Prepublication Copy Notice:

The EPA Administrator signed the following *Federal Register* document on June 22, 2017:

Title: **Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act**

Action: Final Rule

FRL: 9964-24

Docket No.: **EPA-HQ-OPPT-2016-0636**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0636; FRL-9964-24]

RIN 2070-AK23

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is issuing a final rule that establishes the 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 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 finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under TSCA.

DATES: This final rule is effective [*insert date* 60 *days after date of publication in the* **Federal Register**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0636, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental

Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4321; email address: *blair.susanna@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. What Action is the Agency Taking?

EPA is promulgating this final rule to establish the process 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.

B. Does this Action Apply to Me?

This final rule does not establish any requirements on persons or entities outside

of the Agency. This action may, however, be of interest to entities that are manufacturing 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.

C. Why is the Agency Taking this Action?

This rulemaking is required by TSCA section 6(b)(1)(A), 15 U.S.C. 2605(b)(1)(A). Prioritization of chemical substances for further evaluation will help to 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?

This final rule is issued pursuant to the authority in TSCA section 6(b), 15 U.S.C. 2605(b).

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

This final rule establishes the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It does not establish any requirements on persons or entities outside of the Agency. No incremental impacts are therefore anticipated, and consequently EPA did not estimate potential incremental impacts from this action.

II. Background

A. Statutory Requirements for Prioritization

TSCA section 6(b)(1), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182), requires EPA to establish, by rule, a process 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." 15 U.S.C. § 2605(b)(1)(A). 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, 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 a High-Priority Substance or a Low-Priority Substance. 15 U.S.C. § 2605(b)(1)-(3).

EPA published a proposed rule on January 17, 2017 setting forth the draft process and criteria (Ref. 1). A detailed summary of the statutory requirements for prioritization, EPA's methodology for prioritizing existing chemicals for assessment under the TSCA Work Plan before enactment of the TSCA amendments in 2016, and pre-proposal stakeholder involvement activities and feedback was presented in the proposed rule.

B. Interagency Collaboration.

EPA is committed to engaging and collaborating with partner federal agencies prior to and during the prioritization process. TSCA specifically authorizes other federal agencies, at EPA's request, to: (1) make their services, personnel, and facilities available to the Agency, (2) provide information, data, estimates, and statistics to the Agency, and (3) grant EPA access to all information in its possession as the Agency may reasonably

determine to be necessary for the administration of the Act. 15 U.S.C. 2625(a). EPA has a number of existing mechanisms already in place to facilitate collaboration with the Agency's federal partners and will continue to utilize them. Collaboration with other federal agencies is an important step in identifying chemicals for prioritization, evaluating risks from chemicals, and during the risk management phase, if a chemical use is determined to present an unreasonable risk.

EPA's collaboration with other federal agencies prior to and during the risk-based prioritization process gives other agencies sufficient time to work with the EPA in identifying any information about a particular chemical substance that may be useful for formulating a priority designation for that substance (e.g., conditions of use, exposure scenarios, etc.). The Agency anticipates that it will at times collaborate with the other statutory member agencies of the TSCA Interagency Testing Committee (ITC), i.e., the Consumer Product Safety Commission (CPSC), the Council on Environmental Quality (CEQ), Department of Commerce, the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), the National Science Foundation (NSF); and the Occupational Safety and Health Administration (OSHA). 15 U.S.C. 2603(e)(2)(A). EPA also expects that such collaboration will extend, when appropriate, to other federal agency partners not specifically identified in TSCA as ITC members, such as the Agency for Toxic Substances Disease Registry (ATSDR), the Department of Defense, the National Aeronautics and Space Administration (NASA), and the Office of Management and Budget (OMB). Finally, EPA anticipates that its collaboration with other federal agencies

may include, when appropriate, the Small Business Administration's Office of Advocacy and various other agencies to help facilitate outreach to the business sector.

III. Overview of the Final Rule

This final rule incorporates all of the elements required by statute, some additional criteria the Agency expects to consider, clarifications for greater transparency, and additional procedural steps to ensure effective implementation. In response to public comments on the proposal, EPA is, among other things: (1) deleting the pre-prioritization provisions, and committing to further public comment on how the Agency will identify candidates for prioritization, (2) adding direct references in the final regulation to acknowledge the Agency's commitment to implementing the best available science and weight of the scientific evidence provisions in TSCA, and (3) adding a number of provisions to clarify the limited meaning of a priority designation, and committing the Agency to clear and effective communication throughout the process.

EPA 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.

IV. Detailed Discussion of Final Rule and Response to Comments

This unit provides a more in-depth discussion of the provisions in the final rule, public comments received on the proposal, and revisions made to the rule in response. A separate document that summarizes all comments submitted on the proposal and EPA's responses to those comments has been prepared and is available in the docket for this rulemaking (Ref. 2).

