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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0636; FRL-9957-74]

RIN 2070-AK23

Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a risk-based screening process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The proposed rule describes the processes for identifying potential candidates for prioritization, selecting a candidate, screening that candidate against certain criteria, formally initiating the prioritization process, providing opportunities for public comment, and proposing and finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under recent amendments to TSCA.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0636, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Ryan Schmit, Immediate Office, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0610; email address: schmit.ryan@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

This proposed rule does not propose to establish any requirements on persons or entities outside of the Agency. This action may, however, be of interest to entities that are or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What Action is the Agency Taking?

EPA is proposing to establish the internal processes and criteria by which EPA will identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time.

C. Why is the Agency Taking this Action?

This rulemaking is required by TSCA section 6(b)(1)(A). Prioritization of chemical substances for further evaluation will ensure that the Agency's limited resources are conserved for those chemical substances most likely to present risks, thereby furthering EPA's overall mission to protect health and the environment.

D. What is the Agency's Authority for Taking this Action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b), 15 U.S.C. § 2605(b). See also the discussion in Units II.A and B.

E. What are the Estimated Incremental Impacts of this Action?

This is a proposed rule that would establish the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It would not establish any requirements on persons or entities outside of the Agency. EPA

did not, therefore, estimate potential incremental impacts from this action.

F. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” (Public Law 114-182), which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA’s website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were “grandfathered in” with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemical substances, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, mandatory deadlines for action, and minimum throughput requirements, TSCA effectively creates a “pipeline” by which EPA will conduct existing chemical substances review and management. This new pipeline - from prioritization to risk evaluation to risk management (when warranted) - is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Prioritization is the initial step in this process.

B. Statutory Requirements for Prioritization

TSCA section 6(b)(1) requires EPA to establish, by rule, the process and criteria for prioritizing chemical substances for risk evaluation. Specifically, the law requires EPA to establish “a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.” TSCA sections 6(b)(1) through (3)

provide further specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either High- Priority Substances or Low-Priority Substances. The statutory requirements related to prioritization are described in further detail in this unit.

1. *Prioritization Steps.* Based on TSCA sections 6(b)(1) through (3), EPA is proposing to include four steps or phases in prioritization: (1) Pre-Prioritization, (2) Initiation, (3) Proposed Designation, and (4) Final Designation. During the Pre-Prioritization phase, EPA is proposing to apply the statutory preferences in TSCA section 6(b)(2), along with other criteria, to narrow the pool of potential candidates, and identify a single chemical substance (or category of chemical substances) to screen against the statutory criteria in TSCA section 6(b)(1)(A). Aside from the statutory preferences listed, the law does not direct or limit EPA in how it is to ultimately select a chemical substance on which to initiate prioritization, requiring only that the process be “risk-based.” At the Initiation step, EPA must announce a candidate chemical substance and give the public a 90-day comment period to submit relevant information. 15 U.S.C. 2605(b)(1)(C)(i). At the Proposed Designation step, EPA must propose to designate a chemical substance as either a High-Priority Substance or a Low-Priority Substance, publish the proposed designation and the information, analysis, and basis used to make the designation, and take public comment a second time for 90 days. 15 U.S.C. 2605(b)(1)(C)(ii). At Final Designation, EPA must either finalize a High-Priority Substance designation and initiate a risk evaluation, or finalize a Low-Priority Substance designation in which case it will not conduct a risk evaluation on

the chemical substance unless and until information leads EPA to revisit that priority designation. 15 U.S.C. 2605(b)(3)(A) and (B).

2. *Screening criteria and statutory preferences.* The statute defines a High-Priority Substance as one that the Administrator concludes, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the Administrator. 15 U.S.C. 2605(b)(1)(B)(i). Conversely, the law specifies that a Low-Priority Substance is one that the Administrator concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for designating a chemical substance a High-Priority Substance. 15 U.S.C. 2605(b)(1)(B)(ii).

In designating the priority of a chemical substance, EPA must screen a candidate chemical substance against certain criteria specified in TSCA section 6(b)(1)(A). These include the hazard and exposure potential of the chemical substance (e.g., persistence and bioaccumulation, potentially exposed or susceptible subpopulations, and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed. EPA interprets “significant changes in” conditions of use to have relevance primarily in the context of revising a priority designation. With respect to an initial prioritization decision, any changes in use that have occurred in the past would already be captured by the concept of “conditions of use,” as defined in TSCA section 3.

The results of this screen will help inform EPA's proposed priority designation. However, given that the statutory deadlines are triggered at the initiation of prioritization, and that EPA will want to have a good understanding of the chemical substance before triggering those deadlines, EPA will consider these screening criteria earlier in the process. As discussed in more detail in Unit III., EPA is therefore proposing to include the screening review in the rule as part of the pre-prioritization phase.

In designating High-Priority Substances, EPA is to give preference to chemical substances that are listed in the 2014 Update of the TSCA Work Plan for Chemical Assessments (Ref. 1) that: (1) have persistence and bioaccumulation scores of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. 15 U.S.C. 2605(b)(2)(D). The law further requires that 50% of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that, at least at the outset of the program, EPA will need to draw at least 50% of High-Priority Substance designations from the same list. 15 U.S.C. 2605(b)(2)(B).

3. Metals and metal compounds. When prioritizing metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 2) (or a successor document that addresses appropriate considerations for conducting a risk assessment on a metal or metal compound and is peer reviewed by the Science Advisory Board). 15 U.S.C. 2605(b)(2)(E). However, during the prioritization process, EPA will not be conducting chemical risk assessments; and, consequently, much of this guidance will not be directly relevant. EPA interprets this provision to ensure that the analysis and considerations during the prioritization process take into account the special attributes and behaviors of metals and metal compounds that are relevant to judgments of

risk. For example, this might include consideration of the document's Key Principles that differentiate inorganic metals and metal compounds from organic and organometallic compounds, and their unique attributes, properties, issues, and processes. Because EPA will not conduct risk assessments on metals or metal compounds for purposes of prioritization, EPA will not refer to sections that provide guidance on how to incorporate the Key Principles into risk assessments.

