

# OFFICE OF ADVOCACY

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The Honorable Scott Pruitt  
Administrator  
United States Environmental Protection Agency  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460-001

**Re: Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act and Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; Docket Nos. EPA-HQ-OPPT-2016-0636, EPA-HQ-OPPT-2016-0654**

Dear Administrator Pruitt:

The U.S. Small Business Administration's (SBA) Office of Advocacy (Advocacy) submits the following comments in response to two of the Environmental Protection Agency's (EPA) proposed rules, "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act"<sup>1</sup> and "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act."<sup>2</sup> Small businesses have expressed concerns regarding the consideration of small businesses issues in the two processes proposed by the agency. Small businesses also expressed the need for transparency and increased communication from the agency as it moves chemicals under its pipeline approach from prioritization to risk evaluation to any potential risk management. Advocacy urges EPA to carefully address these small business concerns.

**The Office of Advocacy**

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily

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<sup>1</sup> 82 Fed. Reg. 4825 (January 17, 2017).

<sup>2</sup> 82 Fed. Reg. 7562 (January 19, 2017).



reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),<sup>3</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>4</sup> gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives. EPA is required by the RFA to conduct a SBREFA panel to assess the impact of the proposed rule on small entities,<sup>5</sup> and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.<sup>6</sup> The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.<sup>7</sup>

## **Background**

The Toxic Substances Control Act (TSCA)<sup>8</sup> was recently amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.<sup>9</sup> Under the amended TSCA, EPA is required to establish the process and criteria for prioritizing chemical substances for risk evaluation.<sup>10</sup> The amended TSCA also requires the agency to establish a process to conduct the risk evaluation.<sup>11</sup>

On January 17, 2017, EPA proposed to establish a risk-based screening process and criteria to use in identifying chemical substances as either High-Priority Substances for risk evaluation or Low-Priority Substances that will not require a risk evaluation. Prioritization is the first step under the new TSCA in determining unreasonable risks. The proposal includes 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.

On January 19, 2017, EPA proposed to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk under TSCA Section 6. Risk evaluation is the second step, after a rule has been designated as a High-Priority Substances under the Prioritization process described above. The proposed components of the risk

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<sup>3</sup> 5 U.S.C. §601 et seq.

<sup>4</sup> Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

<sup>5</sup> Under the RFA, small entities are defined as (1) a "small business" under section 3 of the Small Business Act and under size standards issued by the SBA in 13 C.F.C. § 121.201, or (2) a "small organization" that is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field, or (3) a "small governmental jurisdiction" that is the government of a city, county, town, township, village, school district or special district with a population of less than 50,000 persons. 5 U.S.C. § 601.

<sup>6</sup> Small Business Jobs Act of 2010 (PL. 111-240) §1601.

<sup>7</sup> *Id.*

<sup>8</sup> 15 U.S.C. § 2601 et seq. (1976)

<sup>9</sup> Pub. L. 114-182 (June 22, 2016).

<sup>10</sup> 15 U.S.C. § 2605(b)(1).

<sup>11</sup> *Id.* § 2605(b)(4).

evaluation process include scope, hazard assessment, exposure assessment, risk characterization, and a risk determination. EPA is required to finalize both rules by June 2017.

EPA has certified that there is no significant economic impact on a substantial number of small entities for both rules. For the procedural rule for prioritization, EPA does not estimate any impact on small businesses because it describes the regulation impacting only its internal processes. For the procedural rule for chemical risk evaluation, EPA explains that although this rule is also primarily for internal procedures, there are minimal impacts on small entities due to the manufacturer requests for conducting risk evaluations.

### Advocacy Involvement in the Rulemaking Process

Throughout the rule development process Advocacy engaged with EPA and the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) as well as with small businesses and small business representatives. In addition, following the publication of the proposed rule, Advocacy held a roundtable on February 17, 2017 at which EPA presented its proposals.

