EPA Issues Final TSCA Framework Rules

The U.S. Environmental Protection Agency (EPA) released on June 22, 2017, the pre-publication *Federal Register* notices of the final framework actions under the Toxic Substances Control Act (TSCA), as revised by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA). The final rules include the prioritization process rule, which establishes EPA's process and criteria for identifying High-Priority chemicals for risk evaluation and Low-Priority chemicals for which risk evaluation is not warranted at this time; the risk evaluation process rule, which establishes EPA's process for evaluating High-Priority chemicals to determine whether or not they present an unreasonable risk to health or the environment; and the TSCA Inventory active-inactive rule, which requires industry to report chemicals manufactured, imported, or processed in the U.S. over the past ten years. EPA also published pre-publication notices concerning the scopes of the risk evaluations to be conducted for the first ten chemical substances under new TSCA and a guidance document to assist interested persons in developing and submitting draft risk evaluations.

This memorandum reflects our summary and analysis of the three framework rules. On the whole, the final rules improve upon the proposed rules, adding clarity and specificity where needed, and eliminating provisions and or preamble text that, in our view, enhance the clarity of the rules. Not everyone will be happy, however, as the rules reconsider, revise, and in some instances retreat from positions taken in the proposed rules issued under the Obama Administration. Our analysis identifies these changes.

Final Prioritization Process Rule

The final prioritization process rule establishes the process and criteria for identifying High-Priority chemicals for risk evaluation and Low-Priority chemicals for which risk evaluation is not warranted at this time. The final rule describes the processes for formally initiating the prioritization process on a selected candidate, providing opportunities for public comment, screening the candidate against certain criteria, and proposing and preparing in final priority designations. EPA notes that prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under new TSCA.

EPA states that the final rule incorporates all of the elements required by statute, some additional criteria EPA expects to consider, clarifications for greater transparency, and additional procedural steps to ensure effective implementation. In response to public comments on the January 17, 2017, proposed rule, EPA is, among other actions: (1) deferring action on the proposed pre-prioritization provisions, and committing to a prompt public stakeholder process to obtain further public comment (perhaps as early as the Fall of 2017) on best practices for pre-prioritization activities before taking the appropriate next step; (2) adding direct references in the final regulation to acknowledge EPA's commitment to implementing the best available science and weight of the scientific evidence provisions in TSCA Sections 26(h) and (i), respectively; (3)

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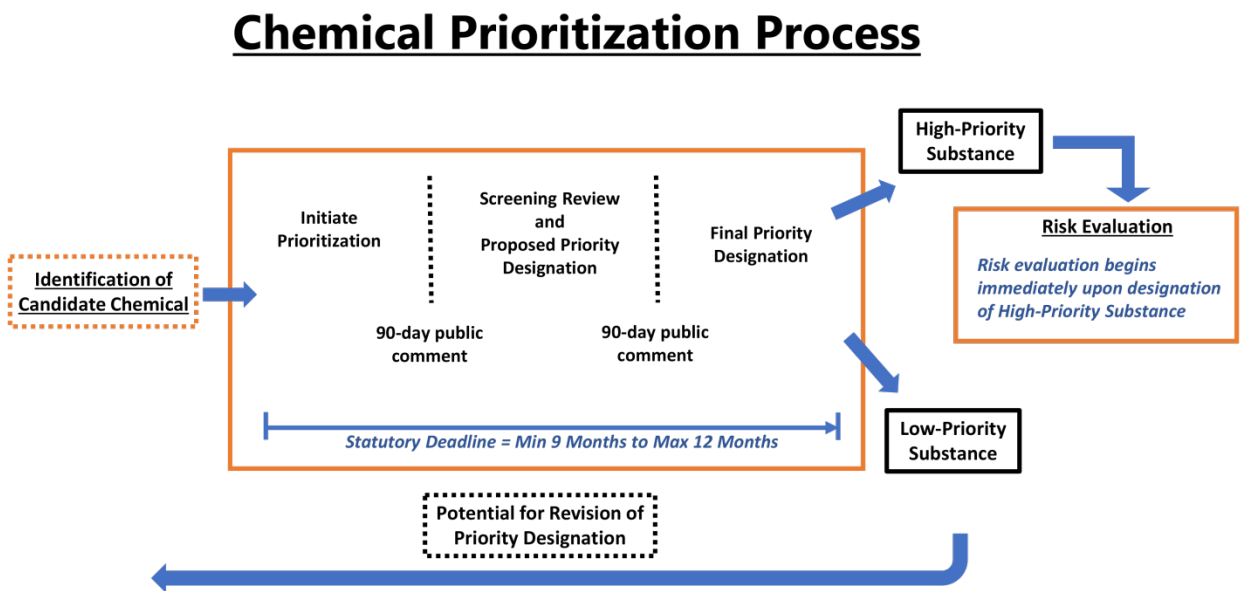
adding provisions to clarify the limited meaning of a priority designation; and (4) committing EPA to clear and effective communication throughout the process.

The notice includes an in-depth discussion of the provisions of the final rule, public comments received on the proposed rule, and revisions EPA made in response to comments. EPA states that it prepared a separate document that summarizes all comments submitted on the proposed rule and its response to those comments, and that it will be available in the docket for this rulemaking. EPA's web page on the prioritization process includes the following graphic that provides an overview of the process:



The final rule will be effective 60 days after publication in the *Federal Register*. EPA states that it intends that the provisions of this rule be severable. In the event that any individual provision or part of the rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

Policy Objective

The prioritization process serves to help EPA identify priorities for further risk evaluation, to ensure that those priorities are grounded in risk-based considerations, and to provide the public and interested stakeholders with notice and an opportunity to engage with EPA and provide relevant information prior to the start of the risk evaluation process on a particular chemical. As a general matter, according to EPA, the primary objective of the process should be to guide EPA towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first. The prioritization process is not intended to be an exact scoring or ranking exercise, and EPA is not adopting such a system. EPA states that it intends to conserve its resources and "deeper analytic efforts" for the actual risk evaluation. As a policy matter, EPA is

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committed to making Low-Priority designations on an ongoing basis beyond the statutory minimum. EPA also states that eventually, all TSCA Work Plan chemicals will be prioritized.

Scope of Designations

Consistent with the proposed rule, EPA will designate the priority of a "chemical substance" as a whole, and will not limit its designation to a specific use or subset of uses of a chemical substance. EPA will consider those activities that the Administrator determines fall within the definition of "conditions of use" during prioritization. When publishing proposed and final priority designations, EPA expects to identify the information, analysis, and basis used to support the designations, as well as the specific condition(s) of use that were the basis for a High- or Low-Priority designation. EPA states that a chemical substance can be designated as a Low-Priority only if the "conditions of use" do not meet the standard for High-Priority designation.

Timeframe

TSCA Section 6(b)(1)(C) requires that the prioritization process be completed in no fewer than nine months and no greater than 12 months. Accordingly, the final rule specifies that the process, from initiation to final designation, shall last between nine and 12 months.

Categories of Chemical Substances

EPA included in the final rule several provisions from the proposal with respect to categories of chemical substances, without revision. EPA included, as proposed, a statement in the regulation that nothing in the subpart shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances. EPA is not adopting a regulatory definition of a "category of chemical substances," as the term is defined in TSCA Section 26 (c)(2)(A). Should EPA determine to prioritize a category of chemical substances, however, EPA would describe the basis for such a determination in the *Federal Register* notice published to initiate prioritization.

Metals and Metal Compounds

New TSCA mandates use of the March 2007 "Framework for Metals Risk Assessment" (Metals Framework) to account for the unique attributes of metals and metal compounds. In the final rule, EPA states that it fully recognizes the special attributes and behaviors of metals and metal compounds, and the mandate to use the Metals Framework. Importantly, EPA revised the final rule to strike certain proposed text such as "as appropriate" and "relevant considerations" to "avoid confusion" about EPA's intention to apply the Metals Framework as directed by Congress. In this context, EPA states that it interprets the Metals Framework provision in TSCA "to require EPA to take into account the special attributes and behaviors of metals and metal compounds as described in the [Metals] Framework document" while noting that TSCA does not contemplate completion of a full risk assessment during the prioritization stage. Interests in the

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metals and metal compounds community will no doubt welcome the clarity of this statement, and the elimination of terms like "as appropriate," which introduced considerable uncertainty and speculation.