4. *Timeframe.* TSCA requires that the prioritization process last between nine and twelve months. 15 U.S.C. 2605(b)(1)(C). This timeframe takes on particular significance, given that the statute does not authorize EPA to "pause" or delay the prioritization once it has been initiated, and that a final High-Priority Substance designation results in the chemical substance moving immediately into a risk evaluation process that must be generally completed within three years. 15 U.S.C. 2605(b)(4)(G).

5. *Opportunities for public participation.* As already mentioned, TSCA requires EPA to provide two 90-day public comment periods during prioritization – one following initiation, and a second following a proposed designation. 15 U.S.C. 2605(b)(1)(C)(i) and (ii). TSCA further requires that EPA include a process for extending the comment deadline for up to three months in order to receive or evaluate information coming from a TSCA section 4 test order. 15 U.S.C. 2605(b)(1)(C)(iii). These public comment periods, coupled with the nine month minimum timeframe for prioritization, ensure that the public will be on notice of EPA's intention to further evaluate a chemical's risks and will have opportunity to engage early in the process before the risk evaluation has started.

6. *Default to High-Priority Substance Designation.* If, after prioritization has been initiated, the public has been given an opportunity to submit relevant information, and EPA

has extended the comment period pursuant to TSCA section 6(b)(1)(C)(iii) in order to receive or evaluate additional information, EPA determines that the available information is insufficient to enable the designation of the chemical substance as a Low-Priority Substance, the statute requires EPA to propose a High-Priority Substance designation. 15 U.S.C. 2605(b)(1)(C)(iii). Based in part on this provision, and as discussed further in Unit III, EPA is proposing to require a default-to-high in all cases in which insufficient information exists to designate the chemical as a Low-Priority Substance at both the proposed and final designation.

7. Initial ten chemicals for risk evaluation. TSCA requires EPA to, within six months of enactment, ensure that risk evaluations are being conducted on ten chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments, and to publish a list of those chemical substances during that same period. 15 U.S.C. 2605(b)(2)(A). The initial ten chemical substances are not subject to the prioritization process or the procedures in this rule. However, completion of these risk evaluations triggers the ongoing designation requirement discussed in Unit II.B.8.

8. Ongoing designations. Upon completion of a risk evaluation (other than those requested by a manufacturer pursuant to TSCA section 6(b)(4)(C)(ii)), EPA must designate at least one additional High-Priority Substance to take its place. 15 U.S.C. 2605(b)(2)(C). Because designation as a High-Priority Substance results in the chemical substance moving immediately to risk evaluation, this provision prevents the number of existing chemical substances undergoing risk evaluation from ever decreasing over time. In addition, EPA must designate at least twenty chemical substances as High-Priority Substances by three and one half years after enactment, effectively doubling the number of chemical substances in the

review pipeline. 15 U.S.C. 2605(b)(2)(B). The statute also requires that at least twenty chemical substances be designated as Low-Priority Substances by three and one half years after enactment, but without a comparable requirement to continue designating additional Low-Priority Substances after that. 15 U.S.C. 2605(b)(2)(B), (b)(3)(C). Although EPA must continue to prioritize and evaluate chemical substances “at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines,” this provision does not modify the minimum throughput or other ongoing designation requirements for High-Priority Substances. 15 U.S.C. 2605(b)(2)(C). It does, however, suggest that EPA must have adequate resources should EPA plan to designate more than twenty chemical substances as High-Priority Substances at any given time.

9. *Revision of designation.* TSCA allows the Administrator to revise the designation of a Low-Priority Substance to a High-Priority Substance “based on information made available to the Administrator.” 15 U.S.C. 2605(b)(3)(B). This provision does not restrict the basis for a revision to the discovery or receipt of new information. For example, EPA could also justify a revision based on information that was available but was not considered at the time of the original prioritization decision, or information that was considered but which EPA now views differently as a result of changes in scientific understanding (e.g., changes in scientific understanding of how a chemical can enter or interact with the human body).

10. *Other relevant statutory requirements.* TSCA imposes new requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to “...reduce and replace, to the extent practicable, [...] the use of vertebrate animals in the

testing of chemical substances...” and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA use certain scientific standards and base those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the prioritization of chemical substances, EPA is not obliged to include them in this proposed rule. By their express terms, these statutory requirements apply to EPA’s decisions under TSCA section 6, without the need for regulatory action. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements “by rule;” it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions. E.g., *United States v. Storer Broadcasting Co.*, 351 U.S. 192 (1956).

A number of stakeholders raised questions as to whether EPA should define a number of important terms in this rule (e.g., “best available science”, “weight-of-the-evidence”, “sufficiency of information”, “unreasonable risk”, and “reasonably available information”). Many of the terms used in the proposed rule are not novel concepts and are already in use, and their meaning is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases “best available science”, “weight-of-the-evidence”, and “sufficiency of information” can be found in EPA’s Risk Characterization Handbook (Ref. 3), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases

in this rule may inhibit the flexibility and responsiveness of the Agency to quickly adapt to and implement changing science. The Agency intends to use existing guidance definitions and to update definitions and guidance as necessary.

While EPA is seeking public comment on all aspects of this proposed rule, the Agency is specifically requesting public input on this issue. The Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable.

C. Prioritization under the 2012 TSCA Work Plan Methodology

Prioritization of chemical substances for review is not a novel concept for the Agency. In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemical substances for near-term review and assessment under TSCA (Ref. 4). EPA also published an initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program in 2012 (Ref. 5), and an updated list of chemical substances for further assessment in 2014 (Ref. 1). The process for identifying these chemical substances was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics.

Congress expressly recognized the validity of EPA's existing prioritization methodology for the TSCA Work Plan. For example, the law requires that EPA give certain preferences to chemical substances listed on the 2014 Update to the TSCA Work Plan. 15

U.S.C. §2605(b)(2)(D). Moreover, the law requires that at least 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan. 15 U.S.C. §2605(b)(2)(B). The statutory screening criteria in TSCA section 6(b)(1)(A) also significantly overlaps with the considerations in the Work Plan methodology (e.g., persistence, bioaccumulation, toxicity, carcinogenicity, etc.).