### Advocacy's comments

#### **I. EPA Should Provide For the Specific Consideration of Small Business Input by Engaging in Small Business Outreach Early and Throughout Its Processes for Chemical Prioritization and Chemical Risk Evaluation**

Advocacy commends EPA for including Advocacy in its interagency collaborations in developing the risk evaluation process for the first ten high-priority chemicals. Small business representatives, however, are concerned that the agency did not include any outreach plans to small businesses in both of the proposals to discuss the chemical uses, exposure scenarios, and data that will be used to support a high-priority designation and to develop a risk evaluation. Small business representatives noted that small businesses often have limited resources and employees that may or may not have the expertise or the time to dedicate to tracking a scientific and complicated risk evaluation. Small businesses have expressed concerns that the evaluation and the potential regulations of existing chemicals will impact downstream or end users who are often not readily aware of the presence of a chemical use in their process or product.

### *Recommendation*

Advocacy recommends that EPA inform and engage small businesses early and throughout the process of prioritization and chemical evaluation by planning specific targeted outreach. Specifically, the agency should make concerted efforts to identify and contact small businesses that would be covered by the conditions of use of the chemical being considered for prioritization and any subsequent risk evaluation. In particular, EPA should provide background information and plan to solicit input from the relevant small businesses early in the prioritization phase and engage small businesses throughout the various stages of the risk evaluation.

## **II. EPA Should be Transparent and Provide Consistent and Clear Communication Regarding its Consideration of Chemicals for Prioritization and Methods of Risk Evaluation**

Small business representatives have stressed the importance of transparency and communication in both the process for chemical prioritization and risk evaluation. In the procedure for chemical prioritization, small business representatives have identified the pre-prioritization phase as the most important step. EPA has stated that because of statutory time limits, it may be constrained in addressing information gap issues during the prioritization and or risk evaluation processes and therefore plans to do a significant amount of upfront data gathering and review (i.e., at the pre-prioritization stage). Small business representatives are concerned that, based on the agency's description, the remaining steps will move forward as an administrative process.

Small business representatives have criticized EPA because the agency has not completely developed nor provided a structure for pre-prioritization. For instance, they are concerned that the proposal does not provide important information about when EPA will develop a potential candidate list of chemicals being considered during pre-prioritization phase and how EPA will narrow down its selection to a candidate for high-priority. Small business representatives also noted that it is unclear how the agency will pursue to fill any information gaps to narrow down the selection of its candidate chemical. Further, small business representatives stated that the agency has not identified what it considers to be a data gap or how the agency will communicate whether there is a data gap. During Advocacy's roundtable meeting on this rule, small businesses representatives suggested listing potential candidates on a website and encouraged the agency to informally (via holding a public meeting or through an open docket) seek information and identify data gaps.

Small business representatives also noted that the agency's references (and web links) to its guidance documents for its risk evaluation processes are inadequate and fail to ensure a comprehensive understanding of EPA's approach or method that will be used to evaluate a chemical. Under the amended TSCA, EPA must develop guidance that is necessary to carry out both the prioritization and risk evaluation process.<sup>12</sup>

### *Recommendation*

Advocacy recommends that EPA be transparent in its considerations for designating a high-priority chemical and methods used to conduct a risk evaluation of a chemical. Advocacy also recommends that EPA provide information to the public that is easily accessible and reliable. Advocacy further recommends that the agency issue a unified guidance document that explains the specific process and policies EPA intends to follow to prioritize chemicals and conduct chemical risk evaluations. Specifically, Advocacy recommends that the agency provide more details and other relevant information on its pre-prioritization phase to address the small business concerns above.

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<sup>12</sup> 15 USC 2625(I).

**Conclusion**

Advocacy suggests that EPA include a commitment to engage, through specific outreach, with small businesses early and throughout its processes for both chemical prioritization and chemical risk evaluation. Advocacy also suggests that EPA provide transparency and consistent communication as it analyzes chemicals through its prioritization and risk evaluation processes. Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you.

If you have any questions or require additional information please contact me or Assistant Chief Counsel Tayyaba Waqar at (202) 205-6970 or by email at [twaqar@sba.gov](mailto:twaqar@sba.gov).

Sincerely,



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