Chemicals Subject to Prioritization

EPA states that it is adopting these provisions from the proposed rule without revision. EPA chose not to exclude certain groups of chemicals altogether, such as new chemicals recently reviewed under TSCA Section 5 and inactive chemicals. EPA states that it expects that new chemicals are unlikely to be selected as early High-Priority candidates in light of the risk-related determination that EPA must make pursuant to new TSCA Section 5(a)(3). Although nothing in new TSCA prohibits EPA from initiating the prioritization process on an "inactive" chemical, EPA notes that whether a chemical substance is actively manufactured would generally be relevant to informing EPA's exposure judgments during the prioritization process, and such chemicals may be less likely to be selected as early High-Priority candidates.

Section 26 Scientific Standards

According to EPA, as a matter of practice, it has been, and will continue to be, "committed to basing its decisions on the best available science and the weight of the scientific evidence." In response to public comments on the proposed rule, EPA made a number of additions to the final rule to ensure that the science standards in TSCA are more explicitly incorporated into the prioritization process. According to EPA, these changes clarify that EPA's proposed and final designations for both High- and Low-Priority Substances will be consistent with TSCA's new requirements in Section 26 related to best available science and weight of the scientific evidence.

Definitions

The final rule incorporates the following key definitions, the first four of which are taken directly from the law:

- High-Priority Substance: A chemical substance that EPA determines, 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 EPA;

- Low-Priority Substance: A chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance;

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- Conditions of Use: The circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of;

- Potentially Exposed or Susceptible Subpopulation: A group of individuals within the general population identified by the EPA 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; and

- Reasonably Available Information: Information that EPA possesses or can reasonably generate, obtain, and synthesize for use, considering the deadlines specified in TSCA Section 6(b) for prioritization and risk evaluation. Reasonably available information includes information in EPA's possession that is confidential business information (CBI). In some instances, information that can be obtained through testing is "reasonably available."

Pre-Prioritization Considerations

According to the notice, the details of implementing pre-prioritization activities were the subject of "widely differing, and often irreconcilable views by commenters." EPA states that it does not believe it would be appropriate to adopt a final pre-prioritization process without further discussions with interested stakeholders. As such, EPA deferred a final decision on the proposed pre-prioritization provisions as part of this rule, and the final rule at this time promulgates only the prioritization process required under new TSCA. EPA intends to initiate an additional stakeholder process, perhaps by the Fall of 2017, to include an additional public comment opportunity addressing pre-prioritization activities and to proceed as outlined earlier.

Information Availability

The notice states that, as a general practice, EPA intends to resolve any concerns it may have about the sufficiency of information concerning a given chemical substance for purposes of prioritization before subjecting that chemical substance to the prioritization process. EPA deleted several references to ensuring sufficient information for purposes of risk evaluation at the prioritization stage. EPA states that it did not intend to suggest that it will routinely use its information gathering authorities for a particular chemical without first evaluating the available information to determine whether this is necessary. EPA revised the final rule to indicate that it generally expects to use a tiered approach to information gathering. As a general matter, this first tier involves a review of existing literature and available information by EPA to determine data needs.

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Candidate Selection

New TSCA requires that EPA give preference to chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are persistent and bioaccumulative; known human carcinogens; and/or highly toxic. New TSCA Section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 update to the TSCA Work Plan for Chemical Assessments, meaning that EPA will need to draw at least 50 percent of High-Priority Substance candidates from the same list. In practice, according to the notice, EPA expects to select for High-Priority Substances those chemicals with the greatest hazard and exposure potential first. EPA will seek to identify candidates for Low-Priority designation where the information on hazard and exposure under the conditions of use for the chemical substance is sufficient to establish that a risk evaluation is not warranted to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Initiation of Prioritization

EPA states that the prioritization process officially begins, for purposes of triggering the nine- to 12-month statutory timeframe, when EPA publishes a notice in the *Federal Register* identifying a chemical substance for prioritization. The final rule includes a new provision clarifying that EPA generally expects to provide an explanation in this notice for why it chose to initiate the process for the particular chemical substance (*e.g.*, whether EPA views this as a potential candidate for High- or Low-Priority). Publication of the notice in the *Federal Register* also initiates a 90-day public comment period. Although the proposed rule specified that EPA would publish the results of the screening review in this same notice, EPA's final rule shifts the timing of the screening review, which will now occur after the close of the initial 90-day public comment period.

Screening Review

Following completion of the initial 90-day public comment period, EPA will screen the selected candidate against the specific criteria and considerations in TSCA Section 6(b)(1)(A): (1) the chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume. The final rule adds an additional criterion that appeared in the proposal: (7) other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

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Proposed Designation

EPA will propose to designate a chemical substance as either a High-Priority Substance or Low-Priority Substance. In making the proposed designation, EPA will not consider costs or other non-risk factors. Under the proposed rule, in the event of insufficient information at this step, EPA would propose a default designation of a High-Priority Substance. EPA states that it has largely stricken this provision from the final rule. According to EPA, EPA believes it is charged by new TSCA, and will be able, to determine which of these priority categories each chemical falls into during the prioritization process, and therefore it is not necessary or appropriate to establish a default. This change is almost certain to cause controversy. At the same time, the rule states, consistent with Section 6(b)(1)(C)(iii), that if information is insufficient to designate a chemical as a Low-Priority at the end of the prioritization process, it will be designated as a High-Priority Substance.

Final Priority Designation

The final rule includes additional regulatory text clarifying that EPA would publish an identification of information, analysis, and basis used to support the final designation, as required under new TSCA. Additionally, EPA amended the proposed rule to provide that EPA generally expects to identify which condition(s) of use were the primary bases for the priority designation. According to the notice, EPA made this revision in response to concerns that a priority designation for a chemical substance "could send strong signals to the public regarding potential risks."

Repopulation of High-Priority Substances

Under new TSCA, EPA must issue a final designation for at least one new High-Priority Substance upon completion of a risk evaluation for another chemical substance, except in the case of a risk evaluation requested by a manufacturer. According to the notice, in the *Federal Register* notice announcing the final designation of a new High-Priority Substance, EPA generally expects to identify the complete or near-complete risk evaluation that the new High-Priority Substance will replace.

Effect of Final Priority Designation

Final designation of a chemical substance as a High-Priority Substance requires EPA to begin immediately a risk evaluation on that chemical substance, while final designation of a chemical substance as a Low-Priority Substance is a final agency action that means that a risk evaluation of the chemical substance is not warranted at the time. A Low-Priority Substance designation is explicitly subject to judicial review. According to EPA, because a High-Priority Substance designation is not a final agency action, it is not subject to judicial review. A High-Priority Substance designation prompts the initiation of a risk evaluation. Upon the conclusion of such a risk evaluation, EPA may determine that a chemical substance does not present an unreasonable

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risk of injury to human health or the environment under the conditions of use. Such a determination must be issued in an order, and is a final agency action subject to judicial review. If, conversely, EPA determines that a chemical substance presents an unreasonable risk of injury to human health or the environment under the conditions of use, that determination is not a final agency action and is not subject to judicial review. New TSCA mandates that EPA must issue a rule to manage the risk of the chemical substance or mixture so that it no longer presents the unreasonable risk. Such a final rule is a final agency action and is subject to judicial review.

Revision of Designation

New TSCA allows EPA to revise a final designation of a chemical substance from a Low-Priority Substance to a High-Priority Substance at any time based on information that is reasonably available to EPA. The final rule outlines the process EPA will take to revise such a designation. New TSCA does not require a process for revising a High-Priority Substance to a Low-Priority, and the final rule does not provide a process for such a revision. Once EPA identifies a chemical as a High-Priority Substance, the risk evaluation process begins. EPA states its belief that Congress intended EPA to complete the risk evaluation process and, if warranted, make a finding that a substance does not pose an unreasonable risk, not to revise a priority designation.

Commentary on Prioritization Rule

The final rule is clearly written and attempts to explain EPA's thinking regarding the approaches reflected in the final rule. In many respects, where the proposal sought to go beyond the particulars contained in the law at several points, the final rule hews closely to the statutory language and retreats from positions that went further. As believers in the rule of law, and given the newness of new TSCA, we applaud these changes. The final rule provides a clear and concise statement of the primary objective of the prioritization process, that being to guide EPA towards identifying High-Priority Substances that have "the greatest hazard and exposure potential first." While these words appeared in the proposal, the final deleted an additional concept in the proposed objective concerning consideration of the hazard and exposure of substitutes, stating that this belonged in the risk management stage. The final rule also makes clear that a Low-Priority designation means that a risk evaluation is not warranted at this time, and that it does not mean that EPA has made a conclusion of no unreasonable risk. Similarly, a High-Priority designation is just that; it is not a determination of unreasonable risk. The new language clarifying the limited meaning of priority designation is a welcomed and necessary addition and reflects EPA's commitment to clear and effective communication.