However, there are a number of key differences between EPA's TSCA Work Plan process and the prioritization process that TSCA now requires. First, the Work Plan process involved culling through thousands of chemical substances to create a list that EPA could, over time and without prescribed deadlines, focus its limited resources on. The TSCA Work Plan did not require EPA to assess listed chemical substances, and included no deadlines for completing risk assessments or addressing identified risks. Prioritization under this proposed rule will involve a similar culling, but upon designating a chemical substance as a High-Priority Substance, the Agency must start a risk evaluation, and generally complete that evaluation within a specified amount of time. If EPA determines in the risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must also initiate a risk management rulemaking subject to statutory deadlines. 15 U.S.C. §2605(c). As such, EPA will need to be judicious in selecting the chemical substances that go into prioritization.

Further, while chemical substances listed on the TSCA Work Plan were likely to be well-characterized for hazard and have at least some information indicating potential exposure, Work Plan chemical substance assessments have generally focused on specific chemical uses. Given the statutory deadlines, EPA generally intends to ensure it has a more complete set of data upfront that would allow EPA to evaluate a chemical substance under all

conditions of use (a broader scope) within the statutory deadlines. For chemical substances with insufficient information to conduct a risk evaluation, EPA generally expects to pursue a significant amount of data gathering before initiating prioritization.

Finally, the TSCA Work Plan process focused solely on identifying potential high risk chemical substances for further review. Because the statute also requires the identification of Low-Priority Substances – those chemical substances that EPA has determined, based on sufficient evidence, do not warrant further review at the time – EPA will need to undertake new and different analyses than it has done to date under the TSCA Work Plan.

While EPA has drawn from the TSCA Work Plan methodology and EPA's experience in implementing that process in developing this proposed rule, EPA is proposing to tailor the process for prioritization to the specific requirements in the new statute.

D. Stakeholder Involvement

On August 10, 2016, EPA held a one day public meeting to hear from stakeholders to better understand their viewpoints on the development of the prioritization rule. The meeting began with a presentation from EPA on how the Agency has prioritized chemicals for further review under the TSCA Work Plan methodology. The remainder of the day was reserved for public comment. Commenters had approximately four minutes to present their comments orally and there was a total of 28 oral comments on the prioritization rule. Further information is available on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control>.

Stakeholders were also able to provide written comments. EPA received 50 written comments on the prioritization rule, although many of those who presented orally also

submitted written versions as well. These comments and a transcript of the meeting are accessible in the meeting's docket, identified by Docket ID No. EPA-HQ-OPPT-2016-0399, available online at <https://www.regulations.gov/>.

The commenters included representatives from industry, environmental groups, academics, private citizens, trade associations, and health care representatives, and provided a diversity of perspectives. Overall, there was a general expression of support for the new law and EPA's inclusive approach to implementation to date. Most groups agreed that the prioritization rule had the potential to increase transparency in EPA's chemical substance review and management process, and urged the Agency to work towards this goal.

A number of commenters suggested codifying specific details in the rule, such as a system for scoring and ranking chemical substances; a listing of the specific hazard and exposure information upon which EPA will base prioritization decisions; and definitions of terms referenced in the statute like "weight of evidence" and "best available science." Others encouraged EPA to keep the rules focused on a framework for general process, to retain Agency discretion where appropriate, and to reserve specific scientific considerations for Agency guidance.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the Agency's proposed process for chemical substance prioritization as presented in this document.

III. Summary of Proposed Rule

This proposed rule incorporates all of the elements required by statute, but also supplements those requirements with additional criteria the Agency expects to consider, some clarifications for greater transparency, and additional procedural steps to ensure

effective implementation. Specific components of the approach are discussed in this unit. EPA requests comments on all aspects of this proposed rulemaking.

A. Policy Objective

The prioritization process under TSCA is the principal gateway to risk evaluation. EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment. As a general matter, the overall objective of the process should be to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first. EPA may also consider the relative hazard and exposure of a potential candidate's likely substitute(s) in order to avoid moving the market to a chemical substance of equal or greater risks. However, the prioritization process is not intended to be an exact scoring or ranking exercise and EPA is not proposing such a system in this rule. The precise order in which EPA identifies High-Priority Substances (all of which must meet the same statutory standard) should not be allowed to slow the Agency's progress towards fully evaluating the risks from those chemical substances. Further, the level of analysis necessary to support an exact ranking system is not appropriate at the prioritization stage, where the sole outcome is a decision on whether EPA will further evaluate the chemical substance. EPA intends to conserve its resources and the Agency's deeper analytic efforts for the actual risk evaluation. This policy objective is stated directly in the proposed rule.

Low-Priority Substance designations serve some of the same policy objectives. Although the statute does not require EPA to designate more than twenty Low-Priority Substances, doing so ensures that chemical substances with clearly low hazard and exposure potential are taken out of consideration for further assessment, thereby conserving resources

for the chemical substances with the greatest potential risks. There is also value in identifying Low-Priority Substances as part of this process, as it gives the public notice of chemical substances for which potential risks are likely low or nonexistent, and industry some insight into which chemical substances are likely not to be regulated under TSCA.

B. Scope of Designations

EPA will designate the priority of a “chemical substance,” as a whole, under this established process, and will not limit its designation to a specific use or subset of uses of a chemical substance. EPA is proposing this in response to clear statutory directives: the relevant provisions of TSCA section 6 repeatedly refer to both the designation and evaluation of “chemical substances” under the “conditions of use.” “Conditions of use” are broadly defined as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. 2602.

Although some commenters at the public meeting suggested that the prioritization process should allow EPA to designate a specific use of a chemical substance as a High-Priority Substance or a Low-Priority Substance, EPA does not interpret the statute to support such an interpretation. To the contrary, the addition of the phrase “conditions of use” (emphasis added) was intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a comprehensive approach to chemical substance management. While EPA clearly retains some discretion in determining those conditions of use, as a matter of law, EPA considers that it would be an abuse of that discretion to simply disregard known, intended, or reasonably foreseen uses in its analyses.

