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WHITE PAPER

October 2017

An Assessment and Comparison of New TSCA and REACH

Passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, or “New Toxic Substances Control Act,” introduces a number of changes to regulations for the collection and assessment of information concerning certain chemicals. Some changes apply to the testing, regulation of, and disclosure of data relating to new chemicals, but the most significant changes introduced by the New TSCA pertain to the regulation of existing chemicals.

This *White Paper* discusses New TSCA and compares its amended provisions to the European Union’s Registration, Evaluation, Authorization and Restriction of Chemicals, or “REACH,” program.

Until recently, the European Union (“EU”) regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (“REACH”) and the United States’ Toxic Substances Control Act (“TSCA”), were not close to being parallel in their scope. That changed with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“New TSCA”) in June 2016.

REACH first went into effect in June 2007. It established procedures for collecting and assessing information about all existing and new chemical substances imported, produced, or used within the EU, both in industrial processes and consumer products. Companies are required to register their substances, which are then evaluated by the European Chemicals Agency (“ECHA”). ECHA assesses the risks associated with certain chemicals and determines how and whether such risks can be reduced or eliminated.

TSCA was first enacted in 1976. Under TSCA, the United States Environmental Protection Agency (“EPA”) had maintained an [Inventory](#) of chemical substances made or used within the United States and performed evaluations of new chemicals entering the marketplace. Unlike REACH, however, TSCA did not previously require a risk assessment of all chemicals in the Inventory.

New TSCA brought about a number of significant changes to the TSCA regime. Most importantly, and similar to REACH, New TSCA obligates EPA to undertake risk evaluations for chemicals in the Inventory and to eliminate identified risks. This *White Paper* discusses New TSCA and compares the amended provisions to the REACH program.

NEW TSCA OVERVIEW

New TSCA brought about significant changes to the existing law. Some of the key amendments are highlighted below.

Section 4—Chemical Testing

Under Section 4, EPA can require testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found. New TSCA revised Section 4 to grant additional authority to EPA to require the development of new information relating to a chemical substance. Additionally,

New TSCA expanded the situations under which EPA is required to take action against chemicals presenting significant risks. Importantly, under New TSCA, EPA may not consider non-risk factors (such as cost) in determining whether a risk is unreasonable.

Section 5—Regulation of New Chemicals

Section 5 requires pre-manufacture notice for new chemical substances. EPA also issues significant new use rules when it identifies a new use of a chemical substance that could result in exposures to, or releases of, a substance of concern. New TSCA strengthened the existing Section 5 process. The law requires manufacturers and processors to submit pre-manufacture notices to EPA 90 days before beginning to manufacture or process the chemical substance. EPA must then review all new chemicals and significant new uses, make a determination, and take required action during that 90-day window. Again, during its review process, EPA is prohibited from considering costs or other non-risk factors.

Section 14—Disclosure of Data

TSCA has various provisions relating to the submission and protection of Confidential Business Information (“CBI”). As to CBI, New TSCA brought significant changes to Section 14. Under New TSCA, information that is not protected as CBI includes:

- General information describing manufacturing volumes (expressed in either aggregated volumes or ranges);
- General descriptions of the process used to manufacture or process a chemical substance or the industrial, consumer, or commercial functions of a chemical substance, mixture, or article containing a chemical substance or mixture; and
- Previously protected information regarding a chemical substance or mixture that is later banned.

Further, when making a confidentiality claim for information that may be protected under New TSCA, the applicant must submit a certification statement. In general, if EPA approves a claim of confidentiality, the information will be protected from disclosure for 10 years. EPA may require reassertion/resubstantiation of a confidentiality claim sooner than the standard 10 years under certain circumstances.

The biggest changes under New TSCA were in Section 6, regarding the regulation of existing chemicals. Three implementation rules (Notification, Prioritization, and Risk Evaluation) regarding these Section 6 changes were recently finalized by EPA and are outlined in more detail below.