The final rule added some new elements that either did not appear in the proposal or received only light treatment. These include: an explicit statement of EPA's intent to collaborate with other agencies as stated in Section 26(a); an objective concerning Low-Priority designations stating that, as a policy matter, EPA was committed to making such designations on an ongoing basis beyond the statutory minimum; a statement that all TSCA Work Plan chemicals will

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eventually be prioritized; and adding direct references to acknowledge EPA's commitment to meet the sound science provisions at Sections 26(h) and (i). The rule also included discussion of the new testing authority in Section 4(a)(2) as well as the Section 4 provisions regarding tiered testing and the vertebrate animal testing. Our analysis of the proposal had noted the absence of a number of these elements and we welcome all of these additions that, together, considerably strengthen the approach that will be applied.

The rule maintained some elements from the proposal such as prioritizing the chemical as a whole and not for some subset of uses. It also retained the additional extra-statutory prioritization criterion concerning "other risk-based criteria" that EPA determines to be relevant.

Regarding insufficient information, EPA has taken a practical and pragmatic approach by stating that it would generally not start prioritization if it did not have sufficient information needed to prioritize the chemical. This is a useful clarification of the approach that evidences a good faith effort to avoid premature initiation of prioritization while also addressing the role of voluntary calls for information and the use of Section 4 or 8 to assist in providing any needed information.

We also note that some of the information sources codified at 40 C.F.R. Section 702.9 in the regulatory text that are to be used in screening review likely do not conform to the scientific standards under Section 26. We draw attention in this regard to those listed in Appendix B of the Work Plan Methods Document that address use and exposure information. It remains to be seen the extent to which these sources meet the Section 26 requirements and are used in the prioritization process.

"Conditions of use" is one of the critical new concepts in the amended law and we appreciate the approach that EPA is implementing in the final rule. EPA states that it would early in the prioritization process identify the "circumstances" that constitute the conditions of use for each chemical and make a determination of the conditions of use that would be considered in the prioritization process. This determination would be presented for public comment as part of the proposed designation. This is a good addition that provides both clarity and transparency to the role played by conditions of use in prioritization while also providing EPA with needed flexibility. Thus, EPA will propose to designate a chemical as a High-Priority Substance if it meets the statutory requirement for High-Priority "under one or more activities that the Agency determines constitute conditions of use." EPA then intends to evaluate the chemical's conditions of use in the risk evaluation stage as part of determining if the chemical presents an unreasonable risk.

Two additional changes merit mention. EPA notes in the preamble that it "intends that the provisions of this rule be severable. In the event that any individual provision or part of this rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place." This is a useful addition, but not a lock on severability. According to legal scholars, "the current judicial doctrine suggests that a reviewing court should not defer to it [administrative severability clauses]." C.

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Tyler and E. Elliott, Administrative Severability Clauses, *Yale Law Journal* (May 2015). These scholars argue otherwise, and suggest that reviewing courts should defer to administrative severability clauses and that agencies should more routinely include them in their rulemakings.

The second issue relates to EPA's striking of the "issue preclusion" provision in the proposed rule relating to proposed designations as Low-Priority Substances. Under the proposed rule, comments that could be raised on the issues in the proposed designation must be raised during the comment period or would be considered waived. *See* 82 Fed. Reg. 4825, 4833, col. 1 (Jan. 17, 2017) ("issues not raised will be considered to have been waived"). EPA notes in the final rule that general provisions of administrative law provide sufficient assurance that comments will be raised timely, and deleted the proposed regulatory text. This too is a good change as the inclusion of this "issue preclusion" language was unnecessary and conspicuously punitive.

Final Risk Evaluation Process Rule

The final risk evaluation process rule establishes EPA's process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. EPA states that this process incorporates the science requirements of new TSCA, including best available science and weight of the scientific evidence. EPA notes that risk evaluation is the second step, after prioritization, in a new process of existing chemical substance review and management established under new TSCA. The final rule identifies the steps of a risk evaluation process, including scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. EPA will use this process for the first ten chemical substances undergoing evaluation from the 2014 update of the TSCA Work Plan for Chemical Assessments, to the maximum extent practicable. Chemical substances designated as High-Priority Substances during the prioritization process and those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request will always be subject to this process. The final rule includes the required "form and criteria" applicable to such manufacturer requests.

In response to public comments on the January 19, 2017, proposed rule, EPA states that it is: (1) adding direct references in the final rule to acknowledge EPA commitment to implementing the best available science and weight of the scientific evidence provisions in TSCA; (2) codifying its commitment to interagency collaboration; (3) allowing manufacturers to limit their requests for EPA-conducted risk evaluations to one or more specified conditions of use; and (4) allowing for risk determinations to be made on individual conditions of use or categories of conditions of use at any time once the Final Scope is published. EPA's web page on the risk evaluation process includes the following overview of the steps in the process for existing chemicals:

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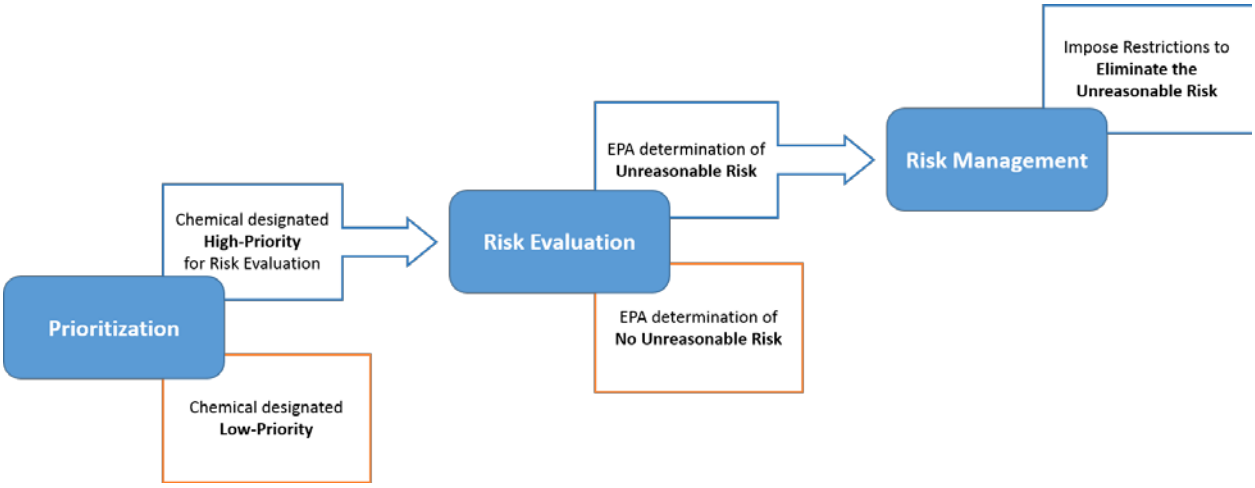

As with the final prioritization process rule, EPA states that it intends that the provisions of the final risk evaluation process rule be severable. In the event that any individual provision or part of the rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place. As noted above, while useful, there is no guarantee a reviewing court will defer to EPA's wishes in this regard.

Policy Objectives

The objective of the final rule is to codify the process by which EPA evaluates risks from chemical substances under TSCA Section 6. EPA discusses those components of TSCA risk evaluation and key factors necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted and to provide predictability in how they will be conducted.

Scope of Evaluations

Given the strength and variety of the concerns presented in comments on the January 19, 2017, proposed rule, EPA reevaluated its proposal. EPA states that it went back to the direction on risk evaluation provided in new TSCA Section 6(b) and the legislative history, and developed an approach to the term "the conditions of use" that is "firmly grounded in the law, while accounting for the various policy considerations necessary for effective implementation of section 6." According to EPA, its objective "is to ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, and that it always includes an evaluation of the conditions of use that raise greatest potential for risk." EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance on a case-by-case basis. For most chemical substances, EPA expects to make this determination primarily during the prioritization of a chemical substance. For chemicals that are the subject of a manufacturer request, EPA intends to make this determination as part of the process for determining whether the request satisfies EPA's criteria.

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EPA may, on a case-by-case basis, exclude certain activities that it has determined to be conditions of use to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination.

General Provisions

The general provisions of the final rule outline the purpose, scope, applicability, and enforcement of the rule.