C. Timeframe

As discussed in Unit II., TSCA section 6(b)(1)(C) requires that the prioritization process last between nine and twelve months. EPA is proposing in this rule that initiation of the prioritization begins upon publication of a notice in the **Federal Register** that identifies a chemical substance for prioritization and provides the results of the screening review. The process is complete upon publication of a notice in the **Federal Register** announcing a final priority designation. Accordingly, the proposed rule specifies that the process – from initiation to final designation – shall last between 9 and 12 months.

This timeframe serves dual purposes. The minimum 9-month timeframe ensures that the general public; potentially-affected industries; state, tribal and local governments; environmental and health non-governmental organizations; and others have ample notice of upcoming federal action on a given chemical substance, and opportunity to engage with EPA early in the process. The 12-month maximum timeframe, coupled with the default-to-high provision discussed later, keeps the existing chemical substances review pipeline in a forward motion, and prevents EPA from getting mired in analysis before ever reaching the risk evaluation step.

D. Categories of Chemical Substances

TSCA section 26 provides EPA with authority to take action on categories of chemical substances. 15 U.S.C. 2625(c). “Category of Chemical Substances” is defined at 15 U.S.C. 2625(c)(2)(A). Although the proposed rule most often references “chemical substances,” EPA is also proposing to include a clear statement in the regulation that nothing in the proposed 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 prioritize and evaluate categories of chemical substances.

E. Chemicals Subject to Prioritization

Generally, all chemical substances listed on the TSCA Inventory are subject to prioritization. TSCA contemplates that, over time, all chemical substances on the TSCA Inventory will be prioritized into either High- or Low-Priority Substances, and that all High-Priority Substances will be evaluated. EPA notes that chemical substances newly added to the TSCA Inventory following EPA's completion of pre-manufacture review under section 5 of TSCA (15 U.S.C. 2604) are also candidates for prioritization, although EPA expects that such chemical substances are not likely to be High-Priority candidates in light of the risk-related determination that the Agency must make pursuant to TSCA section 5(a)(3).

TSCA further requires EPA to go through a separate process of determining which chemical substances on the TSCA Inventory are still actively being manufactured, and EPA has initiated a separate rulemaking for that purpose (RIN 2070-AK24). This distinction will inform EPA's exposure judgments during the prioritization process. However, there is nothing in TSCA that prohibits EPA from initiating the prioritization process on an "inactive" chemical substance and ultimately designating that chemical substance as either a High-Priority Substances (e.g., if exposures of concern arise from ongoing uses) or Low-Priority Substance.

F. Pre-prioritization Considerations

As discussed earlier, TSCA requires that EPA establish a process, including criteria for designating a chemical substance as either a High-Priority Substances or Low-Priority Substance. 15 U.S.C. 2605(b)(1). Aside from the statutory preferences for chemical substances on the 2014 Update to the TSCA Work Plan (Ref. 1), the statute leaves EPA with broad discretion to choose which chemical substance to put into that process. Accordingly,

this proposed rule includes a discussion of the criteria EPA expects to use to cull through the chemical substances on the TSCA Inventory. These include criteria that will be used to identify potential candidates for High-Priority Substances or Low-Priority Substances, and that describe how the extent of available information on potential candidates will affect whether they are selected for prioritization.

For example, in identifying potential candidates for High-Priority Substance designations, EPA is proposing to seek to identify chemical substances where available information suggests that the chemical substance may present a hazard and that exposure is present under “one or more conditions of use,” but where an “unreasonable risk” determination cannot be made without a more extensive or complete assessment in a risk evaluation. EPA interprets the statutory definition of a High-Priority Substance (“...may present an unreasonable risk [...] because of a potential hazard and a potential route of exposure...”) to set a fairly low bar, and EPA expects that a large number of chemical substances will meet this definition. Although EPA will prioritize a “chemical substance” as a whole, EPA may base its identification of a potential candidate as a High-Priority Substance, and ultimately the proposed designation, on a single condition of use, provided the hazard and exposure associated with that single use support such a designation. This proposal is based on the statutory definition of a High-Priority Substance, which is clear that the standard for the chemical as a whole can be met based on a single condition of use (“...because of *a* potential hazard and *a* potential route of exposure...”).

Conversely, in identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for “all conditions of use” are so low

that EPA can confidently set that chemical substance aside without doing further evaluation. By comparison, then, TSCA's definition of Low-Priority Substance ("...based on sufficient information, such *substance* does not meet the standard for [...] a high-priority substance...") is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-Priority Substance standard. Consequently, EPA expects it will be more difficult to support such designations. Unlike High-Priority Substances, EPA will not be able to designate a chemical substance as a Low-Priority Substance without first looking at all of the conditions of use. While not determinative, EPA believes that its Safer Chemicals Ingredients List (SCIL) (Ref. 6) will be a good starting point for identifying potential candidates for Low-Priority Substance designations.

EPA is also proposing to include the following list of additional exposure and hazard considerations that can be used to narrow the field of potential candidates: (1) Persistent, bioaccumulative, and toxic; (2) Used in children's products; (3) Used in consumer products; (4) Detected in human and/or ecological biomonitoring programs; (5) Potentially of concern for children's health; (6) High acute and chronic toxicity; (7) Probable or known carcinogen; (8) Neurotoxicity; or (9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency. These criteria are drawn from EPA's 2012 TSCA Work Plan methodology (Ref. 4), which, as discussed earlier, was the process EPA had been using to prioritize chemical substances for assessment under TSCA. EPA will evaluate one or more of these nine considerations, and chemical substances that meet one or more of these criteria may be identified as potential candidates for High-Priority Substance designations. For example, if a chemical substance is highly toxic and used in consumer products, EPA may wish to consider that chemical substance as a potential High-Priority

Substance candidate. EPA may also choose to identify potential candidates based on other criteria that suggest the chemical substance may otherwise present a human health or environmental concern, as contemplated in the “catch-all” provision (9). The fact that a chemical substance meets one of these criteria is not determinative of an outcome, including whether or not EPA will select the chemical substance to go into the prioritization process and/or the priority designation that the chemical substance will ultimately receive.

