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TSCA

Practitioner Insights: A Review and Analysis of TSCA Reform Provisions Pertinent to Manufacturers and Processors of Nanoscale Materials

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On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, and in so doing significantly revised the Toxic Substances Control Act (TSCA) for the first time since its enactment in 1976. This article reviews and analyzes TSCA as amended and focuses narrowly on how new TSCA specifically impacts nanoscale materials. Although the new TSCA dramatically changes how the Environmental Protection Agency (EPA) evaluates and manages industrial chemicals, including nanoscale chemicals, the absence of words or phrases such as nano or nanoscale materials means that there are no specific or additional requirements that apply explicitly to such materials. This was a significant shift from many of the earlier TSCA reform bills, which explicitly addressed nanoscale materials by proposing new definitions such as ''substance characteristics'' and ''special substance characteristics'' that included concepts such as size or size distribution; shape; surface structure; and reactivity. The new TSCA is noticeably silent on this subject and does not distinguish nanoscale materials or treat such materials differently from other chemical substances regulated under TSCA.

We also note that the Obama administration staunchly supported emerging technologies, including nanotechnology. In 2011, for example, the White House Emerging Technologies Interagency Policy Coordination Committee issued two memoranda setting forth the Obama administration's principles for the regulation and oversight of emerging technologies, including nanotechnology. The first memorandum, issued March 11, 2011, addressed emerging technologies, such as nanotechnology, and says that ''[w]here possible, regulatory policies should promote innovation while also advancing regulatory objectives.'' The second memorandum, issued June 9, 2011, directly addressed applications of nanotechnology and nanomaterials.

While the previous administration's support is welcome, this does not mean that manufacturers or processors of nanoscale materials have nothing to worry about under new TSCA. We focus below on the key changes in new TSCA that could affect manufacturers and processors of nanoscale materials, and note opportunities for stakeholders to engage in forthcoming rulemaking processes and other regulatory initiatives to ensure EPA is successful in implementing new TSCA.

TSCA Section 2: U.S. Policy Section 2 sets forth U.S. policy regarding industrial chemical management under TSCA. New TSCA makes only very minor revisions to this section, and it remains the policy 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 chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.'' In keeping Section 2 intact, Congress reaffirmed its steadfast commitment to the joint goals of appropriate regulation of chemical substances and ensuring innovation continues. For nanoscale materials, Section 2 and the policy it represents are enormously important.

TSCA Section 3: Definitions New TSCA generally retains the definitions in old TSCA without change and introduces several new definitions:

■ ''conditions of use,'' which refers to ''the circumstances, as determined by the EPA administrator, under which a chemical substance is intended, known, or rea-

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sonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.''

■ ''guidance,'' which means ''any significant written guidance of general applicability prepared by the administrator; and

■ ''potentially exposed or susceptible subpopulation,'' which is defined as ''a group of individuals within the general population identified by the administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.''

The term ''conditions of use'' could have a significant effect on regulatory considerations relating to the manufacture, processing and use of nanoscale materials. ''Conditions of use'' covers nanoscale materials from the time of their manufacture through their disposal. Questions have been raised concerning the potential for exposure to nanoscale materials in the workplace during manufacture and processing, in subsequent phases of their commercial life span, including disposal, and their introduction into the environment through production processes, such as their inclusion in wastewater effluent and air emissions.

The addition of the term ''potentially exposed or susceptible subpopulation'' is intended to ensure that when EPA evaluates unreasonable risk or determines the need for and nature of control actions, it considers and addresses the risks posed to subpopulations such as pregnant women, infants, the elderly, and workers when identified by EPA as being at greater risk.

TSCA Section 4: Testing New TSCA provides EPA with significant new authority to require the development of data and submission of information. Under new TSCA Section 4(a)(2)(A), EPA may through rule, order, or consent agreement, require the development of new information when it needs the information to review a notice under Section 5; perform a risk evaluation under Section 6(b); or implement a requirement imposed under Sections 5(e) or (f), or Section 6(a). New TSCA Section 4(a)(2)(B) allows EPA to require the development of new information to prioritize chemical substances under Section 6(b) if EPA determines that the information is necessary to establish the priority of the chemical substance, subject to certain limitations. When EPA requires the development of new information, it must identify the need for the new information and use a tiered screening and testing process, unless EPA can justify proceeding to advanced testing without first conducting screening-level testing.