A. Policy Objective

The final rule adopts the proposed codification of the policy objective without revision. The prioritization process serves a limited, but important, purpose in the new pipeline of existing chemical review and management to help the Agency identify priorities for further risk evaluation, to ensure that those priorities are grounded in risk-based considerations (which may include, among other considerations, the nature and extent of any existing regulation that is intended to mitigate the hazards of a chemical substance), and to provide the public and interested stakeholders with notice and an opportunity to engage with the Agency and provide relevant information prior to the start of the risk evaluation process on a particular chemical. Through the process of prioritization, EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment. As a general matter, the primary 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. The prioritization process is not intended to be an exact scoring or ranking exercise and, consistent with the proposed rule, EPA is not adopting such a system in this rule. The precise order (e.g., ranking or ordering chemicals based on their hazard and exposure potential) in which EPA identifies High-Priority Substances (all of which must meet the same statutory definition) should not be allowed to slow the Agency's progress towards evaluating the risks from those chemical substances. EPA intends to conserve its resources and the Agency's deeper analytic efforts for the actual risk evaluation.

Low-Priority Substance designations serve the same policy objectives. Chemical substances with low hazard and/or exposure potential that meet the definition of Low-

Priority Substances are taken out of consideration for further assessment. This gives the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent, and provides some insight into which chemical substances are likely not to need additional evaluation and risk management under TSCA. As a policy matter, EPA is committed to making Low-Priority designations on an ongoing basis beyond the statutory minimum.

B. Scope of Designations

Consistent with the proposed rule, 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. The statute is clear that EPA is to designate the priority of the "chemical substance" – not a condition of use for a chemical substance. See, e.g., 15 U.S.C. §§ 2605(b)(1)(A) ("the Administrator shall establish, by rule, a risk-based screening process, including criteria for <u>designating chemical substances as high-priority substances</u> for risk evaluations")(emphasis added); 2605(b)(1)(B) (definitions of high and low priority chemical substances.)

Public comments on the proposed rule were split with respect to this issue. Some commenters suggested that EPA should designate a specific use of a chemical substance as High-Priority or a Low-Priority. In general, these commenters argued that EPA should focus only on chemical "uses of greatest concern," in order to conserve EPA resources, raising concern that EPA would be unable to meet its statutory deadlines by focusing so broadly. These commenters argue that nothing in the statute would foreclose this interpretation, and that EPA's reading of the statute to require designation of "chemical substances" as either High or Low-Priority is strained. One commenter pointed to the

"sentinel exposure" provision in the risk evaluation context as evidence that Congress envisioned such a partial, use-based approach.

EPA disagrees that the statutory text would support such an interpretation for purposes of prioritization. The statute directs EPA to make prioritization determinations on a "chemical substance" or "substance," not on "uses," see, e.g., 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to "the conditions of use." Had Congress intended EPA to designate individual uses as high or low priority, the statute would have used a different phrase or would have otherwise clearly directed EPA to make determinations on high or low priority "uses." The clearest support for EPA's interpretation is found in the statutory definitions of a High and Low Priority Substance. Note, first, that these are definitions of high and low priority "substances." More critically, the definitions themselves make clear that Congress intended EPA to prioritize the chemical as a whole, rather than to prioritize particular uses or subsets of uses. A High Priority substance is one that presents "<u>a potential hazard and a potential route of exposure</u> under <u>the conditions</u> of use;" in other words, the statute directs that the *substance* is High Priority based on a potential risk from a single one of the chemical's various conditions of use. Similarly, the statute directs that EPA can only designate a substance as low priority if "such *substance* does not meet the standard…for designating a chemical substance a high-priority substance."

More generally, EPA believes the addition of the phrase "the <u>conditions</u> 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 more inclusive approach to chemical substance management. Note that the phrase is plural, rather than singular

(conditions, not condition). While under the definition of "conditions of use," the Administrator retains some discretion to "determine" the conditions of use for each chemical substance, that discretion is not unfettered. As EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of determining in a risk evaluation whether a chemical substance – not just individual uses or other individual activities – presents an unreasonable risk. In that regard, EPA will be guided by its best understanding, based on legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations.

However, this does not mean that in prioritization, EPA will necessarily consider every activity involving the chemical substance to be a "condition of use." TSCA defines a chemical's "conditions of use" 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(4). As discussed at greater length in the final rule addressing procedures for chemical risk evaluation under TSCA (RIN 2070-AK20), published elsewhere in this issue of **Federal Register**, based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities generally should not be considered to be "conditions of use."[1] Thus early in the prioritization process, EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance. A proposed determination would be

[1] In the Risk Evaluation rule published elsewhere in this issue of the **Federal Register**, EPA is adopting other revisions that are applicable solely to the risk evaluation process, based on statutory provisions that are exclusive to risk evaluations.

presented for public comment as part of the proposed designation of the substance as High- or Low-Priority.

Accordingly, those activities that the Administrator determines fall within the definition of "conditions of use" will be considered during prioritization. When publishing proposed and final priority designations pursuant to 40 CFR 702.9 and 40 CFR 702.11, the Agency 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. A chemical substance can only be designated as a Low-Priority if the "conditions of use" (as determined by the Administrator) do not meet the standard for High-Priority designation.