Conversely, chemical substances that meet none of these criteria may be good potential candidates for Low-Priority Substance designation. The considerations are intended to serve as a general guide for the Agency, based on EPA’s current understanding of important considerations regarding potential chemical risk. It should also be noted that while these considerations are drawn from EPA’s 2012 Work Plan methodology (Ref. 4), EPA will apply them differently for prioritization. In the TSCA Work Plan context, only chemical substances that met these initial criteria were eligible for listing on Work Plan. For purposes of prioritization under TSCA, the considerations do not determine eligibility, but rather are designed to help EPA to narrow its focus.

G. Information Availability

Another key consideration in the pre-prioritization phase is the existence and availability of risk-related information on a candidate or potential candidate chemical substance. Because EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, immediately initiate a risk evaluation for High-Priority Substance, and complete the risk evaluation within three years of initiation, EPA cannot assume that it will be able to require the generation of critical information during these time frames. Furthermore, the statute does not grant EPA the

discretion to significantly delay either of these processes, pending development of information. Consequently, prior to initiating the prioritization process for a chemical substance, EPA will generally review the available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete both prioritization and risk evaluation processes. As part of such an evaluation, EPA expects to consider the quality, objectivity, utility, and integrity of the available information. To the extent the information is not currently available or is insufficient, EPA will determine whether or not information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. The proposed rule makes it clear that sufficiency of available information is likely to be a crucial factor in the selection of the chemical substances that EPA chooses to put into the prioritization process.

As noted, if information gaps are identified *during* the prioritization or risk evaluation processes, EPA expects that it could be difficult to require the development of necessary chemical substance information, and receive, evaluate, and incorporate that information into analyses and decisions within the statutory timeframes. Tests necessary for risk evaluation, for example, could take months or years to develop and execute, plus additional time for EPA to issue the order or rule, and to collect, review and incorporate the new information. To avoid such a scenario, EPA believes that it will need to do a significant amount of upfront data gathering and review. This approach ensures that EPA stays on track to meet relevant statutory deadlines – particularly those for risk evaluation.

The proposed rule makes clear that EPA generally expects to use this new authority, as appropriate and necessary, to gather the requisite information prior to initiating prioritization. This could include, as appropriate, TSCA information collection, testing, and

subpoena authorities, including those under TSCA sections 4, 8, and 11(c), to develop needed information.

Given the importance of ensuring that sufficient information is available to conduct the prioritization and risk evaluation processes, EPA is proposing to include this consideration during the earliest stage in the process: during the identification of potential candidates. However, this criterion remains relevant even after EPA has selected a candidate and screened that chemical substance against the statutory criteria in TSCA section 6(b)(1)(A). Thus, if at any time prior to the publication of a notice in the **Federal Register** initiating prioritization, EPA determines that more information will be necessary to support a prioritization designation or a subsequent risk evaluation, EPA can choose not to initiate prioritization for that chemical substance pending development of additional information.

H. Selection and Screening of a Candidate Chemical Substance

As noted in Unit II., TSCA requires that EPA give preference to chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that (1) have a Persistence and Bioaccumulation Score of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. 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. By operation of the statute, TSCA requires that all TSCA Work Plan chemical substances eventually be prioritized. However, it is premature to presume that those chemical substances will necessarily be prioritized as High-Priority Substances, or that EPA would find unreasonable risk.

Aside from these statutory preferences, however, TSCA does not limit how EPA must

ultimately select a candidate chemical substance to put into the prioritization process. EPA is proposing that it will select a candidate – for either High-Priority Substances or Low-Priority Substance - based on the policy objectives described in Unit III.A. and the pre-prioritization considerations described in Unit III. F. and G. The development of the proposed rule, including these policy objectives, considerations and criteria, was informed by EPA’s experience implementing the 2012 TSCA Work Plan methodology, which has been the Agency’s primary tool for identifying candidate chemical substances for further assessment under TSCA. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback *during* the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase. Further, given EPA’s objective to avoid simply moving the market to substitute chemical substances of equal or greater risks, EPA requests comment on whether and how information on the availability of chemical substitutes should be taken into account during this phase of the prioritization process.

Once a single candidate chemical substance (or category of chemical substances) is selected, EPA will screen the selected candidate against the specific criteria and considerations in TSCA section 6(b)(1)(A). Those criteria and considerations are: (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. Because TSCA does not prohibit EPA from expanding the statutory screening criteria, the proposed rule also provides an additional criterion: (7) any other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion. This final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks. In addition, EPA fully recognizes the important role that stakeholders can play in helping the Agency to identify candidates for prioritization or to better understand the unique uses or characteristics of a particular chemical. EPA continues to welcome this type of engagement and dialogue early in the process, including during the pre-prioritization phase. While the proposed rule provides multiple opportunities for public feedback during the prioritization process, EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase.

The screening review is not a risk evaluation, but rather a review of available information on the chemical substance that relates to the screening criteria. EPA expects to evaluate all relevant sources of information while conducting the screening review, including, as appropriate, the hazard and exposure sources listed in Appendices A and B of the 2012 TSCA Work Plan methodology (Ref. 4). Ultimately, the screening review and other considerations during the pre-prioritization phase are meant to inform EPA's decisions on (1) whether to initiate the prioritization process on a particular chemical substance, and (2) once initiated, the proposed designation of that chemical substance as either a High-Priority Substances or Low-Priority Substance.

I. Initiation of Prioritization

The prioritization process officially begins, for purposes of triggering the nine to twelve month statutory timeframe, when EPA publishes a notice in the **Federal Register** identifying a chemical substance for prioritization. The proposed rule also specifies that EPA will publish the results of the screening review in the **Federal Register**, describing the information, analysis and basis used to conduct that review and providing in the docket copies of relevant information not otherwise protected as confidential business information under TSCA section 14. Publication of the notice in the **Federal Register** also initiates a 90-day public comment period. For each chemical substance, EPA will open a docket to facilitate receipt of public comments and access to publicly available information throughout this process. Interested persons can submit information regarding the results of the screening review or any other information relevant to the chemical substance. Of particular interest to EPA will be information related to “conditions of use” that are missing from the screening results. EPA will consider all relevant information received during this comment period. Consistent with TSCA section 6(b)(1)(C)(iii), the proposed rule further allows EPA to extend this initial public comment period for up to 3 months to receive and/or evaluate information developed from a test order, commensurate with EPA’s need for additional time to receive and/or evaluate this information. As a practical matter, EPA is unlikely to often extend this initial public comment, given EPA’s intention to ensure that all or most of the necessary information is available before initiating the prioritization process. Further, a three month window would not often provide a sufficient time to gather, let alone consider, new test data for the prioritization process. This is generally expected to be the case even with the authority to more quickly collect such information under the new test order authority in TSCA section 4.