Definitions

EPA notes that new TSCA defines a number of key terms necessary for its interpretation, and the statutory definitions apply to this rule. To increase clarity and transparency, EPA included additional definitions in the rule. In the proposed rule, EPA asked for comments specifically on whether to codify definitions of terms, including "best available science," "weight-of-the-scientific evidence," "sufficiency of information," "unreasonable risk," and "reasonably available information," among others. EPA states that it chose to define only terms that appear in new TSCA, including best available science, reasonably available information, and weight of the scientific evidence, among others. According to the notice, EPA agrees with many of the comments that defining these terms in the final rule "will instill confidence, increase transparency, and provide the public with assurance that EPA will adhere to the requirements of the statute." Based on its review of the public comments received, EPA has also revised the proposed definitions to increase their clarity. The definitions include:

- Best Available Science: Science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data);

- Conditions of Use: The circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of;

- Potentially Exposed or Susceptible Subpopulations: A group of individuals within the general population identified by the EPA 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;

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- Reasonably Available Information: Information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. There is a preference for reasonably available information that is consistent with the required quality standards, however. Information that meets the terms of the preceding sentence is reasonably available information whether or not it is claimed as CBI; and

- Weight of the Scientific Evidence: A systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

EPA chose not to codify definitions for some terms, such as "systematic review," "sufficiency of information," or "unreasonable risk." EPA reportedly intends to provide further details on systematic review and weight of scientific evidence approaches under TSCA in future guidance documents. EPA states that it agrees with commenters that the information required for chemical risk evaluations can be highly variable, and given the case-by-case nature of the hazard and exposure scenarios, it is difficult to have an overarching definition of "sufficiency of information" applicable to all evaluations. EPA identified considerations that it will use in making a risk determination, but has not defined "unreasonable risk" because "each risk evaluation will be unique."

Timing of Risk Evaluations

A risk evaluation is initiated upon the final designation of a High-Priority Substance at the completion of the prioritization process or through the completed manufacturer request process. A risk evaluation is complete upon the publication of the final risk evaluation, which includes the final risk determination for all the conditions of use identified in the Scope document. New TSCA requires EPA to complete risk evaluations within three years, with the possibility of a single six-month extension.

Chemical Substances for Risk Evaluation

New TSCA defines a "chemical substance" to mean any organic or inorganic substance of a particular molecular identity, including: (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring nature; and (2) and element or uncombined radical. Chemical substances do not include: (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product;

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(4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subsequent to the tax imposed by Section 4181 of the Internal Revenue Code of 1954; and (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. EPA states that it may be appropriate to consider potential risk from these non-TSCA uses in evaluating whether a chemical substance presents an unreasonable risk (as an aspect of background or aggregate exposure, for example), although these uses would not be within the scope of the risk evaluation nor could such risks be managed under TSCA.

Process and Criteria for Manufacturer-Requested Risk Evaluations

Scope of Request

EPA states that it modified its proposal in several ways. First, the final rule allows manufacturers to submit requests for risk evaluation on only the conditions of use of the chemical substances that are of interest to the manufacturer. According to the notice, EPA intends to conduct a full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that EPA identifies. EPA will determine the additional conditions of use during the process of determining whether to grant or deny the manufacturer request.

Information That Must Be Submitted as Part of Request

In the proposed rule, EPA required manufacturers to submit any risk assessment or evaluation that they might possess. EPA states that its intent was to use this as another source of information, and not as the basis for its decision. In response to public comments, EPA removed the requirement that the manufacturer must commit to providing EPA existing risk assessments on the chemical. According to the notice, EPA believes that all relevant risk information would be required to be provided pursuant to TSCA Section 8(e), and/or would be submitted in response to the regulatory provision that requires that the requesters provide any information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

Process for Evaluating Requests

Upon receipt of the request, EPA will verify that the request appears to be valid. Within 15 business days of receiving a facially valid request, EPA will publish on its website or in an e-mail announcement a public notice of the receipt, which will include the manufacturer request. Within 60 days from receipt, EPA will submit for publication an announcement of the receipt of the request in the *Federal Register*, open a docket for the request, make available the information that has been submitted (taking into account any valid CBI claims), and provide no less than a

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45-day comment period. The notice will include the manufacturer request and EPA's proposed determinations as to whether the activities identified are conditions of use that warrant risk evaluation, and whether there are additional conditions of use that need to be included in the risk evaluation.

Within 60 days after the end of the comment period, EPA will review the request along with any additional information received to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. If EPA determines that the request is compliant, EPA will grant the request. Otherwise, EPA will deny the request. Requesters may resubmit any denied request. Within 30 days of the notice that EPA will grant the request, the requester may withdraw the request for any reason. The process for conducting the risk evaluation will follow the regulatory requirements applicable to High-Priority chemical risk evaluations and will not be expedited or otherwise afforded special treatment. EPA will initiate the risk evaluation upon payment of the required fees. EPA states that it will address the fee amount in a separate rulemaking.

EPA will give preference to requests where there is evidence that restrictions imposed by one or more states have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial preference, EPA will give further preference to requests in the order in which a request is received. Unlike the proposed rule, the final rule does not include a preference for chemicals where EPA determined that there were relatively high estimates of hazard and/or exposure for the chemical substance.

Interagency Collaboration

In the proposed rule, EPA did not limit potential interagency collaboration by proposing to codify any particular process. EPA states that it codified collaboration in the final rule, however, "to give the public confidence that EPA will work with other agencies to gain appropriate information on chemical substances." EPA notes that by mandating consultation at any particular stage, it does not intend to imply that collaboration will occur solely at that step of the process, "but including this collaboration upon initiation gives other agencies sufficient time to work with the EPA to identify any information that will be useful for EPA risk evaluation (*e.g.*, existing regulations or mission critical uses) of the chemical substance." According to the notice, EPA also plans to engage with state and local agencies where they may have information to inform risk evaluations and to increase collaboration with tribes, "as they can be impacted by chemical substances differently due to unique traditional activities and lifestyles."

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Risk Evaluation Requirements

Considerations

This subpart identifies and discusses what EPA will consider in conducting a risk evaluation. The first subpart identifies the necessary components of the risk evaluation process -- a scope, which will include a Conceptual Model and Analysis Plan, a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. EPA is not codifying a list of guidance (with the exception of the Metals Framework as mandated by new TSCA), but states that guidance may be used if it constitutes the best available science, and is consistent with the weight of the scientific evidence.

Agency Guidance

The final rule does not codify a list of guidance (with the exception of the Metals Framework as mandated by new TSCA), but states that the scope of each risk evaluation will identify those guidance documents that the Agency expects to utilize to inform the risk evaluation to the degree that they represent the best available science appropriate for the particular risk evaluation. At the same time, EPA recognizes that some guidance may be outdated and may rely on defaults.

Categories of Chemical Substances

EPA states that the final rule includes a clear statement that nothing in the rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can evaluate categories of chemical substances.

Science Requirements

EPA incorporated into the final rule the statutory requirements regarding best available science and weight of the scientific evidence. Definitions of those terms have also been added. According to the notice, while EPA prefers high quality data, where available, "EPA recognizes that data is not always necessary to reach a scientifically grounded conclusion on the potential risks of a chemical substance, within the timeframes dictated by the statute."

Fit-for-Purpose Risk Evaluations

Each risk evaluation will be fit-for-purpose -- "that is to say, the level of refinement will vary as necessary to determine whether the chemical substance presents an unreasonable risk, given the nature of the evidence, for the conditions of use of a specific chemical substance."

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Timing of a Risk Determination

The final rule explicitly recognizes that EPA may make early risk determinations to manage unreasonable risks as they are identified, through the issuance of a regulation under TSCA Section 6(a), or to notify the public as soon as possible of the safety of a chemical substance under a particular condition of use.

Metals or Metal Compounds

As required by new TSCA, when evaluating metals or metal compounds, EPA must use the Metals Framework or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.

Information and Information Sources

For those chemical substances designated as High-Priority for risk evaluation, EPA states that it expects to initiate the process when it has determined that most of the information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists.

Risk Evaluation Steps

Scope

According to the notice, the scope of each risk evaluation will include the following components: the conditions of use, as determined by the EPA Administrator, that EPA plans to consider in the risk evaluation; the potentially exposed or susceptible subpopulations EPA expects to consider; the ecological receptors; and the hazards to human health and the environment EPA plans to evaluate. In response to comments, under the final rule, the scope will focus on the reasonably available information and science approaches, and reserve uncertainty considerations specifically for the remainder of the risk evaluation. EPA will include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance, as well as an analysis plan that will identify the approaches and methods EPA plans to use to assess exposure, hazards, and risk. The scope will also include the plan for peer review that EPA expects to consider.