C. Timeframe

TSCA section 6(b)(1)(C) requires that the prioritization process be completed in no fewer than 9 months and no greater than 12 months. Accordingly, the final rule specifies that the process—from initiation to final designation—shall last between 9 and 12 months. EPA received no significant comments on these timeframes, which are statutorily mandated. However, some commenters requested that EPA clarify the points of initiation and completion. Consistent with the proposal, initiation of the prioritization process, for purposes of this timeframe, begins upon publication of a notice in the **Federal Register** that identifies a chemical substance for prioritization. Similarly, the prioritization process is complete upon publication of a notice in the **Federal Register** announcing a final priority designation. The publication of a notice announcing a final designation of a chemical as a High-Priority Substance simultaneously initiates a risk evaluation pursuant to TSCA section 6(b)(4).

As indicated in the proposed rule, 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 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). EPA is including in the final rule several provisions from the proposal with respect to categories of chemical substances, without revision. EPA is including, 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. Finally, several commenters asked for clarification with respect to how EPA might define a category of chemical substances. EPA is not adopting a regulatory definition of a category, as the term is defined in TSCA at 15 U.S.C. 2625(c)(2)(A). However, should EPA determine to prioritize a category of chemical substances, EPA would describe the basis for such a determination in the **Federal Register** notice published to initiate prioritization. As discussed elsewhere in this preamble, EPA has revised the regulation at 40 CFR 702.7(b) to state that as part of the initiation notice, EPA will provide an explanation of the rationale for initiating the

process on the chemical substance, thus ensuring the public has notice and an opportunity to comment on any decision to prioritize a category of chemical substances.

As defined in 15 U.S.C. 2625(c), a category of chemical substances means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

EPA proposed to include a consideration of substitutes at the candidate selection phase. This consideration was deleted from the final rule for the reasons discussed in Unit IV(J).

E. Metals and Metal Compounds

A number of commenters expressed concern that EPA may choose not to apply the March 2007 Framework for Metals Risk Assessment when prioritizing metals or metal compounds. The commenters were concerned that metals and metal compounds have unique attributes that are different from organic and organometallic substances, which necessitate special considerations when assessing their human health and ecological risks. TSCA mandates use of the "Framework for Metals Risk Assessment" to account for these attributes. Commenters' concerns stem from a statement in EPA's proposed rule that it would consider "relevant considerations" from this document "as appropriate" when prioritizing chemicals.

EPA fully recognizes the special attributes and behaviors of metals and metal compounds, and the mandate to use the Framework document. EPA did not intend the words "as appropriate" and "relevant considerations" to suggest that EPA was seeking to avoid that mandate or to otherwise diminish the significance of those considerations. Accordingly, EPA revised the final rule to strike those words and eliminate the confusion.

However, EPA notes that TSCA does not contemplate completion of a full risk assessment during the prioritization phase. As the Metals Framework is intended to guide EPA in conducting a risk assessment on a metal or metal compound, the phrase "as appropriate" was merely intended to reflect that no risk assessment would be conducted at this phase, and thus certain sections of the Framework specific to conducting risk assessments would not be relevant. In the context of prioritization, EPA 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 Framework document. For example, the document's Key Principles discuss the differences between inorganic metals and organic and organometallic compounds, and the unique attributes, properties, issues, and processes associated with metals and metal compounds. Nevertheless, to avoid confusion, EPA has deleted the phrase "as appropriate" from the regulation.

F. Chemicals Subject to Prioritization

EPA is adopting these provisions from the proposal without revision. Some commenters encouraged EPA to exclude certain groups of chemicals from prioritization altogether, such as new chemicals recently reviewed under TSCA section 5 and

"inactive" chemicals. Congress intended prioritization to be a public and transparent process of determining which chemicals on the TSCA Inventory deserve further evaluation. EPA does not believe TSCA allows EPA to simply exclude chemical substances from this process. Chemical substances that do not warrant risk evaluation would instead be proposed as Low-Priority Substances, and the public given an opportunity to comment on that determination through the procedures in this final rule.

With respect to 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), EPA expects that such chemical substances are not likely to be selected as early High-Priority candidates in light of the risk-related determination that the Agency must make pursuant to TSCA section 5(a)(3). Chemicals that are designated as "inactive" pursuant to the Active/Inactive Inventory rule (RIN 2070-AK24) are still chemicals substances on the TSCA Inventory, and therefore subject to prioritization. Nothing in TSCA prohibits EPA from initiating the prioritization process on an "inactive" chemical substance and ultimately from designating the priority of that chemical substance. However, similar to chemical substances newly added to the TSCA Inventory, such chemicals may be less likely to be selected as early High-Priority candidates. Whether or not a chemical substance is actively manufactured would generally be relevant to informing EPA's exposure judgments during the prioritization process.