New TSCA Section 4 also requires EPA to reduce and replace the use of vertebrate animals in the testing of chemical substances ''to the extent practicable, scientifically justified, and consistent with the policies'' of the act. Under new TSCA, EPA must ''tak[e] into consideration . . . reasonably available existing information'' prior to requiring vertebrate animal testing. It is called on to encourage and facilitate the use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals; the grouping of two or more chemical substances into scientifically appropriate categories; and the formation of industry consortia to avoid unnecessary duplication of tests.

New TSCA Section 4 expands EPA's authority to require, through a rule, order or consent agreement, the development of information necessary for EPA to make a risk determination or meet other needs, such as for reviewing a notice submitted under Section 5. EPA is generally required to apply a tiered testing approach, and new TSCA gives EPA explicit authority to require testing for exposure endpoints (such as chamber studies to determine air concentrations following volatilization from a product).

Nano stakeholders are encouraged to monitor how EPA interprets and deploys this new authority. Given the inherent uncertainty and novelty presented by nanoscale materials, in conjunction with explicit authority to require testing on new chemicals, including for hazard and exposure endpoints, testing burdens on nanoscale materials could be significant, particularly in light of the changes to Section 5, as described below.

TSCA Section 5: Manufacture and Processing Notices 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, and companies must notify EPA under Section 5 prior to manufacturing, processing or importing new chemicals, including new chemical nanoscale materials. As discussed below, the notices include premanufacture notifications (PMN) and exemption requests. To answer the question of whether a nanoscale material is considered a ''new'' chemical for TSCA purposes, EPA in 2008 published its approach to the TSCA Inventory status of nanoscale substances. EPA states that historically it has not used particle size to distinguish substances that are known to have the same molecular identity for the purposes of the TSCA Inventory. In determining whether a nanoscale material is a new or existing chemical, EPA clarified that it intended to continue to apply its historic approach based on molecular identity rather than focus on physical attributes, such as particle size. Thus, a nanoscale material that has the same molecular identity as an Inventory listed conventionally-sized chemical is considered an existing chemical.

Under old TSCA, EPA assessed over 170 nanoscale materials as new chemicals. EPA has taken actions intended to control and limit exposure, including limiting the use of the nanoscale material; requiring the use of personal protective equipment (PPE) and engineering controls; limiting environmental releases; and requiring testing to generate health and environmental effects data.

Under old TSCA, if EPA did not respond to a PMN and take action within 90 days, then a company could submit a notice of commencement and begin manufacture, processing or import. New TSCA revises Section 5(a)(3) to require EPA to review PMNs, make one of three affirmative determinations, and take the appropriate action depending upon the determination. EPA's review may not consider costs or other non-risk factors in determining that the new chemical presents an unreasonable risk. New TSCA also requires EPA to consider unreasonable risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use in making determinations under Sections 5(a)(3)(A) and (C).

The first of the affirmative determinations that EPA can make is that the new chemical ''presents'' an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors,

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and considering unreasonable risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use. If EPA makes this determination, it 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.

The second affirmative determination that 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, 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. It must also then either promulgate a SNUR or explain why it is not initiating such a rulemaking. Although the language of this second determination under new TSCA is similar to old TSCA Section 5(e), the presence of the first italicized ''or'' in lieu of the ''and'' in this provision in old TSCA substantially broadens the scope and effect of the provision, allowing EPA to take regulatory action based on a lack of hazard information. Given EPA's position that it needs information on nanoscale materials, EPA could use this provision in new TSCA to compel manufacturers, importers, and processors of new nanoscale materials to develop information.

The third determination that EPA can make is that the new chemical is not likely to present an unreasonable risk of injury to health or the environment, and that the PMN submitter may commence manufacture, import, or processing. New TSCA requires EPA to publish a statement of its finding, which EPA has stated that it intends to publish on its website and in the Federal Register.