EPA will publish a notice in the *Federal Register* announcing the availability of the final scope within six months of the initiation of the risk evaluation. Although not required under new TSCA, EPA states that it will publish a draft scope and provide for no less than a 45-calendar day public comment period during this six-month period.

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Hazard Assessment

In compliance with new TSCA Section 6(b)(4)(F), EPA will conduct a hazard assessment on each chemical substance or category, under the conditions of use as identified in the scope. EPA states that a hazard assessment identifies the types of adverse health or environmental effects or hazards that can be caused by exposure to the chemical substance in question, and to characterize the quality and weight of the scientific evidence supporting this identification. EPA will present the hazard information, as identified in the scope, for the identified exposure scenarios, and including any identified potentially exposed or susceptible subpopulation. For human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope. EPA states that it will use an appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other information or methodology consistent with scientific standards. An environmental hazard assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response. This assessment may be conducted using reasonably available information from field or laboratory data, modeling strategies, and species extrapolations, if needed.

Exposure Assessment

An exposure assessment will include information on chemical-specific factors, including but not limited to physical-chemical properties and environmental fate and transport parameters. EPA notes that it included these considerations in the proposed rule, however, it added "transport" to the final text. EPA states that an exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. According to EPA, exposure can be measured directly, but when data are unavailable, it is estimated indirectly through consideration of measured concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of human intake or environmental exposure over time.

Risk Characterization

New TSCA Section 6(b)(4)(F) requires that a risk evaluation "integrate and assess available information on hazards and exposures." EPA states that a risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. EPA amended the final rule to include all of the statutory requirements of the risk evaluation process, including: not considering costs or other non-risk factors; taking into account the likely duration, intensity, frequency, and number of exposures under the condition(s) of use; and a description of the weight of scientific evidence for the

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identified hazards and exposures. The EPA's Information Quality Guidelines will be used to provide guidance for presenting risk information in the risk characterization section of the risk evaluation.

Peer Review

For each risk evaluation conducted on chemicals identified pursuant to new TSCA Section 6(b)(4)(A), EPA will conduct a peer review using the guidance provided in executive branch peer review directives, including in the Office of Management and Budget Final Information Quality Bulletin for Peer Review and in the EPA Peer Review Handbook or its updates. EPA will take public comment on the charge questions given to peer reviewers. According to the notice, the peer review will address aspects of the science underlying the assessment, including but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. EPA will include this information as part of the draft scoping document on which public comment will be solicited for each chemical substance that undergoes risk evaluation.

Unreasonable Risk Determination

EPA states that the final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. According to the notice, EPA will make individual risk determinations for all uses identified in the scope. EPA notes that it amended this part of the regulation from the proposed rule to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach that ensures each condition of use covered by the risk evaluation receives a risk determination. In responding to comments, EPA agreed to clarify in the draft and final risk evaluation documents specifically which condition(s) of use warrant risk management and which do not.

Reassessment of Unreasonable Risk Determination

EPA stated in the proposed rule that it may reassess determinations of unreasonable risk. Following review of the comments, EPA deleted the provision, however. Generally, EPA notes, agencies are authorized to revisit determinations they are charged by statute to make, and nothing in new TSCA prevents EPA from doing so.

Additional Publicly Available Information

Pursuant to TSCA Section 26(j), and subject to TSCA Section 14, the final rule specifies that EPA will make available: (1) the draft scope, final scope, draft risk evaluation, and final risk evaluation; (2) all notices, determinations, findings, consent agreements, and orders; (3) any information required to be provided to EPA under Section 4; (4) a nontechnical summary of the risk evaluation; (5) a list of the studies, with the results of the studies, considered in carrying out

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each risk evaluation; (6) each determination as to whether the chemical substance presents an unreasonable risk under one or more conditions of use, along with an identification of the information, analysis, and basis used to make the designation; (7) the final peer review report, including the response to peer review and public comments received during peer review; and (8) response to public comments received on the draft scope and the draft risk evaluation. EPA states that the final rule includes a few "slight changes" from the proposed rule, largely to conform to changes made to other sections of the rule.

Commentary on Risk Evaluation Rule

The final risk evaluation rule is a well written document that uses clear language and terminology to describe the role of statutory requirements in conducting a TSCA risk evaluation. The stated policy objective of this action is to codify the process by which the Agency evaluates risks from chemical substances under TSCA Section 6. To advance this objective, EPA incorporated the scientific standards under Section 26 and provided definitions for key terms that appear in the rule for specific components of the risk evaluation process. Codified definitions include: aggregate exposure; best available science; conditions of use; pathways; potentially exposed or susceptible subpopulations; reasonably available information; routes; sentinel exposure; uncertainty and variability; and weight of the scientific evidence. Definitions incorporated but not codified include: systematic review; sufficiency of information; and unreasonable risk. The definitions for aggregate exposure, pathways, routes, and uncertainty and variability reflect current Agency policies and practices. The definition for sentinel exposure follows approaches widely used by government institutions in Canada and the European Union. The definitions for systematic review, sufficiency of information, and unreasonable risk were crafted to reflect the evolving nature of the activity and the flexibility necessary to adapt to changes in practices.

Among the codified definitions, there are some that signal a policy shift relative to early public statements by EPA. EPA states that it interprets the mandates under Sections 6(a) and (b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur prospectively or ongoing. This approach would exclude evaluation of the risks associated with legacy uses, associated disposal, and legacy disposal (each of these concepts is discussed in the rule preamble). EPA relies upon established principles of statutory construction that generally presume laws are not to be interpreted retroactively or to have retroactive effect. Legal scholars may disagree, however, if there is a meaningful and important distinction between applying a law retroactively and allowing EPA to consider past manufacturing, processing, distribution, use, and disposal practices of a chemical substance in conducting a risk evaluation of a chemical substance. This is the context for EPA's interpretation of the statutory definition of conditions of use, which require activities under conditions of use to be ongoing or prospective only. EPA declined to formulate at this time a specific test for identification of reasonably foreseen conditions but indicated that the described case-by-case approach will be highly fact-specific and not based upon hypotheticals or

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conjecture. EPA also makes clear that it is not required to consider all conditions of use in a risk evaluation and may focus its efforts on those exposures that are likely to pose the greatest concern. EPA generally expects to exercise its discretion under Section 6(b)(4)(D) to exclude uses from the scope of risk evaluations.

Weight of the scientific evidence is another key definition in this process. This carefully crafted definition applies to both human health and ecological risk evaluations and follows basic principles of scientific review that combine into a general definition that retains flexibility and allows for the incorporation of scientific advances. A key phrase in the definition "… applied in a manner suited to the nature of the evidence or decision ..." recognizes that not all conditions of use require the same level of evaluation and it signals that different weight of scientific evidence review methods may be appropriate for different information, types of evaluation, or decisions. This is consistent with the concept of "fit-for-purpose," which means that while EPA will consistently apply the principles contained in the definition, the depth or extent of the analysis will be commensurate with the nature and significance of the decision. These are welcome actions that contribute to increase transparency and confidence in the process.

This rule defines a process with standards and features unique to TSCA. As such, it represents a significant step toward the development of a scientifically strong and reliable TSCA framework for the risk evaluation of chemicals.

Final TSCA Inventory Notification (Active-Inactive) Rule

The final TSCA Inventory notification (active-inactive) rule establishes a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes during the ten-year time period ending on June 21, 2016, with provision to also allow notification by processors. EPA will use these notifications to distinguish active substances from inactive substances. EPA states that it will include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. The final rule also establishes procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for nonexempt commercial purposes is expected to resume. On receiving forward-looking notification, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. The final rule establishes the procedures regarding the manner in which such retrospective and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.

The final rule will be effective upon publication in the *Federal Register*. As with the final prioritization process rule and risk evaluation process rule, EPA states that it intends that the provisions of the final TSCA Inventory rule be severable. In the event that any individual

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provision or part of the rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place. As noted, it is unclear if reviewing courts will defer to EPA in this regard.

Reportable Chemical Substances and Activities under the Final Rule

The retrospective reporting requirements apply to chemical substances listed on the TSCA Inventory that were manufactured for nonexempt commercial purposes during the ten-year period ending on June 21, 2016. EPA notes that this "lookback period" is set by new TSCA. The forward-looking reporting requirements apply to substances listed as inactive on the Inventory that are to be reintroduced into U.S. commerce for nonexempt purposes. The Inventory is available at https://www.epa.gov/tsca-inventory.