G. Section 26 Scientific Standards

The proposed rule explained that EPA did not need to specifically reference or incorporate statutory requirements in the proposed rule in order for them to have effect. A number of commenters opined on EPA's lack of reference to the new scientific

standards in section 26 of TSCA. Some encouraged EPA to broadly address how the new scientific terms apply to prioritization decisions/process, and to acknowledge the role of section 26 in the prioritization process. Commenters were split on whether and how EPA should further define some of these terms.

As a matter of practice, EPA 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 proposal, EPA has determined to make a number of additions to the final rule to ensure that the science standards in TSCA are more explicitly incorporated into the prioritization process. Specifically, the final rule states that EPA's proposed priority designations under 40 CFR 702.9 and final priority designations under 40 CFR 702.11 will be consistent with the scientific standards in 15 U.S.C. 2625(h) and the weight of the scientific evidence in 15 U.S.C. 2625(i). 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.

H. Definitions

The final rule incorporates a number of key definitions. As in the proposed rule, the final rule includes a definition of High-Priority Substances and Low-Priority Substances. 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. A 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.

EPA also incorporated the statutory definition of conditions of use at 15 U.S.C. 2602(4). Conditions of use means 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.

EPA further incorporated the statutory definition of potentially exposed or susceptible subpopulation at 15 U.S.C. 2602(12). Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

Finally, in response to comments that favored a definition of "reasonably available information," EPA incorporated the definition proposed in EPA's risk evaluation rule with some modifications to be consistent with the definition in the final risk evaluation rule. In the final rule, reasonably available information means 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 under 15 U.S.C. 2613. Several commenters encouraged EPA to take full advantage of its new information gathering authorities and

not limit the basis of its decisions to "existing" information. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be generated through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. Thus, the final rule modifies the definition of "reasonably available information" to delete the word "existing." Note that EPA will, as appropriate, also require longer-term testing, and at times will need to do so to more completely consider the hazard characteristics and exposure pathways of a chemical substance. However, EPA does not think information that could be generated through such testing should be viewed as "reasonably available". Ultimately, EPA will tailor its information gathering efforts. Further, the addition of the reference to confidential business information was intended to clarify that information in EPA's possession that is confidential business information under 15 U.S.C. 2613 is also "reasonably available."

I. Pre-Prioritization Considerations

EPA received a significant number of comments regarding the pre-prioritization phase (§702.5 in the proposed rule) included in the proposed rule. As EPA noted in the proposal, TSCA does not require EPA to articulate in the prioritization rulemaking its expected activities before prioritization, including those related to information gathering or putting chemicals into some type of queue for input into the prioritization pipeline. However, in an attempt to be more transparent about these expected activities, EPA included in the proposal some considerations for identifying both potential High- and Low-Priority candidates, and general hazard and exposure considerations.

While commenters generally supported the concept and importance of pre-prioritization activities, most took issue with the level of detail and criteria in EPA's proposed rule and the expected lack of transparency with respect to EPA's implementation, and most expressed a strong desire to increase public participation and opportunities for comment during the pre-prioritization phase. A number of commenters stated that the Agency's proposed pre-prioritization process was lacking sufficient detail, and that they were not able to provide meaningful comment. In short, the details of implementing pre-prioritization activities were the subject of widely differing, and often irreconcilable views by commenters.

For these reasons, EPA does not believe it would be appropriate to attempt to finalize a pre-prioritization process without further discussions with interested stakeholders. As such, EPA has determined to defer a final decision on the proposed pre-prioritization provisions as part of this rule, and finalize at this time only the prioritization process required under TSCA. The Agency will promptly initiate an additional stakeholder process, to include an additional public comment opportunity addressing EPA pre-prioritization activities. EPA is fully committed to further dialogue on best practices for pre-prioritization activities, and to carrying out these activities in a transparent, science based manner, to ensure successful implementation of the prioritization and risk evaluation processes.

Further, EPA appreciates the time commenters spent developing and sharing their views on this particular subject. Commenters should rest assured that these comments have been informative to the Agency and will be considered as EPA continues to implement the recent amendments to TSCA. EPA expects to re-engage the public on this

matter as early as Fall 2017, and these comments will serve as a solid foundation for those discussions.

Following the additional stakeholder process, and in consideration of public comments received, EPA will issue an appropriate final action. While it is premature to determine the outcome of this future process, it could foreseeably result in EPA formally establishing pre-prioritization procedures in a final rule - either by first re-proposing, or by finalizing based on the proposed rule. Alternatively, for example, EPA may issue a guidance document that further describes the pre-prioritization process. EPA will promptly evaluate public comments received in response to the additional stakeholder process and take the appropriate next steps. In the interim, the Agency fully expects to move forward with prioritizing chemicals in accordance with the procedures of the final rule. Indeed, TSCA compels the Agency to proceed with designating a certain number of chemicals as High- or Low-Priority by December of 2019. 15 U.S.C. 2605(b)(2)(B). Pre-prioritization is not statutorily mandated, and, as a legal matter, not a necessary precursor to the designation of High- and Low-Priority substances. Pre-prioritization was intended to be a phase of expected activities (e.g., potential candidate identification, information gathering/review, etc.) to ensure a smooth process of moving chemicals through the new pipeline of prioritization, risk evaluation, and (where warranted) risk management. To illustrate, the Agency could, as a general matter, draw potential candidates for prioritization from existing Agency resources (including but not limited to, the 2014 update of the TSCA Work Plan for Chemical Assessments (Ref. 3) and the Safer Chemicals Ingredients List (Ref. 4)). However, until EPA takes final action on pre-prioritization as discussed above, the Agency will not follow a formal process that