J. Proposed Priority Designation

Based on the results of the screening review, relevant information received from the public in the initial comment period, and other information as appropriate, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, as those terms are defined in TSCA. In making this proposed designation, as directed by the statute, EPA will not consider costs or other non-risk factors.

This proposed rule provides that EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a second comment period of 90 days, during which time the public may submit comments on EPA's proposed designation. EPA proposes to use the same docket for this step of the process. Because the supporting documentation for a proposed High-Priority Substance designation is likely to foreshadow what will go into a scoping document for risk evaluation, EPA will be particularly interested in early comments on the accuracy of scope-related information such as the chemical's "conditions of use."

In the event of insufficient information at the proposed designation step, EPA is proposing to designate a chemical substance as a High-Priority Substance. EPA expects this situation to occur infrequently based on its application of the criteria and considerations during the pre-prioritization phase. However, if for some reason the information available to EPA is insufficient to support a proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period, consistent with the statute, the proposed rule requires EPA to propose to designate the chemical substance as a High-Priority Substance. The statute requires that the prioritization

process lead to one of two outcomes by the end of the 12-month deadline: a High-Priority Substance designation or a Low-Priority Substance designation. 15 U.S.C. §2605(b)(1)(B). There is no third option to allow EPA to either require the development of additional information or otherwise toll this deadline. Further, the statute specifically requires that a Low-Priority Substance designation be based on “information sufficient to establish” that a chemical substance meets the definition. 15 U.S.C. 2605(b)(1)(B)(ii). There is no comparable statutory requirement for High-Priority Substance designations. 15 U.S.C. 2605(b)(1)(B)(i). It is also relevant that the effect of designating a chemical as High-Priority Substance is that EPA further evaluates the chemical substance; by contrast, a Low-Priority Substance designation is a final Agency determination that no further evaluation is warranted - a determination that constitutes final agency action, subject to judicial review. 15 U.S.C. §2618(a)(1)(C)(i).

The logical implication of this statutory structure is that scientific uncertainty in this process (including as a result of insufficient information) is to weigh in favor of a High-Priority Substance designation, as it is merely an interim step that ensures that the chemical will be further evaluated. EPA's proposal would also ensure that this process would not create any incentives for parties to withhold readily available information, or inadvertently discourage the voluntary generation of data, as could occur were EPA to establish, for example, a default designation to Low-Priority. As a practical matter, however, EPA expects this situation to occur infrequently, based on its proposed criteria and considerations that will generally ensure that sufficient information is available to conduct a risk evaluation before initiating prioritization. Priority designations, whether they were based on sufficient information or a lack of sufficient information, are neither an affirmation of risk nor safety.

EPA therefore recognizes that all priority designations will need to be carefully communicated to the public.

For proposed designations as Low-Priority Substances, EPA is proposing to require that all comments that could be raised on the issues in the proposed designation must be presented during the comment period. Any issues not raised will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding. This is a well-established principle of administrative law and practice, e.g., *Nuclear Energy Institute v EPA*, 373 F.3d 1251, 1290-1291 (DC Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate here. EPA is restricting this to Low-Priority Substance designations, as it is the last opportunity for public input before EPA's action becomes final, and thus it is imperative that any issues are shared during this public comment period. By contrast, designation of a chemical substance as a High-Priority Substance is not final agency action. The statute mandates additional opportunities for public input during the risk evaluation process, and EPA does not consider it appropriate to restrict the public's ability to comment during these subsequent processes based on this early phase proceeding.

K. Final Priority Designation

After considering any additional information collected during the proposed designation step, as appropriate, the last step in the prioritization process is for EPA to finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance. The proposed rule specifies that EPA will publish the priority designation in the **Federal Register**, and will use the same docket. Again, TSCA prohibits costs or other non-risk factors from being considered in this designation. And, as with the proposed

designation step, if information available to EPA remains insufficient to support the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation as a High-Priority Substance. Although final High-Priority designations based on insufficient information are unlikely for all the reasons described in Unit III.J., such a designation would require EPA to conduct a risk evaluation on that substance, and to support the risk evaluation with adequate information. EPA would need to develop or require development of the necessary information and complete the risk evaluation within the 3-year statutory deadline.

L. Repopulation of High-Priority Substances

TSCA requires EPA to finalize a designation for at least one new High-Priority Substance upon completion of a risk evaluation for another chemical substance, other than a risk evaluation that was requested by a manufacturer. Because the timing for the completion of risk evaluation and/or the prioritization process will be difficult to predict, EPA intends to satisfy this 1-off-1-on replacement obligation as follows: in the notice published in the **Federal Register** finalizing the designation of a new High-Priority Substance, EPA will identify the complete or near-complete risk evaluation that the new High-Priority Substance will replace. So long as the designation occurs within a reasonable time before or after the completion of the risk evaluation, this will satisfy Congress' intent while avoiding unnecessary delay and the logistical challenges that would be associated with more perfectly aligning a High-Priority Substance designation with the completion of a risk evaluation.

M. Effect of Final Priority Designation

Final designation of a chemical substance as a High-Priority Substance requires EPA to immediately begin a risk evaluation on that chemical substance. It is important to note

that High-Priority Substance designation does not mean that the Agency has determined that the chemical substance presents a risk to human health or the environment - only that the Agency intends to consider the chemical substance for further risk review and evaluation. A High-Priority Substance designation is not a final agency action and is not subject to judicial review or review under the Congressional Review Act (CRA), 5 U.S.C. 801 et seq.

Final designation of a chemical substance as a Low-Priority Substance means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation, if warranted. Notably, a Low-Priority Substance designation is explicitly subject to judicial review. 15 U.S.C. 2618(a)(1)(C).