Exemptions from Reporting

The scope of chemical substances covered under the final rule is reflected in the definitions of "chemical substance subject to commercial activity designation" and "reportable chemical substance" at 40 C.F.R. Section 710.23, which exclude substances that are not chemical substances and substances that are not listed on the Inventory. For example, according to EPA, a substance that is not considered a "chemical substance" (as provided in new TSCA Section 3(2)(B) and in the definition of "chemical substance" in 40 C.F.R. Section 710.3(d)) is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance" and it thus cannot become an "active substance" or an "inactive substance." A similar analysis applies with respect to a mixture (as defined in 40 C.F.R. Section 710.3(d)), although EPA notes that individual Inventory-listed substances present in the mixture may be subject to reporting. Additionally, a substance that has not been added to the Inventory because it is manufactured solely under a TSCA Section 5(h) exemption (*e.g.*, low release and low exposure exemption, low volume exemption (LVE), polymer exemption, research and development exemption, test marketing exemption) is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance" and it cannot become an "active substance" or an "inactive substance."

Naturally occurring chemical substances also are excluded from reporting provided the manufacturing and processing of such substances meet the criteria set forth in 40 C.F.R. Section 710.27(b). EPA states that it is designating the category of "Naturally Occurring Chemical Substances" as active substances, thereby excluding them from reporting.

Manufacturing or processing a chemical substance listed on the Inventory solely for an exempt commercial purpose is not subject to reporting requirements. EPA states that while it expects that many chemical substances manufactured or processed for exempt commercial purposes will not be listed on the Inventory (due to similar exemptions under premanufacture notification (PMN) regulations), and therefore are already excluded from reporting, the activity exemptions listed at 40 C.F.R. Section 710.27(a) clarify circumstances under which a person is exempt from

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reporting requirements for the manufacturing or processing of a chemical substance that has been listed on the Inventory (*e.g.*, due to another manufacturer's actions). For example, according to EPA, the manufacturing or processing of impurities or byproducts that have no subsequent commercial purpose will not trigger reporting obligations. Additionally, manufacturing or processing in small quantities solely for research and development is exempt as described in 40 C.F.R. Sections 710.3(d) and 710.27(a)(1). Furthermore, according to EPA, the import or processing of substances solely as parts of articles is not subject to reporting under the rule. *See* 40 C.F.R. Section 710.27(a)(2). EPA revised the rule to clarify that manufacturing or processing a chemical substance solely for export from the U.S. or for test marketing purposes are also exempt commercial purposes not subject to reporting requirements. *See* 40 C.F.R. Section 710.27(a)(4) and (5).

The final rule establishes an exemption from the retrospective reporting requirement for three different circumstances in which EPA has already received equivalent notice that a chemical substance was manufactured during the lookback period, and further requirement to submit a notice would therefore be inconsistent with new TSCA Section 8(a)(5)(B):

(1) Chemical substances that are on the interim list of active substances described in new TSCA Section 8(b)(6) will be designated as active substances, by operation of the final rule, and they are exempted from retrospective notification requirements. The interim list will be available on the TSCA Inventory web page (*see* https://www.epa.gov/tsca-inventory), and is comprised of all chemical substances reported in 2012 or 2016 under the Chemical Data Reporting (CDR) rule;

(2) Chemical substances added to the Inventory during the ten-year time period ending on June 21, 2016, pursuant to a Notice of Commencement (NOC) under 40 C.F.R. Section 720.102 received by EPA between June 21, 2006, and June 21, 2016, will be designated as active substances, by operation of the final rule, and they are exempted from retrospective notification requirements under the rule. An NOC is required to be submitted on or no later than 30 calendar days after the first day of manufacture for commercial purpose. Additionally, an NOC substance is considered to be added to the Inventory on the date the NOC is received by EPA, provided that EPA determines the NOC to be valid during its review; and

(3) A manufacturer is exempt from the retrospective notification requirements under the rule, for a particular chemical substance, if the manufacturer has evidence in the form of a Central Data Exchange (CDX) receipt, documenting EPA's receipt of a [Notice of Activity (NOA)] Form A from another manufacturer. *See* 40 C.F.R. Section 710.25(a). EPA notes that manufacturers "bear the risk of failing to submit a required forward-

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> looking notification (NOA Form B) notice if they rely on this Form A exemption, and the Form A notice (for which they have a CDX receipt) is later withdrawn, leading to the substance being designated as inactive.

EPA states that persons who manufactured or processed a chemical substance on the confidential portion of the Inventory, that was added to the Inventory prior to June 22, 2016, should recognize that they must submit an NOA Form A if they wish to indicate that they "seek to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential." This includes persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for which EPA already has an equivalent notice. It may also potentially include persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for an exempt commercial purpose, if such substance is designated active due, for instance, to EPA's receipt of an equivalent notice (such as an NOC or CDR report). In connection with extending manufacturers' reporting exemptions to cover substances on the confidential portion of the Inventory, EPA states that it revised 40 C.F.R. Section 710.25(b) to clarify manufacturers' and processors' discretion to report. If manufacturers elect not to submit a notice because they are availing themselves of one of the exemptions described above, "then they are foregoing their opportunity to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential." EPA notes that it is required, by statute, to move from the confidential to the public portion of the Inventory any active chemical substance for which no request is received to maintain an existing CBI claim for chemical identity.

Chemical substances added to the Inventory on or after June 22, 2016, will be designated as active, and such substances are not subject to reporting under the rule. Furthermore, according to EPA, such substances are beyond the scope of the CBI claim maintenance provision under new TSCA Section 8(b)(4)(B)(ii). This CBI maintenance provision is intended to address "existing claim[s] for protection against disclosure of the specific chemical identity." EPA states that it interprets this "to be a reference to CBI claims asserted prior to June 22, 2016."

Timing of Reporting

Retrospective Reporting Period for Manufacturers

Manufacturers must report to EPA not later than 180 days after the final rule is published in the *Federal Register*. According to EPA, the 180-day time period for this retrospective reporting for manufacturers is the maximum time allowed under new TSCA Section 8(b)(4)(A). Following this retrospective reporting for manufacturers, EPA will include the active designations, determined by the notices received, on a draft of the Inventory. EPA will publish the draft Inventory with the active designations "as soon as is practicable" following the close of the 180-day submission period. The draft Inventory will not have the legal effect of actually designating any chemical substance as inactive, however, and EPA does not construe it as the list with "designations of active substances and inactive substances" from which forward-looking

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reporting commences. EPA states that it concludes that new TSCA is referring to the completed product of the initial cycle of sorting between active and inactive substances, not the preliminary product of the initial cycle of such sorting.

Retrospective Reporting Period for Processors

Processors may report to EPA not later than 420 days after the final rule is published in the *Federal Register*. EPA had proposed that processors report not later than 360 days after the final rule is published in the *Federal Register*. Commenters suggested that the additional 180-day submission period for processors should begin on the date on which the draft Inventory is published, which EPA anticipates will likely occur approximately 60 days after the 180-day submission period for manufacturers closes, and that the rule should specify a fixed date on which the processor submission period will end.

According to EPA, processors have the option "to simply not report under TSCA section 8(b)(4) and continue processing until the effective date of EPA's designation of a chemical substance as inactive on the Inventory." At such time, any further processing of the substance for a nonexempt commercial purpose, without prior notification to EPA, will be prohibited by new TSCA Section 8(b)(5). EPA notes that earlier notification under new TSCA Section 8(b)(4) will allow EPA to add the substance to the Inventory as an active substance, so that processing can continue without the need for a later notification.

Forward-Looking Reporting

According to the final rule, the forward-looking reporting period begins on the effective date of EPA's final active/inactive substance designations. Manufacturers and processors intending to reintroduce into U.S. commerce for a nonexempt commercial purpose a chemical substance designated as inactive on the Inventory must report to EPA not more than 90 days before the anticipated date of manufacturing or processing.

Transitional Period Reporting and Effective Date for Inactive Substance Designations

EPA states that the structure of the reporting requirements under new TSCA Sections 8(b)(4)(A) and 8(b)(5)(B) results in a transitional period beginning on June 22, 2016 (the day after the lookback period for retrospective reporting ends), and ending on the date that EPA designates chemical substances on the Inventory as active or inactive (the day that forward-looking reporting begins). It is possible that substances that were not manufactured or processed during the lookback period -- and therefore cannot be designated as active through retrospective reporting -- may be reintroduced into U.S. commerce during this transitional period. In response to comments, EPA is establishing an effective date provision for the designation of a chemical substance as an inactive substance. As "inactive substance" is now defined, a substance is not considered to be "inactive" until 90 days after EPA has designated the substance as inactive.