identifies a chemical as being "in pre-prioritization."

J. Information Availability

EPA expects to consider the existence and availability of risk-related information on a candidate chemical substance before initiating the prioritization process. EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, and then immediately initiate a risk evaluation for a High-Priority Substance, and complete the risk evaluation within three years of initiation. As a general practice, EPA intends to resolve any concerns it may have about the sufficiency of information about a given chemical substance for purposes of prioritization, relative to the considerations in §702.9(a), before subjecting that chemical substance to the prioritization process. Should EPA identify a critical data need after the prioritization process has already begun, it may be difficult or impossible for the Agency to develop or acquire the necessary information, consistent with statutory deadlines for prioritization. Although EPA will not establish or implement a minimum information requirement of broader applicability, the Agency anticipates that the types of information that are helpful to inform and support prioritization decisions will become clearer as the Agency gains experience with the prioritization process while also allowing for advances in science and information gathering.

Commenters argued that EPA should not overuse its information gathering authorities for a particular chemical before that chemical has been identified as a High-Priority Substance for risk evaluation. To avoid confusion, EPA has deleted several references to ensuring sufficient information for purposes of risk evaluation at the prioritization stage. While EPA has broad authorities to gather and require generation of

information, EPA 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 expects to review and consider the reasonably available existing hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete the prioritization process within the statutory deadlines. To the extent the information is not currently available or is insufficient, EPA will determine on a case-by-case basis how to best proceed to ensure that information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner.

To further clarify this intent, EPA has modified the final rule to indicate that EPA generally expects to use a tiered approach to information gathering. As a general matter, a tiered approach to data gathering first involves a review of existing literature and available information by EPA to determine data needs. EPA is also mindful of its requirements with respect to the reduction of testing on vertebrate animals under 15 U.S.C. 2603(h). For identified data needs, EPA may issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed, as necessary, by exercise of EPA's authorities under TSCA to require submission or generation of new data.

K. Candidate Selection

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. 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 this statutory directive, all TSCA Work Plan chemical substances will eventually be prioritized. These preferences are incorporated into the final rule during candidate selection at 40 CFR 702.5(c), without revision from the proposal. Aside from these statutory preferences, however, TSCA does not specifically limit how EPA must ultimately select a chemical substance to put into the prioritization process.

As described in the proposed rule, in practice, EPA expects to select for High-Priority Substances those chemicals with the greatest hazard and exposure potential first, consistent with the policy objectives codified in 40 CFR 702.5(a). EPA has not revised the regulatory text at 40 CFR 702.5(c) to include additional preferences.

The proposed rule included a statement that EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order. EPA is striking this statement. Some commenters encouraged EPA to adopt such a system and EPA is retaining the discretion to do so by rule in the future. EPA does not believe the statement in the proposed rule was necessary or had any legal effect, since nothing in the rule or TSCA requires EPA to implement an ordering or ranking system in selecting candidate chemical substances for prioritization.

The proposed rule included a general objective for identifying candidates for High-Priority Substances. In response to comments that EPA more explicitly recognize Low-Priority designations as part of the process, the final rule now includes a general objective for selecting candidates for Low-Priority, consistent with the statutory definition for Low-Priority Substances. As defined in TSCA, Low-Priority Substances

are those for which risk evaluation is not warranted at this time. 15 U.S.C. § 2605(b)(1)(A). As described in the final rule, 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.

EPA included in its proposed rule a general statement that EPA "may consider the relative hazard and exposure of potential candidate's substitutes" in selecting a chemical for prioritization. Some commenters believe strongly that EPA should not consider substitutes as part of the prioritization phase because it is a consideration more appropriate for the risk management phase. Others had concern that considering the relative risk of substitutes had the potential to lead to unlawful consideration of the availability of substitutes at this phase – a non-risk factor the commenters assert is expressly excluded from consideration during the prioritization process. Several commenters expressed general support for consideration of substitutes to the extent that it could help to avoid regrettable substitution, and conserve both Agency and industry time and resources that would result from inappropriate switches to other dangerous chemicals. EPA has stricken the provision in question from the final rule. EPA agrees that the consideration of alternatives is most appropriately considered as part of any risk management rule.