NEW TSCA—NOTIFICATION RULE

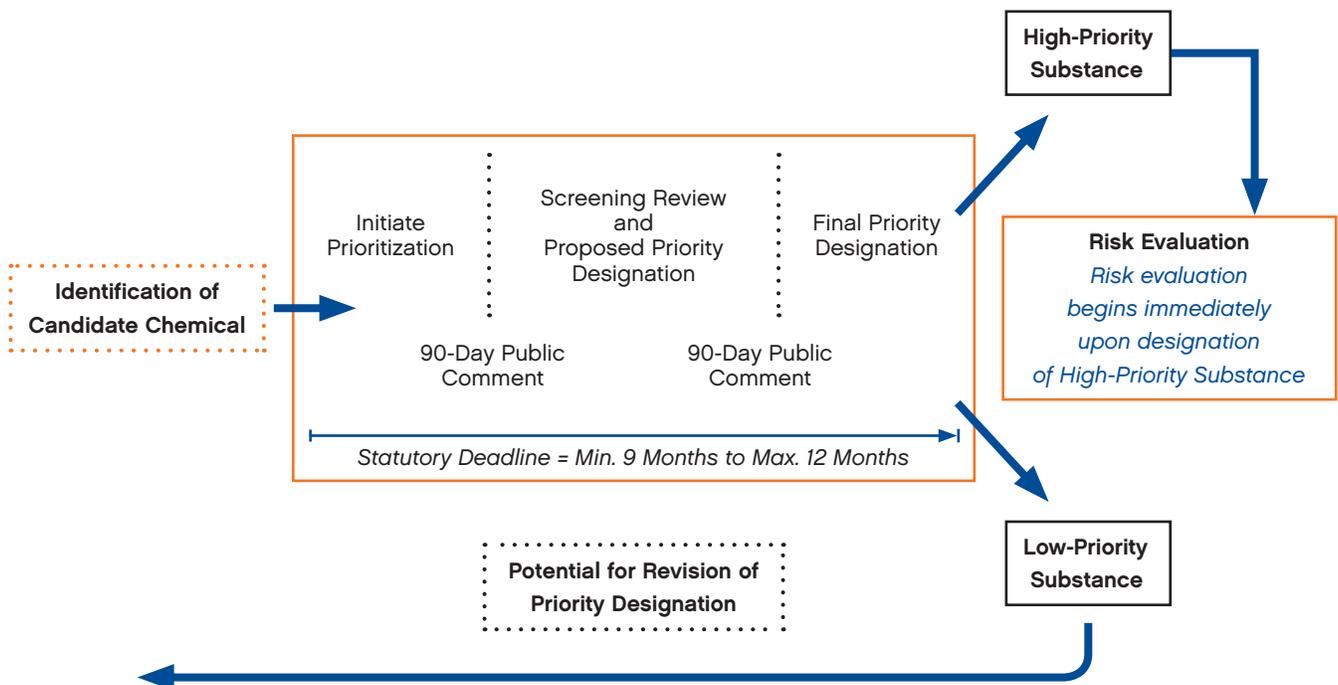
On August 11, 2017, EPA published in the *Federal Register* a final rule titled “TSCA Inventory Notification (Active-Inactive Requirements)” (“Notification Rule”).² Any company that domestically manufactured, imported, or processed a chemical substance listed on the Inventory for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016, is affected by the Notification Rule. Manufacturers must report to EPA by February 7, 2018. Processors may report to EPA by October 5, 2018. The reporting requirement involves providing basic information such as the name and address of the submitting company, a list of the company’s reportable chemical substances, and information about those

substances (such as the relevant [Chemical Abstracts Service Registry Number](#)). The notifications must be submitted and certified by an authorized official of the company. EPA will use the notifications to distinguish active substances from inactive substances. The Notification Rule also establishes procedures for future notifications in the event that the manufacturing or processing of an inactive chemical substance resumes.