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EPA states that it will identify chemical substances for inactive designation in a signed action accompanying the first version of the Inventory with all final active-inactive listings.

Accordingly, the final rule clarifies that the obligation to submit an NOA Form B does not arise until 90 days after EPA has identified chemical substances for the inactive designation. The rule also clarifies that manufacturers and processors will be permitted to submit an NOA Form B for a substance that EPA has identified for inactive designation, before the effective date of such designation, and thus before the substance has the legal status of being inactive.

Information That Will Be Reported

Information Reported by Manufacturers during Retrospective Reporting

Manufacturers reporting for the retrospective reporting period must provide chemical identity information and indicate whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. EPA removed the proposed requirements to report commercial activity type and date range, as EPA determined these requirements are unnecessary to achieve the objective of designating substances as active or inactive on the Inventory. The final rule clarifies that persons required to report will provide information to the extent it is known to or reasonably ascertainable by them. EPA states that it is not establishing a formal corrections provision in the regulation, but will allow a manufacturer or processor to withdraw an NOA Form A, provided that the withdrawn notice is submitted prior to the end of the submission period for processors, *i.e.*, not later than 420 days after the final rule is published in the *Federal Register*. The manufacturer may effect a correction by filing a new NOA Form A following withdrawal, so long as the new Form A is filed within the time provided in the rule for the initial filing (*i.e.*, no later than 180 days after the final rule is published in the *Federal Register*).

Information Reported by Processors during Retrospective Reporting

EPA states that processors that choose to report for the retrospective reporting period will be required to provide chemical identity information and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. EPA removed the proposed requirements to report commercial activity type and date range as these requirements were deemed unnecessary to achieve the objective of designating substances as active or inactive on the Inventory. EPA states that it is not establishing a formal corrections provision in the regulation for an NOA Form A, but will allow a processer to withdraw an NOA Form A, provided that the withdrawn notice is submitted not later than 420 days after the final rule is published in the *Federal Register*. As with manufacturers, EPA notes that processors can effectuate a correction by filing a new Form A within the time provided in the rule for the initial filing (*i.e.*, no later than 420 days after the final rule is published in the *Federal Register*).

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Information Reported during Forward-Looking Reporting

The final rule will require that persons that intend to manufacture or process an inactive substance for nonexempt commercial purpose provide chemical identity information, the anticipated date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. EPA states that it removed the proposed requirement to report commercial activity type as this requirement was deemed unnecessary to achieve the objective of re-designating inactive substances as active, and revised the date of manufacturing or processing for nonexempt commercial purpose from actual to anticipated date. Persons that have already commenced manufacturing or processing for nonexempt commercial purpose (*e.g.*, during the transitional period prior to the effective date of a substance's inactive designation) may provide the most recent date of manufacturing or processing in lieu of an anticipated future date, if the forward-looking notice is submitted prior to the effective date of the substance's inactive designation.

The proposed rule related the timing of the reporting to a future "actual date of manufacturing and processing." In response to comments about the need for greater flexibility regarding the timing of a forward-looking notice, under the final rule, the validity of the notice does not depend on whether the intended manufacturing or processing actually occurs by the anticipated date. Therefore, manufacturers or processors need not supplement a forward-looking notice with confirmation of whether the intended manufacturing or processing of the chemical substance actually occurred by the anticipated date. By the same token, EPA states, it will designate such substances as active, irrespective of subsequent changes in the intentions of the submitter of the forward-looking notice. With respect to substances re-designated as active for which the intended manufacturing or processing has not been actualized after an extended period of time and not corrected, EPA may later adjust the status of such substances, through procedures that would be established by future rulemaking, to further implement new TSCA Section 8(b)(5)(A).

In response to requests that submitters be able to withdraw an NOA Form B if their intent to re-commence manufacture or process of a chemical substance later changes, EPA will allow a submitter to request to withdraw its NOA Form B, and EPA may do so, if EPA has not yet altered the Inventory status of the substance in response to the original submission (*i.e.*, EPA has neither re-designated the substance from inactive to active nor moved the substance from the confidential portion of the Inventory to the public portion of the Inventory as a result of a request in the original submission for a CBI claim to be withdrawn). EPA notes that because another person may have commenced manufacturing or processing for non-exempt commercial purpose in reliance on a substance being re-designated as active, the rule does not allow for EPA to revert a substance re-designated as active back to inactive status based on a request to withdraw an NOA Form B, or for EPA to revert a non-CBI substance back to a CBI substance based on a request to withdraw a Form B.

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Reporting Forms

The NOA Form A will be used by manufacturers for the retrospective reporting period. It will also be used by processors who choose to report for the retrospective reporting period. The NOA Form B will be used by manufacturers and processors for forward-looking reporting, which includes reporting chemical substances reintroduced into U.S. commerce during the transitional period.

Submission of Information to EPA

The final rule requires electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA and in accordance with Section 3.2000 of 40 C.F.R. Part 3. Submitters will use EPA's CDX and EPA's Chemical Information Submission System (CISS), a web-based reporting tool, for all reporting under the rule. EPA states that it expects that electronic reporting will minimize time requirements, support improved data quality, and provide efficiencies for both submitters and EPA.

Handling of CBI Claims and Requests

Notices pursuant to the rule may contain two different types of CBI assertions: claims for protection of information other than specific chemical identity, and requests to maintain existing claims for protection of specific chemical identity. EPA states that it extensively re-wrote the substantiation questions from the proposed rule in a manner intended to secure more succinctly responses for CBI assertions of discrete data elements, as well as CBI concerns on the linkage of data elements.

Information Other Than Specific Chemical Identity

For all new claims for protection (*i.e.*, for all CBI assertions other than requests to maintain existing claims for protection of specific chemical identity), new TSCA Section 14(c)(1)(B) and 14(c)(5) require that persons claiming CBI must provide a specific certification statement regarding the basis for the CBI claims. In addition, new TSCA Section 14(c)(3) and this rule require that all such claims be substantiated at the time of submission. EPA will review a representative subset of these claims as specified by new TSCA Section 14(g)(1).

Requests to Maintain Existing CBI Claims for Chemical Identity

Any manufacturer or processor submitting an NOA under new TSCA Section 8(b)(4)(A) may seek to maintain an existing CBI claim for specific chemical identity, regardless of whether that person asserted the original claim that caused the specific chemical identity to be listed on the confidential portion of the Inventory. EPA states that it believes this is the correct interpretation of "a manufacturer or processor . . . that seeks to maintain an existing claim for protection

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against disclosure" of specific chemical identity in new TSCA Section 8(b)(4)(B)(ii). According to EPA, "[a] number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, even when such persons did not originally report that chemical identity to EPA and therefore were not in a position to assert a CBI claim for that chemical identity." EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants did not file under new TSCA Section 8(b)(4)(B)(ii).

Pursuant to new TSCA Section 8(b)(4)(B)(iv), EPA will move an active substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an NOA under new TSCA Section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific chemical identity of that chemical substance. EPA states that, as a courtesy, its practice is to notify original claimants and/or the public when it has moved substances from the confidential portion of the Inventory to the public portion of the Inventory, *e.g.*, through direct contact with the original claimant or publication of a *Federal Register* notice. A chemical substance for which EPA has received a request to maintain an existing CBI claim for specific chemical identity will remain on the confidential portion of the Inventory pending EPA's review of the claim pursuant to a review plan to be promulgated at a later date in accordance with new TSCA Section 8(b)(4)(C)-(D).

While the final rule requires submitters to indicate whether they seek to maintain an existing CBI claim for specific chemical identity, the rule does not include mandatory substantiation requirements for CBI requests for specific chemical identity on an NOA Form A. New TSCA Section 8(b)(4)(B)(iii) stipulates that EPA shall "require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph C." EPA states that it will conduct a separate rulemaking to establish this review plan. The review plan will include mandatory requirements for substantiating a CBI request for specific chemical identity reported in an NOA Form A and specify when such substantiation is to be provided. If EPA receives an NOA Form A in which the submitter requests to maintain an existing CBI claim for specific chemical identity but chooses not to substantiate such at the time of filing, EPA will continue to list the chemical substance on the confidential portion of the Inventory pending the submission of any substantiation required under the review plan and EPA's review of the claim pursuant to the review plan.

EPA notes that in this rule, it is allowing companies to submit substantiation for the CBI claims for specific chemical identity at the same time that the NOA Form A is filed, however, if they so choose. Provided the period between the date these earlier substantiations are received and the due date to be established in the review plan (yet to be proposed) is not more than five years, these substantiations will exempt the company from the requirement to submit additional substantiation under the terms of the review plan. EPA will review requests to maintain CBI claims for specific chemical identity in accordance with the new TSCA Section 8(b)(4)(D) review plan in the timeframe mandated by TSCA Section 8(b)(4)(E).