L. Initiation of Prioritization

The prioritization process officially begins, for purposes of triggering the 9 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). This was in response to commenters' concerns that initiation of the prioritization process could send strong signals to the public regarding potential risks, even if certain uses of that chemical did not prompt the initiation of prioritization. Note that a proposed priority designation, as EPA clarified in the final rule, is not a finding of unreasonable risk by the Agency.

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 are welcome and encouraged during this time to submit information relevant to the chemical substance. Because TSCA specifically requires the prioritization process to be risk-based and EPA's determinations to exclude non-risk factors, relevant information at this stage is limited to that which is risk-related.

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 this initial 90-day public comment period. A number of commenters expressed concern that the proposed rule did not guarantee any opportunity for public comment prior to the screening review, and many felt strongly that the Agency needed to engage the public to inform prioritization decisions. The shift in

timing puts the screening review squarely within the prioritization process and affords the public an opportunity to inform EPA's screening review before that review. Thus, commenters are encouraged to submit relevant information that may inform EPA's screening review. EPA will consider all relevant information received during this comment period.

M. 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). 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. The Agency will develop guidance, consistent with OMB's *Final Bulletin for Agency Good Guidance Practices* (72 FR 3432, January 25, 2007), to describe the implications of the criteria and considerations and to explain how EPA generally expects to apply them during the screening review step.

The final rule also includes an additional criterion, consistent with the proposal: (7) other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority. As explained in the proposal, this final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks. Should EPA rely on this criterion to support a proposed designation, EPA

would describe in the publication of proposed designation the specific factors considered for such designation, thereby affording the public notice and an opportunity to comment on the basis for the proposed designation under this criterion. The screening review is not a risk evaluation, but rather a review of reasonably available information on the chemical substance that relates to the screening criteria. EPA expects to review all sources of relevant information, consistent with the scientific standards in 15 U.S.C. 2625(h), while conducting the screening review.

N. Proposed Designation

Based on the results of the screening review, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, as those terms are defined in 40 CFR 702.3. In making this proposed designation, as directed by the statute, EPA will not consider costs or other non-risk factors.

The final 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. Pursuant to 15 U.S.C. 2625(j), EPA shall make this information available to the public in the docket, subject to 15 U.S.C. 2613. Publication of this notice begins a second period of public comment for 90 days, during which time the public may submit comments on EPA's proposed designation. EPA will reopen the same docket opened upon initiation of the prioritization process to facilitate receipt of comments and information. 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 comments on the

accuracy of scope-related information such as the chemical's "conditions of use," at this step.

In the event of insufficient information at the proposed designation step, the proposed rule required EPA to propose to designate the chemical as a High-Priority Substance. A number of commenters felt that a "default" to High-Priority Substance would be an unfair result for affected industries and/or irresponsible action by the Agency. This provision has largely been stricken from the final rule, except for the circumstance that is explicitly required in 15 U.S.C. 2505(b)(1), which is now described in 40 CFR 702.9(e). TSCA 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). On further consideration, EPA believes the Agency is charged by the statute, 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. EPA notes that the statute specifically prohibits a default to Low-Priority, requiring 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).

In response to a number of concerns raised by public commenters, EPA is striking the "issue preclusion" provision related to proposed designations as Low-Priority Substances, which stated that all comments that could be raised on the issues in the proposed designation must be presented during the comment period, or would be

considered waived and could not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding. Under general principles of administrative law, commenters are required to identify relevant available information and raise objections that could be raised during established comment periods, and courts generally will require commenters to have done so as a matter of exhaustion of administrative remedies. EPA has concluded that these principles provide sufficient assurance that commenters will raise timely objections and provide timely information and has therefore decided to strike the proposed regulatory text.

Although the final rule makes other clarifications to the "Proposed Priority Designation" provision, the standard for designating High- and Low-Priority Substances has not changed from the proposed rule. EPA will prioritize a "chemical substance," and the standard for a High-Priority Substance (". . . may present an unreasonable risk [. . .] because of a potential hazard and a potential route of exposure . . .") can be met by identification of one or more condition of use that meet that standard. Conversely, in designating a Low-Priority Substance (". . . based on sufficient information, such substance does not meet the standard for [. . .] a high-priority substance . . ."), TSCA requires EPA to determine that under none of the conditions of use, as determined by the Administrator, does the chemical substance meet the definition of a High-Priority Substance.

O. Final Priority Designation

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. EPA will consider additional relevant information received during the proposed designation

step before finalizing a priority designation, excluding any consideration of costs or other non-risk factors. The final rule specifies that EPA will publish a notice of the final priority designation in the **Federal Register**, using the same docket that was used for the initiation and proposal steps.

EPA has included additional regulatory text in the final rule, clarifying that EPA would publish an identification of information, analysis, and basis used to support the final designation, as required under 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. This was made in response to some concerns that a priority designation for a chemical substance could send strong signals to the public regarding potential risks.

P. 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 generally expects to 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.