Section 5(h), which concerns exemptions from PMN notification, has been retained with generally conforming changes in new TSCA. The exemptions include Test Market and Low Volume exemptions. Exemptions can be requested by notifiers and be granted by EPA if requirements can be met.

Under new TSCA, EPA has the authority to require significant new use (SNU) notification by rule for the import or processing of a chemical substance as part of an article or category of articles, only if EPA makes an affirmative finding that the reasonable potential for exposure to the chemical substance through the article or category of articles justifies notification. The requirement for an affirmative finding will likely reduce the number and limit the scope of notifications for articles.

To date, under TSCA, the subpopulation of key concern for nanomaterials has been workers. New TSCA Section 5(f)(5) requires EPA, to the extent practicable, to consult with the U.S. Occupational Safety and Health Administration (OSHA) prior to adopting any prohibition or other restriction relating to a chemical with respect to which EPA has made a determination under Section 5(a)(3)(A) or (B) to address workplace exposures. This requirement is of particular significance to manufacturers and processors of new nanoscale materials, given OSHA's position that ''existing occupational exposure limits for a substance may not provide adequate protection from nanoparticles of that substance.'' In addition, just a month after the enactment of new TSCA, in July 2016, EPA proposed changes to the regulations governing SNUs, including changes based on issues identified by EPA and issues raised by public commenters on previous SNURs. The proposed changes include making it a SNU not to implement a hierarchy of controls to protect workers. EPA states that it proposed this change partly due to comments received on recently promulgated SNURs. EPA cites proposed SNURs published in the Dec. 28, 2011, Federal Register. The Dec. 28, 2011, proposed rule included five SNURs for multi-walled carbon nanotubes, one SNUR for single- and multi-walled carbon nanotubes, and seven SNURs for fullerenes. In the July 28, 2016, proposed rule, EPA notes that commenters on the December 28, 2011, proposed SNURs suggested using the ''hierarchy of controls'' approach before requiring PPE for worker protection. When EPA promulgated final SNURs in June 2013, the final SNURs containing SNUs pertaining to PPE for workers included language requiring the consideration and implementation of engineering controls and administrative controls where feasible. Since June 26, 2013, all new chemical SNURs have included language to consider and implement engineering controls, and administrative controls where feasible, when the SNURs contained SNUs concerning the lack of PPE for workers.

TSCA Section 6: Prioritization, Risk Evaluation, and Regulation Under old TSCA Section 6, if EPA found there was a reasonable basis to conclude that a chemical presented an unreasonable risk of injury to health or the environment, EPA had the authority to prohibit its manufacture, processing, or distribution using the ''least burdensome requirements.'' EPA had difficulty implementing the least burdensome requirements, however, and new TSCA removes this language. New TSCA makes other notable revisions to Section 6 as well, including adding prioritization and risk evaluation steps to the process and codifying ambitious timelines for EPA to complete key steps including prioritizations, risk evaluations, and risk management actions. New TSCA Section 6 simplifies the procedural requirements for EPA to promulgate risk management rules, while also adding new requirements and providing for certain exemptions from such rules. Nanoscale existing chemicals are subject to the new Section 6 provisions and could be the focus of EPA's future efforts if significant issues are identified. As discussed above, new Section 6 does not include language specific to nanoscale materials.

New TSCA lays out a detailed prioritization process that includes specific goals and deadlines that EPA must meet. EPA must establish a risk-based screening process that includes criteria for designating chemicals as high-priority substances for risk evaluation versus low-priority substances. New TSCA specifies that the

prioritization process will consider, among others: hazard and exposure potential; persistence and bioaccumulation; and storage near significant sources of drinking water.

High-priority chemicals are those that may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA. Chemicals that do not meet this standard are low-priority chemicals. Under new TSCA, EPA may not consider costs or other nonrisk factors in making these designations. Low-priority designations may be legally challenged.

The prioritization process for a given chemical must be completed within one year, and include a 90-day period for interested persons to submit relevant information before EPA proposes a priority designation. EPA may extend this period for up to three months to receive or evaluate prioritization testing conducted under Section 4(a)(2)(B). The prioritization process must also include a 90-day public comment period on the proposed designations for high- and low-priority chemicals. If the information available at the end of the 12-month period is insufficient for EPA to designate the chemical as low-priority, then EPA will designate the chemical as high-priority.