N. Revision of Designation

TSCA provides that EPA may revise a final designation of a chemical substance from a Low-Priority Substance to a High-Priority Substance at any time based on information available to the Agency. The proposed rule outlines the process the Agency will take to revise such a designation. Specifically, EPA would (1) re-screen the chemical substance incorporating the relevant information, (2) re-initiate the prioritization process and take public comment, (3) re-propose a priority designation and take public comment, and (4) re-finalize the priority designation. EPA will not revise a final designation of a chemical substance from High-Priority Substance to Low-Priority Substance, but rather see the risk evaluation process through to its conclusion.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket,

even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014. Available online at: https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.
2. EPA. Framework for Metals Risk Assessment. EPA 120/R-07/001. March 2007. Available online at: <https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf>.
3. EPA. Science Policy Council Handbook: Risk Characterization. EPA/100/B-00/002. December 2000. Available online at: <https://www.epa.gov/risk/risk-characterization-handbook>.
4. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012. Available online at: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.
5. EPA. 2012 TSCA Work Plan Chemicals. June 2012. Available online at: https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf.
6. EPA. Safer Chemical Ingredients List (SCIL). Available online at: <https://www.epa.gov/saferchoice/safer-ingredients>. See also Master Criteria, September 2012, Version 2.1, available online at: https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review.

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA).

This action does not contain any information collection activities that require approval under the PRA, 44 U.S.C. 3501 *et seq.* This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

C. Regulatory Flexibility Act (RFA)

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public, including small entities.

D. Unfunded Mandates Reform Act (UMRA).

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism.

This action does not have federalism implications as specified in Executive Order

13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments.

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks.

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

I. National Technology Transfer and Advancement Act (NTTAA).

This rulemaking does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This rulemaking addresses internal EPA operations and procedures and does not have any impact on human health or the environment.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical Substances, Hazardous Substances, Health and Safety, Prioritization, Screening, Toxic Substances.

Dated: December 27, 2016

Gina McCarthy,

Administrator.

Therefore, 40 CFR chapter I, subchapter R, is proposed to be amended as follows:

PART 702--[AMENDED]

1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

2. Add subpart A to read as follows:

PART 702--GENERAL PRACTICES AND PROCEDURES

Subpart A – Procedures for Prioritization of Chemical Substances for Risk Evaluation

702.1 General Provisions

702.3 Definitions

702.5 Considerations for Potential Candidates for Prioritization

702.7 Candidate Selection and Screening Review

702.9 Initiation of Prioritization Process

702.11 Proposed Priority Designation

702.13 Final Priority Designation

702.15 Revision of Designation

702.17 Effect of Designation as a Low-Priority Substance

702.19 Effect of Designation as a High-Priority Substance

* * * * *

Authority: 15 U.S.C. § 2605 and 2619

Subpart A – Procedures for Prioritization of Chemical Substances for Risk Evaluation

§702.1 General Provisions.

(a) *Purpose.* This regulation establishes the risk-based screening process for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b) of the Toxic Substances Control Act, as amended (15 U.S.C. 2605(b)).

(b) *Scope of designations.* EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of use of a chemical substance.

(c) *Categories of chemical substances.* Nothing in this subpart shall be interpreted as

a limitation on EPA's authority under 15 U.S.C. 2625(c) to take action, including the actions contemplated in this subpart, on a category of chemical substances.

(d) *Prioritization timeframe.* The Agency will publish a final priority designation for a chemical substance in no fewer than 9 months and no longer than 1 year following initiation of prioritization pursuant to 40 CFR 702.9.

(e) *Metals or metal compounds.* In identifying priorities for chemical substances that are metals or metal compounds, EPA will, as appropriate, refer to relevant considerations from the Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum, dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(f) *Applicability.* These regulations do not apply to any chemical substance for which a manufacturer requests a risk evaluation under TSCA section 6(b)(4)(C) (15 U.S.C. 2605(b)(4)(C)).

§702.3 Definitions.

For purposes of this subpart, the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*)

EPA means the U.S. Environmental Protection Agency.

High-Priority Substance means 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 means 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.

§ 702.5 Consideration of Potential Candidates for Prioritization.

(a) *Potential High-Priority Substance Candidates.* In identifying potential candidates for High-Priority Substances, EPA will generally consider whether information available to the Agency suggests there is hazard and exposure under a condition or conditions of use, and whether a risk evaluation would be needed to determine whether there is an unreasonable risk of injury to health or the environment.

(b) *Potential Low-Priority Substance Candidates.* In identifying potential candidates for Low-Priority Substances, EPA will generally consider whether information available to the EPA suggests such low hazard and/or exposure under all conditions of use that EPA is confident the chemical substances does not present 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, even in the absence of a risk evaluation.

(c) *Exposure and Hazard Considerations for Potential Candidates.*

In identifying potential candidates for prioritization, EPA will generally evaluate whether or not the chemical substance meets one or more of the following exposure or hazard considerations:

- (1) Persistent, bioaccumulative, and toxic;
- (2) Used in children's products;
- (3) Used in consumer products;
- (4) Detected in human and/or ecological biomonitoring programs;
- (5) Potentially of concern for children's health;

- (6) High acute and chronic toxicity;
- (7) Probable or known carcinogen;
- (8) Neurotoxicity; or
- (9) Other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency.

A chemical substance that meets one or more of these criteria will generally be considered as a potential candidate for further consideration as a High-Priority Substance. A chemical substance that meets none of these criteria will generally be considered as a potential candidate for further consideration as a Low-Priority Substance.

(d) *Available Information and Resources.* EPA expects it will often be difficult to timely require development of necessary chemical information, and receive, evaluate, and incorporate that information into analyses, during the prioritization and risk evaluation processes, within the statutory deadlines under the Act for prioritization and risk evaluation at 15 U.S.C. 2605 (b)(1)(C) and (b)(4)(G). Therefore, EPA will generally review and analyze the information necessary for both prioritization and risk evaluation prior to initiating the prioritization process for a chemical substance pursuant to 40 CFR 702.9. Specifically, in identifying potential candidates for prioritization, EPA expects to consider:

(1) The availability of information and resources necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Administrator; and

(2) The ability of EPA to timely develop or require development of information necessary and sufficient to support a priority designation pursuant to 40 CFR 702.11; a risk evaluation pursuant to 40 CFR 702, subpart B; or other such action as determined by the

Agency.