A few commenters suggested that EPA define a "reasonable time" for these purposes. Commenters expressed concern that, in the absence of a defined period of time, a completed risk evaluation may never be replaced with a new High-Priority Substance, slowing the pace of EPA's overall progress towards reviewing the backlog of existing chemicals. EPA has determined not to include a specific time frame in the regulation that may be too prescriptive to implement. However, as a general matter, EPA expects to designate a new High-Priority Substance no later than 45 days following completion of a risk evaluation.

Q. 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. 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. This does not preclude EPA from later revising the designation, if warranted. EPA has added a provision in the final rule clarifying that a final priority designation is neither a finding of unreasonable risk to health or the environment, nor a finding of no unreasonable risk.

A Low-Priority Substance designation is explicitly subject to judicial review. 15 U.S.C. 2618(a)(1)(C). A High-Priority Substance designation is not a final agency action and is not subject to judicial review. Rather, a High-Priority Substance designation prompts the initiation of a risk evaluation. 15 U.S.C. 2605(b)(4). Upon the conclusion of such a risk evaluation, EPA may determine that a chemical substance does not present an

unreasonable 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. 15 U.S.C. 2605(i). If EPA conversely 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. TSCA mandates that the Agency must issue a rule to apply certain requirements so that the chemical substance or mixture no longer presents the unreasonable risk. 15 U.S.C. 2605(a). Such a final rule is a final agency action and is subject to judicial review.

R. 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 that is reasonably available to the Agency. The final rule outlines the process the Agency will take to revise such a designation. Essentially, the revision process involves restarting the prioritization process, and applying the provisions in the same way they would apply to a chemical that has not been previously prioritized.

TSCA does not require a process for revising a High-Priority Substance to a Low-Priority, and the final rule does not provide for such revision. This is for good reason. Prioritization serves a limited purpose: to identify chemicals for further evaluation. Once a chemical has been identified as a High-Priority Substance, the risk evaluation begins, the priority designation of the chemical having served its purpose, and EPA is compelled to complete that risk evaluation within a statutory 3-year deadline. Moreover, because the risk evaluation is already underway at this point, EPA believes it would not make

sense to revisit whether or not a risk evaluation is warranted. EPA believes Congress intended EPA to see the risk evaluation process through to its conclusion and to make a finding under 15 U.S.C. 2605(i) that the substance does not pose an unreasonable risk, not to revise a priority designation.

S. Small Business Outreach

A few commenters recommended that EPA conduct targeted outreach to small businesses early in the process of prioritization to identify impacts to small businesses. Commenters suggest that the small business community could benefit from background information on EPA's activities, while EPA could receive valuable input from relevant small businesses.

EPA welcomes the opportunity to engage with small businesses that may use the subject chemical during the prioritization process, particularly during the two 90-day public comment periods built into the prioritization procedural rule, and will provide current information about these activities through the Agency's website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca*. EPA also expects to work closely with its federal partners at the Small Business Administration, Office of Advocacy as a means to engage with the small business community. TSCA mandates that both the prioritization and risk evaluation processes be risk-based. As such, EPA would be most interested in learning from small businesses and other stakeholders about a particular chemical's uses, and potential hazards and exposures. Economic impacts of any potential future regulation have an important role during the consideration of risk management measures, if and when warranted, but TSCA explicitly excludes consideration of these impacts during prioritization and risk evaluation actions.

V. 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. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act; Proposed Rule. **Federal Register** (82 FR 4825, January 17, 2017) (FRL-9957-74).

2. EPA. *Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA: Response to Public Comments*; SAN 5943; RIN 2070-AK23; EPA-HQ-OPPT-2016-0636. 2017.

3. 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.*

4. 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.*

VI. 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. This action is not subject to the requirements of Executive Order 13771, entitled *Reducing Regulation and Controlling Regulatory Costs* (82 FR 9339, February 3, 2017), because this action does not impose any costs.

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.

VII. Congressional Review Act (CRA)

This rule is exempt from the CRA, 5 U.S.C. 801 *et seq.*, because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical substances, Hazardous substances, Health and safety, Prioritization, Screening, Toxic substances.

Dated: June 22, 2017.

E. Scott Pruitt,
Administrator.

Therefore, 40 CFR chapter I, subchapter R, is 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
702.4 [Reserved]
702.5 Candidate Selection
702.7 Initiation of Prioritization Process
702.9 Screening Review and Proposed Priority Designation
702.11 Final Priority Designation
702.13 Revision of Designation
702.15 Effect of Designation as a Low-Priority Substance
702.17 Effect of Designation as a High-Priority Substance

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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 uses 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 702.7.

(e) *Metals or metal compounds*. In identifying priorities for chemical substances that are metals or metal compounds, EPA will use 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 15 U.S.C. 2605(b)(4)(C).

(g) *Scientific standards and weight of the scientific evidence*. EPA's proposed priority designations under 40 CFR 702.9 and final priority designations under 40 CFR 702.11 will be consistent with the scientific standards provision in 15 U.S.C. 2625(h) and the weight of the scientific evidence provision in 15 U.S.C. 2625(i).