New TSCA requires that EPA initiate risk evaluations on all high-priority chemicals, and specifies deadlines and goals for the risk evaluations. New TSCA also creates a process whereby manufacturers can request a risk evaluation, subject to payment of fees and other limitations. The goal of the risk evaluation is to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. The evaluation of unreasonable risk does not consider costs or other non-risk factors, but includes unreasonable risks to a potentially exposed or susceptible subpopulation identified as relevant by EPA. New TSCA includes ambitious deadlines for the risk evaluation, which must be completed within three years after EPA initiates it. New TSCA allows EPA to extend the completion deadline for no more than six months.

In conducting a risk evaluation, EPA must integrate and assess the available information on hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures under the conditions of use were considered; and describe the weight of the scientific evidence for the identified hazard and exposure. If EPA determines, through a risk evaluation, that a chemical presents an unreasonable risk of injury to health or the environment, then EPA must promulgate a Section 6(a) rule to regulate the chemical so that it no longer presents an unreasonable risk. The controls can include various restrictions, labeling requirements, and/or bans/phase-outs.

New TSCA allows EPA a maximum of four years to complete Section 6(a) rulemakings. Section 6(c)(2) specifies the requirements that must be met in taking the regulatory action, including developing a ''statement of effects'' concerning aspects such as the adverse effects and exposure of the chemical, the benefits of the chemical for various uses, and the reasonably ascertainable economic consequences of the rule. When considering bans or phase-out actions, and in setting an appropriate transition period, EPA must 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.''

Section 6(c)(2)(D)(i) is a new provision that provides for a general exemption from Section 6 regulation for certain replacement parts. Section 6(c)(2)(E) limits regulation of articles ''to the extent necessary to address'' the risks from exposure to the chemical from the article. Section 6(g), another new provision, gives EPA authority to grant exemptions by rule from ban or phase-out requirements if certain findings can be made by EPA.

Final Section 6(a) rules and the underlying risk evaluations are legally reviewable, as are risk evaluations that determine that a chemical does not present an unreasonable risk.

EPA proposed on Jan. 17 procedures to establish the risk-based screening process and criteria that EPA will use to identify chemical substances under new TSCA as either high-priority substances for risk evaluation, or low-priority substances for which risk evaluations are not warranted at the time. On Jan. 20, EPA proposed a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. The process would not consider costs or other non-risk factors. Neither of these proposed rules specifically addresses nanomaterials.

TSCA Section 8: Reporting and Retention of Information The new TSCA Section 8 amendments include establishing a ''TSCA Inventory reset'' process; maintaining the use of Class 2 nomenclature that was in use on the date of enactment; treating individual members of the categories identified by EPA as statutory mixtures as being included on the TSCA Inventory; and proposing a rule to limit the reporting requirements for inorganic byproducts that are subsequently recycled, reused, or reprocessed.

To reset the TSCA Inventory, new TSCA calls for EPA to develop, within one year of enactment, a rule requiring manufacturers and possibly processers to notify EPA of each TSCA Inventory chemical manufactured or processed for a nonexempt commercial purpose in any amount during the 10 years before the enactment of new TSCA. EPA will designate chemicals for which it receives notices as active and designate chemicals for which it receives no notices as inactive. Under new TSCA, no chemicals will be removed from the TSCA Inventory through the implementation of the reset process, and chemicals designated as inactive will not be subject to the PMN process. Manufacturers or processors must notify EPA in advance, if they intend to manufacture or process any chemical designated as inactive. EPA issued a proposed rule regarding the TSCA Inventory reset on Jan. 13, and intends to promulgate a final rule in June 2017.

