons to submit written data, views, and arguments in response to a proposed risk management rule and must "make all submissions publicly available." When submitting such information, entities must be prepared to advocate for measures that maintain protections for their intellectual property.

Other concerns include the disclosure of health and safety studies. Section 14(b)(2) disallows health and safety studies submitted under TSCA (for example, under Section 8(d) or Section 4) protection from disclosure. Accordingly, there has been significant debate as to whether EPA can disclose such information in a manner that serves the public interest while affording some protections for the intellectual property rights of the study submitters. While companies are required to submit certain health and safety studies, these firms should consider how to ensure transparency in the public interest while preserving the value of the submitter's investment in developing the data.

Compliance with applicable statutory provisions, including requirements to submit studies to EPA, is vital for regulated entities in the chemical industry to avoid potentially significant civil penalties. EPA and the Food and Drug Administration compliance monitoring programs provide a regulatory and enforcement framework to assure the compliance of entities engaging in data development and, ultimately, ensure the quality and integrity of test data submitted under a number of statutes.

If EPA does order new testing, the agency's Section 4 authority, while broad, is not unfettered. EPA is required to comply with the mandatory elements of TSCA prior to issuing a test order. This includes a threshold determination that the development of new information is necessary to perform a risk evaluation or to evaluate unreasonable risk. Test order recipients have the right to seek judicial review to challenge an order that they claim fails to comply with the law. The decision to sue is costly. So too, however, is the cost of engaging in testing that is neither feasible nor necessary. EPA's test order authority includes measures to ensure that the existence of a data gap does not always constitute a data need warranting a test order. While the agency is required to consider relative costs, there is no exemption from a testing requirement if a test order recipient cannot afford to conduct such testing. Agreeing to exit the market does not, in EPA's view, absolve manufacturers or processors of testing obligations. Regulated entities may not always agree that the agency acted within its authority to order testing, or may disagree with the basis for such requirement, resulting in litigation.

TESTING chemicals is laudable and an important domestic policy under TSCA. The regulations forcing testing are ever-changing, and stakeholders must keep current with harmonized testing guidelines, industry standards, information requirements, accepted alternative methodologies, computational models, and legal precedents to ensure that the data are scientifically meaningful and compliant. Failure to adhere to relevant standardized methods and established enforceable quality principles compromises data utility and reliability. Failure to comply with mandatory test orders invites enforcement scrutiny. Failure to understand adequately the effects of exposure to a chemical can result in product liability and diminished brand value. Bottom line: consider carefully how, when, and why to generate data, and treat the process and curate the results with the rigor important information deserves.