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With respect to requests to maintain existing CBI claims that are submitted on an NOA Form B, new TSCA Section 8(b)(5)(B) stipulates that such requests must be substantiated not later than 30 days after submitting Form B. Substantiation requirements for NOA Form B CBI claims for specific chemical identity are found in 40 C.F.R. Section 710.37(a)(2). EPA states that it will allow companies to submit substantiation at the same time that their NOA Form B is filed, if they so choose. According to EPA, persons submitting an NOA Form B may find it more efficient to provide the substantiation for a CBI claim for specific chemical identity at the time of filing.

Commentary on Inventory Notification Rule

As with the proposed rule, EPA has promulgated a thoughtful final rule. EPA has carefully reviewed its statutory obligations, the many comments on the proposed rule, and balanced the various interests with EPA's resources in promulgating this final rule.

EPA made a number of significant changes. Each is described below.

Date and Type of Activity: EPA has withdrawn its proposal to include the activity type and dates of activity recognizing that the required recordkeeping provides EPA the necessary documentation of the reported commercial activity. The proposal to require dates of activity was especially problematic because records older than five years may not be routinely available and the nature of some manufacturing, processing, and importing practices are highly variable making it difficult for reporters to specify a date range. EPA was persuaded that requiring a certification of the NOA and the recordkeeping requirements was sufficient for EPA to meet its obligations without unduly burdening reporters.

Substances Requiring Reporting: Importantly, EPA clarified which substances must be reported. EPA recognized that any substance for which a NOC was filed in the lookback period satisfies the requirement to demonstrate commercial activity and EPA will add such substances to the list of interim active substances that already included substances reported under the 2012 or 2016 CDR cycles. EPA disagreed with commenters who argued that polymers listed on the Inventory should be designated as active substances. EPA stated that new TSCA required reporting on all substances manufactured during the lookback period; there is no exemption for low hazard substances or substances that might be eligible for an exemption.

EPA further clarified that substances that are not listed on the Inventory but are manufactured under an exemption are exempt from NOA reporting. In the case that a company currently manufactures a substance under an exemption (*e.g.*, a LVE), if the substance is listed on the public portion of the Inventory, the company is required to submit an NOA. On the other hand, if a company manufactures a substance under an LVE that may be listed on the confidential portion of the Inventory, the company need not determine the Inventory status through a *bona fide* intent notice and the company is exempt from NOA reporting. In summary, if a substance is

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manufactured under an exemption (*e.g.*, LVE or polymer exemption) and the substance is not known to the manufacturer to be listed on the Inventory, an NOA is not required.

Rolling Active List: EPA rejected suggestions to publish a rolling list of active substances to permit "one-and-done" reporting. The goal of one-and-done reporting was to reduce duplicative reporting by multiple manufacturers. EPA contends that publication of a rolling list will be overly burdensome to EPA. As an alternative, manufacturers may meet their obligation by obtaining a copy of the CDX receipt reflecting the NOA submitted by another manufacturer. EPA warns that potential reporters that rely on such certifications must ensure that the substance is in fact on the active list when the list is published after retrospective reporting.

EPA also disagreed with comments that every manufacturer of every substance must submit an NOA. In EPA's view, the statute does not require EPA to require reporting of each manufacturer; rather, new TSCA requires that EPA require reporting on each substance manufactured during the look-back period. While we were hopeful that EPA could develop a method to publish updated interim active lists at regular intervals during the reporting period, we recognize that EPA could find such activity burdensome. EPA's alternative permits a consortium approach in which one reporter is responsible for submitting the NOA.

Commencing Commercial Activity: Transition Period: A critical problem that EPA addresses in the final rule relates to the transition period between June 22, 2016, and when the list of active substances is published. The proposed rule required an NOA for activity in the lookback period (prior to June 22, 2016) and NOA submission for inactive substances after the publication of the list of active substances. There was no provision for an NOA for commercial activity that occurred between June 22, 2016, and the publication of the list of active substances. That is, a manufacturer that commenced importing an existing chemical substance in January 2017 had no mechanism to report such activity to EPA and, if no other company reported the substance as active, could find itself importing an inactive substance when the final list is published. To prevent this situation, EPA has implemented a 90-day period after the final list is published in which manufacturers can submit a prospective (Form B) NOA for a substance that appears as inactive on that list.

Time Limitations for Form B Reporting: EPA reconsidered its proposal to require Form B reporting no more than 30 days prior to the commencement of activity for an inactive substance. EPA received comments to both shorten and lengthen the time period. EPA decided on requiring Form B not more than 90 days prior to the anticipated date of commercial activity, balancing the legitimate goal to limit Form B submissions for substances that do not reenter commerce and the need to limit the chances of a manufacturer to manufacture inadvertently an inactive substance.

Known or Reasonably Ascertainable: EPA responded to concerns about the meaning of "Known or Reasonably Ascertainable," especially as the term relates to company mergers, acquisitions, and divestitures. EPA provided additional guidance and refers to the guidance published to

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support the 2016 CDR reporting cycle. In particular, EPA rejected the argument that information that is not "readily obtainable" meets the definition of not known or reasonably ascertainable.

NOA Correction or Withdrawal: EPA responded to comments suggesting that EPA provide a mechanism to correct or withdraw an NOA (Form A or Form B). EPA will allow such corrections or withdrawal prior to EPA taking final action on the NOA. For Form A reporting, the deadline for corrections and withdrawals will be the end of the processor reporting period (420 days after publication of the final rule). For Form B reporting, the deadline for such corrections will be when EPA alters the Inventory status of the substance. Corrections or withdrawals after the respective deadlines would constitute prohibited acts.

Joint Submissions: For manufacturers that do not know the specific identity of a substance because the identity is confidential to another company, EPA will permit NOA reporting based on accession numbers or through the joint submission mechanism used for CDR and Section 5 reporting (*e.g.*, PMN).

Harmonization with Other TSCA Exemptions and Obligations: EPA harmonized provisions such that the Inventory Reset exemptions and obligations are aligned with exemptions and obligations for other provisions, including Inventory listing, PMN notification, and CDR reporting. For example, EPA reinforced the interpretation that components of articles are exempt from listing on the Inventory and from NOA reporting (regardless of whether the substance is listed on the Inventory), but that substances that are intentionally released from an article (*e.g.*, ink or toner) are substances, not articles.

EPA has carefully considered and balanced stakeholder input, statutory obligations, and EPA resources and is to be commended for its effort. We note that publication of this rule is just the first step in resetting the Inventory. Now the hard work begins, and submitters need to prepare their submission, and EPA will prepare to process these submissions.

Scopes of the Risk Evaluations to Be Conducted for the First Ten Chemical Substances and Final Guidance to Assist in Developing Draft Risk Assessments under TSCA

EPA released a pre-publication version of a *Federal Register* notice announcing the availability of the scope documents for the risk evaluations to be conducted for the first ten chemical substances and guidance on preparing draft risk assessments under TSCA. Both are discussed below.

Each scope document includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations EPA expects to consider in conducting the risk evaluation. EPA also announced that it is re-opening existing dockets for the first ten chemicals to allow for the public to provide additional data or information that could be useful to EPA in

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conducting problem formulation, the next step in the process of conducting the risk evaluations for these chemicals. The ten chemicals are:

- Asbestos;
- 1-Bromopropane;
- Carbon Tetrachloride;
- 1, 4 Dioxane;
- Cyclic Aliphatic Bromide Cluster (HBCD);
- Methylene Chloride;
- N-Methylpyrolidone;
- Perchloroethylene;
- Pigment Violet 29; and
- Trichloroethylene.

EPA released a pre-publication version of a *Federal Register* notice announcing the availability of a guidance document, *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act*. EPA states that the guidance document is intended to assist interested persons and external parties in developing and submitting draft risk evaluations to be considered by EPA under TSCA. The notice states that EPA's goal is to ensure that external parties have flexibility to use the best available science by adapting and keeping current with changing science. The guidance may be refined, updated, or superseded in the future to capture the latest changes to the risk evaluation process resulting from EPA experience, advances in science, and future guidance that may be developed or updated. According to the notice, EPA expects external party draft risk evaluations to be of the same high quality as those developed by EPA. To that end, the guidance discusses the science standards, data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft TSCA risk evaluations. Having these key factors in the risk evaluation process laid out in the guidance "will foster predictability by transparently communicating EPA's expectations."

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