Prior to enactment of new TSCA, on Apr. 6, 2015, EPA issued a proposed Section 8(a) rule that would impose reporting and recordkeeping requirements for certain chemical substances when they are manufactured

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or processed at the nanoscale. EPA issued the rule in final on Jan. 12. The rule excludes from the reporting requirement: chemical substances manufactured at the nanoscale as part of a film on a surface; DNA; RNA; proteins, enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms; and chemical substances that dissociate completely in water to form ions that are smaller than one nanometer. The rule requires manufacturers, importers, and processors to report the specific chemical identity, actual or anticipated production volume, methods of manufacture and processing, use, exposure and release information, and existing data concerning environmental and health effects. The rule imposes one-time reporting requirement for discrete forms of existing chemical nanoscale materials manufactured or processed any time prior to May 12, 2017, the effective date of the final rule. It also imposes a reporting requirement for new discrete forms of existing chemical nanoscale materials 135 days before they are manufactured or processed. According to EPA, the information will facilitate evaluation of the nanomaterials and a determination of whether further action, including additional information collection, is needed.

Both new and old TSCA exempt small manufacturers and processors from TSCA Section 8(a) reporting requirements. New TSCA includes a new provision, Section 8(a)(3)(C), requiring EPA to:

- consult with the Small Business Administration (SBA) concerning the adequacy of current standards;
- provide public notice and an opportunity for comment; and
- make a determination as to whether revision of the standards is warranted.

EPA first incorporated the definition of small manufacturer in the 1986 Inventory Update guidance, and EPA has not revised it since. For one of the two standards, the definition uses a $4 million annual sales cap that, given inflation, is now equivalent to $8.79 million in 2016. As the annual sales cap has more than doubled, EPA may well decide to update this small manufacturer standard. On Dec. 15, 2016, EPA published a notice announcing its preliminary determination that revisions to the size standards are warranted. As part of the ongoing review process, EPA requested public comment on whether a revision of the current size standard definitions is warranted at this time.

In the Apr. 6, 2015, proposed Section 8(a) reporting rule, EPA proposed an alternate exemption for small manufacturers that would remove the first standard concerning production volume entirely because, according to EPA, the 100,000-pound threshold ''did not contemplate typical production volumes for chemical substances manufactured at the nanoscale.'' EPA stated further that it ''does not believe production volume should be a relevant consideration in determining whether a nanotechnology company is a small manufacturer or processor.'' The final rule provides an exemption for small manufacturers and processors. For the purposes of the final rule, EPA defined and exempted any small manufacturer or processor as a company that has sales of less than $11 million per year.

EPA's proposed rule would include a continuing reporting requirement, such that manufacturers and processors who did not report previously would be required to report to EPA at least 135 days before beginning the manufacture or processing of a new discrete form of a reportable nanoscale substance. EPA states that the 135-day period is based on its experience with PMN submissions and its determination that the intent to manufacture or process was formed at least 135 days before commercialization. Neither old nor new TSCA authorizes EPA to impose a PMN requirement masquerading as a reporting requirement, however. If EPA's intent is to obtain more information concerning nanoscale materials, then a reporting requirement may be appropriate. The proposed rule states that the information ''would facilitate EPA's evaluation of the materials and a determination of whether further action, including additional information collection, is needed.'' Requiring that information to be submitted 135 days before manufacture or processing suggests that EPA could intend to determine whether further action is necessary before manufacture or processing begins. In the final rule, EPA clarifies that it ''did not intend to create *de facto* new chemical reporting for new discrete forms of nanoscale materials, because the 135-day period is not a formal review-period that prohibits manufacture before the end of the 135-day period.'' There is no obligation upon the company to wait 135 days after reporting to manufacture or process. EPA states that if the company changes its schedule or does not form the intent until a later time, ''it may wish to document supporting facts,'' however. Further, EPA states, the comments made it realize that the proposed regulatory text created an unintended result (and not commented upon). Because (1) the default period of 135 days is greater than the advance periods required for various TSCA Section 5 submissions, and (2) the reporting exemption for TSCA Section 5 submissions in the proposed rule would apply only where the company had already filed a TSCA Section 5 submission, a company proposing to manufacture a discrete form of a reportable substance for which a TSCA Section 5 submission had not been filed might conceivably be required to first file a TSCA Section 8(a) report, followed by a Section 5 submission. EPA states that in such cases, it needs only the Section 5 submission. The final rule includes a new subcategory of non-reportable chemical substances for chemical substances that are not on the TSCA Inventory at the time reporting would otherwise be required. The inclusion of this new subcategory helps to clarify EPA's original intent that if a reportable chemical substance is not on the TSCA Inventory, a manufacturer only needs to submit a new chemical notification under TSCA Section 5.