NEW TSCA—PRIORITIZATION RULE

New TSCA requires EPA to establish a process for evaluating existing Inventory chemicals. Prioritization, whereby a chemical substance is designated as either High-Priority or Low-Priority, is the initial step. To facilitate the prioritization process, on July 20, 2017, EPA published a final rule in the *Federal Register* titled “Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act” (“Prioritization Rule”).³ The Prioritization Rule became effective on September 18, 2017. EPA has provided the following [graphic overview](#) of its chemical prioritization process as specified in the Prioritization Rule:

CHEMICAL PRIORITIZATION PROCESS



Initially, EPA will announce a chemical substance that the agency plans to put through the prioritization process in the *Federal Register* and provide a 90-day comment period. This step begins the prioritization process and starts a nine- to 12-month statutory timeframe during which EPA must designate the chemical substance as either High- or Low-Priority.

EPA will then screen the chemical substance under its “conditions of use,” meaning the circumstances under which a chemical substance is “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” The screening review will consider various criteria, such as:

- The hazard and exposure potential of the chemical substance;
- Persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- The conditions of use or significant changes in the conditions of use of the chemical substance; and
- The volume or significant changes in the volume of the chemical substance manufactured or processed.

Next, EPA will propose to designate a chemical substance as either High-Priority or Low-Priority. The proposed designation will be published in the *Federal Register* for a 90-day comment period. The applicable standards are as follows:

- **High-Priority Substance**—“a chemical substance that the Administrator concludes, without consideration of costs or other non-risk factors, 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 potentially exposed or susceptible subpopulations identified as relevant by the Administrator.”

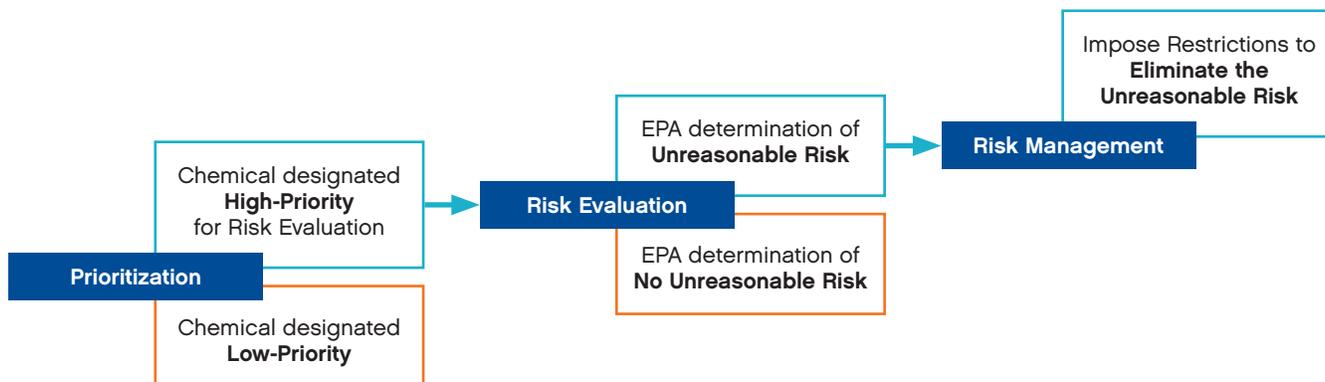
- **Low-Priority Substance**—“if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, that such substance does not meet the [High-Priority] standard.”

Finally, after considering public comments, EPA will either finalize a High-Priority designation (and then initiate a risk evaluation) or finalize a Low-Priority designation (indicating that a risk evaluation is not warranted at that time). EPA’s final priority designation will be published in the *Federal Register*. EPA may revise a designation by restarting the prioritization process.

New TSCA requires that, by December 22, 2019, EPA must have designated at least 20 chemical substances as High-Priority and 20 chemical substances as Low-Priority. New TSCA further requires that upon completion of a risk evaluation, EPA must designate at least one additional High-Priority chemical.