(h) *Interagency collaboration.* EPA will consult with other relevant Federal Agencies during the administration of this subpart.

§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.

Reasonably available information means information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines specified in 15 U.S.C. 2605(b) for prioritization and risk evaluation. Information that meets such terms is reasonably available information whether or not the information is confidential business information that is protected from public disclosure under 15 U.S.C. 2613.

Conditions of use means 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.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of

adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

§ 702.4 [Reserved].

§ 702.5 Candidate Selection.

(a) 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 reasonably available information on the relative hazard and exposure of potential candidates. In selecting candidates for Low-Priority Substance designation, it is EPA's general objective to select those chemical substances with hazard and/or exposure characteristics under the conditions of use such that a risk evaluation is not warranted at the time 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.

(b) *Available information.* EPA expects to ensure that there is reasonably available information to meet the deadlines for prioritization under the Act.

(c) *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 702.11.

(d) *Purpose.* The purpose of the preferences and criteria in subsections (a) through (c) of this section is to inform EPA's decision whether or not to initiate the prioritization process pursuant to 40 CFR 702.7, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to 40 CFR 702.9.

(e) *Insufficient information.* If EPA believes it would not have sufficient information for purposes of prioritization, EPA generally expects to obtain the information necessary to inform prioritization prior to initiating the process pursuant to 40 CFR 702.9, using voluntary means of information gathering and, as necessary, exercising its authorities under the Act in accordance with the requirements of 15 U.S.C. 2603, 15 U.S.C. 2607, and 15 U.S.C. 2610. In exercising its authority under 15 U.S.C. 2603(a)(2), EPA will identify the need for the information in accordance with 15 U.S.C. 2603(a)(3).

§702.7 Initiation of Prioritization Process.

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that the information necessary to prioritize the substance is reasonably available.

(b) EPA will initiate prioritization by publishing a notice in the **Federal Register** identifying a chemical substance for prioritization. EPA will include a general explanation in this notice for why it chose to initiate the process on the chemical substance.

(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) Publication of the 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 that may inform the screening review conducted pursuant to 40 CFR 702.9(a). EPA will open a separate docket for each chemical substance to facilitate receipt of information.

(e) EPA may, in its discretion, extend the public comment period in paragraph (d) 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).

§702.9 Screening Review and Proposed Priority Designation.

(a) *Screening review*. Following the close of the comment period described in 702.7(d), including any extension pursuant to paragraph (e) of that section, EPA will

generally use reasonably 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) Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

(b) *Information sources*. In conducting the screening review in paragraph (a) of this section, EPA expects to consider sources of information relevant to the listed criteria and consistent with the scientific standards provision in 15 U.S.C. 2625(h), 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).

(c) Based on the results of the screening review in paragraph (a), relevant information received from the public as described in 40 CFR 702.7(d), and other information as appropriate and consistent with 15 U.S.C. 2625(h) and (i), EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, along with an identification of the information, analysis, and basis used to support the proposed designation.

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

(e) If information remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance after any extension of the initial public comment period pursuant to 40 CFR 702.7(e), EPA will propose to designate the chemical substance as a High-Priority Substance.

(f) EPA will 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 one or more activities that the Agency determines constitute conditions of use. EPA will propose to designate a chemical substance as a Low-Priority Substance based on the proposed conclusion that the chemical substance meets the definition of Low-Priority Substance in 40 CFR 702.3 under the activities that the Agency determines constitute conditions of use.

(g) 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.

§702.11 Final Priority Designation.

(a) After considering any additional information collected from the proposed designation process in 40 CFR 702.9, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance consistent with 15 U.S.C. 2625(h) and (i).

(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**, along with an identification of the information, analysis, and basis used to support a final designation consistent with 15 U.S.C. 2625(h), (i) and (j). For High-Priority Substance designations, EPA generally expects to indicate which condition(s) of use were the primary basis for such designations.

(d) As required in 15 U.S.C. 2605(b)(3)(C), 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.

§ 702.13 Revision of Designation.

EPA may revise a final designation of a chemical substance from Low-Priority to High-Priority Substance at any time based on reasonably available information. To revise such a designation, EPA will re-initiate the prioritization process on that chemical substance in accordance with 40 CFR 702.7, re-screen the chemical substance and propose a priority designation pursuant to 40 CFR 702.9, and finalize the priority designation pursuant to 40 CFR 702.11.

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

Designation of a chemical substance as a Low-Priority Substance under 40 CFR 702.11 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 702.13, if warranted. Designation as a Low-Priority Substance is not a finding that the chemical substance does not present an unreasonable risk, but rather that it does not meet the High-Priority Substance definition.

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

Final designation of a chemical substance as a High-Priority Substance under 40 CFR 702.11 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 until the date of promulgation of the associated final rule under section 6(a). Designation as a High-Priority Substance is not a finding that the chemical substance presents an unreasonable risk.

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