Old and new TSCA Section 8(a) both require that, to the extent feasible, EPA will not require any reporting that is ''unnecessary or duplicative.'' The proposed continuing reporting requirement will require any new manufacturer or processor of a nanoscale material to submit information to EPA, regardless of whether EPA has already obtained one or a dozen reports for the same nanoscale material. For nanoscale materials that are new chemicals, manufacturers and processors must comply with TSCA Section 5 requirements, submitting a Section 5 notice to EPA.

TSCA Section 9: Relationship to Other Federal Laws While the Section 9 provision of old TSCA was rarely used, new TSCA amends Section 9 to expand its scope and operation, and EPA actions and referrals to other agencies or EPA offices may become more com-

mon. Under new TSCA Section 9(a), when EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical presents an unreasonable risk of injury to health or the environment, and that the risk may be prevented or reduced under a federal law not administered by EPA, EPA must provide the information to the relevant federal agency. New TSCA Section 9(a) has been amended, however, to provide further that if EPA makes a report and the agency to which the report was made fails to act within the timeframe specified by EPA, then EPA shall take action against the unreasonable risk under new TSCA Section 6 or 7.

New TSCA creates Section 9(e), which requires EPA to make information on exposures or releases that may be prevented or reduced under another federal law available to the relevant federal agency or EPA office.

TSCA Section 14: Confidential Business Information New TSCA Section 14, ''Confidential Information,'' significantly revises and replaces old TSCA Section 14, ''Disclosure of Data.'' Under new TSCA Section 14, health and safety studies are identified as information not protected from disclosure. A new provision, new TSCA Section 14(b)(3), allows the release of general information describing manufacturing volumes, such as aggregate volumes, as well as a general description of a process used in the manufacture or processing and functions and uses of a chemical, including information specific to an industry that customarily would be shared with the general public or within an industry.

New TSCA Section 14 imposes new requirements on companies asserting confidential business information (CBI) claims. Companies must assert CBI claims at the time they submit information to EPA and substantiate their CBI claims. If a company fails to substantiate its CBI claim, the information will not be protected from disclosure. A company claiming chemical identity as CBI must submit a structurally descriptive generic name for the chemical. The generic name must be consistent with EPA guidance and describe the chemical structure as specifically as practicable while protecting the features that are claimed as confidential and the disclosure of which would likely cause substantial harm to the company's competitive position. Information generally not subject to substantiation requirements, such as specific information describing the processes used in manufacture or processing, marketing and sales information, information identifying a supplier or customer, specific information regarding the use, and specific production or import volume, will be protected until the company that asserted the claim notifies EPA that the claim is withdrawn, or EPA becomes aware that the information does not qualify for protection from disclosure under Section 14.

Information claimed as CBI will be protected for 10 years, unless the claim is withdrawn sooner or EPA becomes aware that the information does not qualify for protection from disclosure. The 10-year period may be extended if the company making the CBI claim reasserts the claim and submits a request for an extension. New TSCA Section 14 does not limit the number of extensions that may be granted. Under new TSCA Section 14, EPA may require companies that have claimed CBI to reassert and substantiate or re-substantiate their claim after the chemical:

- is designated as a high-priority chemical;
- designated as an active substance under 8(b)(5)(B)(iii); or
- after EPA determines that disclosure of certain information protected from disclosure would be important in conducting risk evaluations or promulgating Section 6 rules.

CBI review is required to determine whether the information qualifies for an exemption from disclosure in connection with a request for information, if EPA has a reasonable basis to believe the information does not qualify for protection, or if EPA determines under TSCA Section 6(b)(4)(A) that the chemical presents an unreasonable risk of injury to health or the environment.

A significant amendment to new TSCA Section 14 allows CBI information to be disclosed if certain requirements are met. The exceptions include disclosure to:

- a state or tribal government to administer or enforce a law;
- a federal, state, or tribal health or environmental professional;
- a treating physician or nurse;
- a state or tribal public health or environmental official; or
- a first responder.