NEW TSCA—RISK EVALUATION RULE

Also on July 20, 2017, EPA published a final rule titled “[Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act](#)” (“Risk Evaluation Rule”).⁴ The purpose of a risk evaluation under New TSCA is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA has provided the [following figure](#) as an overview of the steps in the risk evaluation process for existing chemicals under New TSCA:



In general, EPA will conduct risk evaluations on chemical substances designated as High-Priority through the prioritization process described above. Chemicals also may be evaluated following EPA's approval of a manufacturer's request for a risk evaluation of a chemical they manufacture. The components of a risk evaluation include the following:

- **Scope:** The scope will include the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations EPA expects to consider. The scope will also include a "Conceptual Model" (which will describe the relationships between the chemical, under the conditions of use, and humans and the environment) and an "Analysis Plan" (which will identify the approaches and methods EPA intends to use to assess exposures and hazards). A draft scope will be published in the *Federal Register* no later than three months from the initiation of the risk evaluation process. A docket will be opened for no less than 45 days to facilitate public comment on the draft scope. A final Scope will then be published no later than six months after initiation of the risk evaluation.
- **Hazard Assessment:** EPA will identify the adverse health or environmental effects caused by exposure to the chemical. Hazards may include toxicity with respect to cancer, mutation, reproductive, developmental, respiratory, immune, cardiovascular impacts, and neurological impairments.
- **Exposure Assessment:** EPA will identify the likely duration, intensity, frequency, and number of exposures to a chemical under the conditions of use. This assessment will also include the nature and types of individuals or populations that are exposed to the chemical.
- **Risk Characterization:** EPA will integrate and assess the reasonably available information on hazard and exposure and also will include considerations of information quality and alternative interpretations.
- **Risk Determination:** EPA will issue a draft determination as to whether the chemical substance, under the conditions of use, presents an unreasonable risk to health or the environment.

A draft risk evaluation will be published in the *Federal Register*. Each draft risk evaluation will be peer reviewed. EPA will provide for a 60-day public comment period on the draft risk evaluation. A final risk evaluation will be published no later than three to three-and-a-half years after identification of the chemical as a high priority for risk evaluation.

If EPA determines that a chemical substance presents an unreasonable risk, it must propose a rule within one year, and publish a final rule within two years, that manages the risk. Under New TSCA, the proposed rule does not need to be the "least burdensome" way of reducing or eliminating the risk.

New TSCA requires that for each risk evaluation completed on a High-Priority chemical, EPA must begin a new risk evaluation. By the end of calendar year 2019, EPA must have at least 20 chemical risk evaluations ongoing at any given time.

REACH OVERVIEW

Registration of Chemicals

REACH requires registration with the ECHA of all chemical substances (on their own or in mixtures or in articles with intended release) if manufactured/imported into the EU in quantities above one ton/year per manufacturer/importer. Very few exemptions relate to naturally occurring substances and specific substances of very low risk.

Registrations include not only the information on identity of chemicals, uses, etc., but also a mandatory set of data related to toxicological and environmental hazards (depending on the tonnage). If studies are not available, the registrants must carry out new studies. There is a mandatory data and cost-sharing regime between the registrants of the same substance.

REACH also provides possibilities to adapt the testing requirements in order to limit the testing on vertebrates (e.g., by using existing data on similar chemicals (read-across), or by waiving the testing because there is no exposure, the testing is not technically feasible etc.).

ECHA continuously examines the registrations in order to identify data gaps and invites the registrants to submit new studies if necessary (so-called "compliance check of registrations").

Evaluation of Chemicals

Based on data submitted for the registration, ECHA prioritizes substances with a view to further evaluation. The main criteria for evaluation are hazard profile, exposure, and high aggregated tonnage.