(e) *Insufficient Information*. In the absence of sufficient information to support a priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA may use its authorities under the Act, and other information gathering authorities, to gather or require the generation of the needed information on a chemical substance before initiating the prioritization process for that chemical substance.

§702.7 Candidate Selection and Screening Review.

(a) *Preferences and TSCA Work Plan*. In selecting a candidate for prioritization as a High-Priority Substance, EPA will:

(1) Give preference to:

(A) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3, and

(B) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High-Priority Substance or Low-Priority Substance pursuant to 40 CFR 702.13.

(b) *General Objective*. In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the

greatest hazard and exposure potential first, considering available information on the relative hazard and exposure of potential candidates. EPA may also consider the relative hazard and exposure of a potential candidate's substitutes. EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order.

(c) *Screening Review.* Following selection of a candidate chemical substance, EPA will generally use available information to screen the candidate chemical substance against the following criteria and considerations:

- (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;
- (6) The chemical substance's production volume or significant changes in production volume; and
- (7) Any other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion.

(d) *Information sources.* In conducting the screening review in paragraph (c) of this section, EPA expects to consider sources of information relevant to the listed criteria, including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

(e) The purpose of the preferences and criteria in paragraph (a) of this section and the screening review in paragraph (c) of this section are to inform EPA's decision whether or not

to initiate the prioritization process pursuant to 40 CFR 702.9, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to 40 CFR 702.11.

(f) If, after the screening review in paragraph (c) of this section, EPA believes it will not have sufficient information to support a proposed priority designation pursuant to 40 CFR 702.11, a risk evaluation pursuant to 40 CFR 702, subpart B, or other such action as determined by the Agency, EPA is likely to use its authorities under the Act, and other information gathering authorities, to generate the needed information before initiating prioritization pursuant to 40 CFR 702.9.

§702.9 Initiation of Prioritization Process.

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that all or most of the information necessary to prioritize and perform a risk evaluation on the substance already exists.

(b) EPA will initiate prioritization by publishing a notice in the **Federal Register** identifying a chemical substance for prioritization and the results of the screening review conducted pursuant to 40 CFR 702.7(c).

(c) The prioritization timeframe in 40 CFR 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) The results of the screening review published pursuant to paragraph (b) of this section will identify, in a form and manner that EPA deems appropriate, the information analysis and basis used in conducting the screening process. Subject to 15 U.S.C. 2613, copies of the information will also be placed in a public docket established for each chemical substance.

(e) Publication of a notice in the **Federal Register** pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information regarding the results of the screening review conducted pursuant to 40 CFR 702.7(c), and any additional information on the chemical substance that pertains to the criteria and considerations at 40 CFR 702.7(c).

(f) EPA may, in its discretion, extend the public comment period in paragraph (b) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B).

§702.11 Proposed Priority Designation.

(a) Based on the results of the screening review in 40 CFR 702.7(c), relevant information received from the public as described in 40 CFR 702.9(e), and other information as appropriate and in EPA's discretion, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a proposed priority designation.

(c) If information available to EPA remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance, including after any extension of the initial public comment period pursuant to 40 CFR 702.9(f), EPA will propose to designate the chemical substance as a High-Priority Substance.

(d) EPA may propose to designate a chemical substance as a High-Priority Substance

based on the proposed conclusion that the chemical substance satisfies the definition of High-Priority Substance in 40 CFR 702.3 under any one or more uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602. EPA will propose to designate a chemical substance as a Low-Priority Substance based only on the proposed conclusion that the chemical substance satisfies the definition of Low-Priority Substance in 40 CFR 702.3 under all uses that the Agency determines constitute conditions of use as defined in 15 U.S.C. 2602.

(e) EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a comment period of 90 days, during which time the public may submit comment on EPA's proposed designation. EPA will open a docket to facilitate receipt of public comment.

(f) For chemical substances that EPA proposes to designate as Low-Priority Substances, EPA will specify in the notice published pursuant to paragraph (e) of this section that all comments that could be raised on the issues in the proposed designation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

§702.13 Final Priority Designation.

(a) After considering any additional information collected from the proposed designation process in 40 CFR 702.11, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance.

(b) EPA will not consider costs or other non-risk factors in making a final priority

designation.

(c) EPA will publish each final priority designation in the **Federal Register**.

(d) EPA will finalize a designation for at least one High-Priority Substance for each risk evaluation it completes, other than a risk evaluation that was requested by a manufacturer pursuant to 40 CFR 702, subpart B. The obligation in 15 U.S.C. 2605(b)(3)(C) will be satisfied by the designation of at least one High-Priority Substance where such designation specifies the risk evaluation that the designation corresponds to, and where the designation occurs within a reasonable time before or after the completion of the risk evaluation.

(e) If information available to EPA remains insufficient to enable the final designation of the chemical substance as a Low-Priority Substance, EPA will finalize the designation of the chemical substance as a High-Priority Substance.

§ 702.15 Revision of Designation.

EPA may revise a final designation of chemical substance from Low-Priority to High-Priority Substance at any time based on information available to the Agency. To revise such a designation, EPA will re-screen the chemical substance pursuant to 40 CFR 702.7(c), re-initiate the prioritization process on that chemical substance in accordance with 40 CFR 702.9, propose a priority designation pursuant to 40 CFR 702.11, and finalize the priority designation pursuant to 40 CFR 702.13. EPA will not revise a final designation of a chemical substance from a High-Priority Substance designation to Low-Priority.

§ 702.17 Effect of Designation as a Low-Priority Substance.

Designation of a chemical substance as a Low-Priority Substance under 40 CFR 702.3 means that a risk evaluation of the chemical substance is not warranted at the time, but

does not preclude EPA from later revising the designation pursuant to 40 CFR 702.15, if warranted.

§ 702.19 Effect of Designation as a High-Priority Substance.

Final designation of a chemical substance as a High-Priority Substance under 40 CFR 702.13 initiates a risk evaluation pursuant to 40 CFR 702, subpart B. Designation as a High-Priority Substance is not a final agency action and is not subject to judicial review.

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