The provisions concerning CBI, and particularly chemical identity, may be especially important to manufacturers of new nanoscale materials. For example, in the preamble to a recent direct final rule promulgating SNURs for several chemicals, EPA notes that the rule includes two PMN substances whose reported chemical names include the term ''carbon nanotube.'' EPA states that, because of a lack of established nomenclature for carbon nanotubes (CNT), the TSCA Inventory names for carbon nanotubes are in generic form, and EPA uses the specific structural characteristics provided by the PMN submitter to characterize the individual CNT more specifically. According to the preamble, the PMN submitters claimed those specific structural characteristics as CBI. Manufacturers and processors of nanoscale materials who have made CBI claims should closely monitor EPA's implementation of new TSCA Section 14. If the CBI claims require reassertion or substantiation, manufacturers and processors should do so in a timely manner to ensure protection of their CBI.

TSCA Section 18: State-Federal Relationship The passage of new TSCA was complicated by the issue of state preemption. Under new TSCA, state actions or requirements relating to specific chemical substances enacted before Apr. 22, 2016, or any action taken pursuant to a state law in effect on Aug. 31, 2003, will be preserved. States are prohibited from establishing or continuing to enforce:

- a statute or administrative action that is reasonably likely to produce the same information required under new TSCA Sections 4, 5, or 6;
- a statute, criminal penalty, or administrative action to prohibit or restrict the manufacture, processing, or distribution in commerce or use of a chemical after EPA has already made a Section 6(i)(1) determination or promulgated a final Section 6(a) rule; or

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■ a statute or administrative action requiring the notification of a use of chemical substance that EPA has specified as a SNU and for which EPA has required notification pursuant to a Section 5 SNUR.

New TSCA Section 18(f) establishes a waiver process through which states may seek a waiver from preemption restrictions, provided EPA determines that compelling conditions to protect health or the environment warrant granting the waiver; compliance with the proposed requirement would not unduly burden interstate commerce; compliance with the proposed requirement would not cause a violation of any applicable federal law, rule, or order; and the proposed requirement is designed to address a risk identified with the best available science, using supportive studies, and based on the weight of the scientific evidence. New TSCA Section 18(g) ensures that the preemption provision will not affect state or federal common law.

TSCA Section 26: Administration of the Act New TSCA expands the fee authority granted to EPA under old TSCA, allowing EPA to impose fees related to administering Sections 4, 5, 6 and 14. New TSCA creates a TSCA Service Fee Fund that will hold these fees. New TSCA Section 26 requires EPA to use the best available science in its scientific decision making, and to make decisions under Sections 4, 5 and 6 based on the weight of the scientific evidence. Within two years of enactment of new TSCA, EPA must develop any policies, procedures, and guidance necessary to carry out the amendments. New TSCA creates the Science Advisory Committee on Chemicals to provide independent advice and expert consultation with respect to scientific and technical aspects of issues related to the implementation of new TSCA.

Manufacturers and processors of nanoscale materials could be impacted by the fee EPA is required to assess for Section 5 notifications, as it will likely increase. EPA has already held a stakeholder meeting to obtain feedback on the fee provisions. Although EPA intended to issue a proposed rule in December 2016[GS2] , it has not yet done so to date. EPA intends to promulgate a final rule in June 2017.

Conclusion Enactment of new TSCA represents the successful conclusion of years of debate, countless legislative efforts, congressional hearings and the tireless efforts of many stakeholders. Although a number of bills in earlier sessions of Congress included language targeting nanomaterials, new TSCA does not. Instead, it provides EPA with new authorities to regulate all industrial chemicals, including nanoscale materials. As EPA begins work to meet the first of many deadlines under new TSCA, the specifics of how EPA will implement its new authorities will become clear. Manufacturers and processors of nanoscale materials should read new TSCA and carefully review and analyze how EPA's new authorities and implementation will affect EPA's regulation of nanoscale materials. Engaging with EPA during the implementation process will ensure that the innovation offered by nanoscale materials is recognized and remains protected.