The evaluation of prioritized chemicals itself is carried out by the EU Member States. During the evaluation, the authorities are empowered to request the registrants to submit additional data beyond the registration data set (studies, monitoring data, etc.). The outcome of the evaluation might be that further action is necessary, such as “authorization” or “restriction.”

Authorization

Substances that are either carcinogenic, mutagenic, toxic to reproduction, persistent and bioaccumulative, or causing a similar concern (e.g., endocrine disruptors) may be included in the Candidate List of Substances of Very High Concern. The listing of a substance in the Candidate List triggers additional information obligations in the supply chain and for consumers.

The substances in the Candidate List are further prioritized by ECHA for their inclusion into the authorization list. Once a substance is included in the authorization list and after a specified transition period, the substance cannot be used in the EU any longer unless an authorization has been granted to a manufacturer, importer, or downstream user, or to an actor up their supply chain, for that specific use.

Authorizations are granted by the European Commission after ECHA evaluation of the authorization application. An authorization can be granted only if the risk is adequately controlled or if the socioeconomic benefits of the continuing use outweigh the risk to human health or the environment.

Each authorization is time-limited, and it is subject to a review. If the circumstances have changed (e.g., there is an alternative), the European Commission may withdraw it.

Restriction

If there is an unacceptable risk to human health or the environment arising from the manufacture, use, or placing on the market of substances, the European Commission, after an evaluation by ECHA, may adopt restrictions. A substance on its own, in a mixture or in an article for which there is a restriction, will not be manufactured, placed on the market, or used unless it complies with the conditions of that restriction.

The procedure for adoption of restrictions includes several public consultations, and it takes into account the socioeconomic impact of the proposed restriction.

REACH—NEW TSCA COMPARISON

- REACH requires toxicological and eco-toxicological data for all chemicals (depending on their tonnage). If the studies are not available and there is no possibility to adapt the testing requirements, new studies must be carried out. New TSCA does not automatically require such data for all chemicals, but EPA's authority to require additional information has been expanded under New TSCA, including requiring new information when needed to prioritize chemicals or perform risk evaluations. When utilizing this new authority, however, EPA must explain its reasoning behind the request for new information.
- The evaluation of chemicals under both REACH and New TSCA is based on similar principles. It is likely, however, that the number of evaluations performed will be significantly lower in the United States than in the EU, because in the EU, evaluations are carried out by the authorities of all 28 Member States (27 after Brexit). If the U.S. and EU authorities adopted a system of mutual recognition of evaluated chemicals, this could significantly limit duplication of efforts.
- New TSCA risk management restrictions are based on similar principles as REACH restrictions.
- New TSCA does not include an authorization procedure similar to REACH (i.e., where a specific entity is granted an authorization to use an otherwise banned substance for a specific purpose for a limited period of time). In that regard, the EU authorization process for substances that are already subject to the authorization requirement is currently not working very well, in particular with respect to substances with wide uses. There is increased scrutiny of ECHA and growing skepticism of the EU Member States that need to approve the European Commission's proposals to grant authorization. The workload has become very high. Hence, there is a workability issue. Based on this experience, the competent authorities are reluctant to include additional substances on the REACH authorization list. In the last years, only a few new substances have been added to that list.

In short, New TSCA has moved the U.S. to a system more similar to REACH than old TSCA, but New TSCA and REACH are not identical. It also remains to be seen how smoothly EPA is able to implement its recently enacted New TSCA regulations.

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ENDNOTES

- 1 H.R. 2576, 114th Cong.
- 2 The Notification Rule will be codified at 40 C.F.R. Part 710, Subpart B (Commercial Activity Notification).
- 3 The Prioritization Rule will be codified at 40 C.F.R. Part 702, Subpart A (Procedures for Prioritization of Chemical Substances for Risk Evaluation).
- 4 The Risk Evaluation Rule will be codified at 40 C.F.R. Part 702, Subpart B (Procedures for Chemical Substance Risk Evaluations).

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