CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

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January 19, 2018

VIA ELECTRONIC FILING

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunity for Public Comment, 82 Fed. Reg. 51,415 (November 6, 2017); Docket No. EPA-HQ-OPPT-2017-0585

Dear Administrator Pruitt:

The U.S. Chamber of Commerce (the Chamber), the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and dedicated to promoting, protecting, and defending America's free enterprise system, strongly supports the U.S. Environmental Protection Agency's (EPA's or Agency's) efforts to improve policy and processes relating to the review of new chemicals under the amended Toxic Substances Control Act (TSCA).[1]

I. Background

The Chamber has long supported a high-quality and science-based chemical management and evaluation program. After nearly a decade of reform efforts, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) into law on June 22, 2016. The LCSA amended TSCA for the first time since the statute was enacted in 1976 and provided for much-needed improvements to the chemical management and evaluation program.[2]

The New Chemicals Review Program, as laid out in section 5 of the statute, provides EPA with the authority to review chemicals for safety before they enter the stream of commerce.[3] Under that authority, EPA is required to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such a substance…to the extent necessary to protect against an

[1] New Chemicals Review Program under the Amended Toxic Substances Control Act; Notice of Public Meeting and Opportunity for Public Comment, 82 Fed. Reg. 51,415 (Nov. 6, 2017).
[2] Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016).
[3] 15 U.S.C. § 2604 (1976), as amended by Pub. L. No. 114-182.

unreasonable risk of injury to health or the environment," including potentially exposed or susceptible subpopulations.[4]

The LCSA, however, did not make significant changes to the New Chemicals Review Program. Rather, it simply codified many of the practices and procedures that EPA engaged in prior to enactment of the statute. The New Chemicals Review Program is meant to serve as a screening-level risk assessment prior to the more in-depth risk evaluation a chemical may endure under section 6 of the statute.

The Chamber believes that it is extremely important that EPA work to make the New Chemicals Review Program as efficient, high-quality, and science-based as possible, and applauds the Agency for the outreach efforts that it has held so far in order to achieve that goal. Most recently, EPA held a public meeting on December 6, 2017, to provide stakeholders with an update regarding the implementation of the New Chemicals Review Program under the amended TSCA, specifically touching on two guidance documents – the draft "Points to Consider when Preparing TSCA New Chemical Notifications" and the "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" (collectively, guidance documents) – both made public prior to the meeting.[5]

The Chamber submits these comments in response to that public meeting and appreciates EPA's willingness to engage stakeholders on this important matter. The Chamber believes EPA should strive to develop a New Chemicals Review Program that is as efficient, high-quality, and science-based as possible. Specifically, EPA should continue its progress towards completing premanufacture notice (PMN) determinations as quickly and efficiently as possible, as this will lead to increased predictability and certainty under the New Chemicals Review Program. Meeting this goal incentivizes the development of new chemicals, which is fundamental to U.S. innovation.

II. Congress intended that EPA Review Premanufacture Notices in a Timely Fashion

The Chamber believes that EPA should work to more effectively meet the 90-day window for the New Chemicals Review Program, especially regarding PMNs for new chemicals that will be introduced into the market. Congress intended that EPA meet this schedule, with limited exceptions, as delays can have profound consequences and impacts at all stages in the stream of commerce. Notably, the Senate Report directed EPA to meet that 90-day target whenever possible:

> The Committee notes that…consistent with current law, the Agency should continue the practice of completing new chemical reviews within 90 days to the maximum extent practicable.[6]

Congress also provided a provision in the statute to incentivize EPA's meeting that schedule:

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[4] *Id.* at § 2604(e)(1).
[5] *See* U.S. ENVTL. PROT. AGENCY, DRAFT POINTS TO CONSIDER WHEN PREPARING TSCA NEW CHEMICAL NOTIFICATIONS (NOV. 6, 2017); AND U.S. ENVTL. PROT. AGENCY, NEW CHEMICALS DECISION-MAKING FRAMEWORK: WORKING APPROACH TO MAKING DETERMINATIONS UNDER SECTION 5 OF TSCA (Nov. 2017).
[6] S. Rep. No. 114-67, 114th Cong., 1st Sess. (June 18, 2015) at 14-15.

> If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) [of this title], and the Administrator shall not be relieved of any requirement to make such determination.[7]

When the LCSA was signed into law, Congress effectively "reset" the review clock on approximately 331 PMNs that were under review at the time when it passed the LCSA.[8] This reset created a backlog and related delays in the review process at EPA, which had a negative impact on all affected stakeholders. The number of PMNs in the backlog grew exponentially after that reset, despite EPA having more and more time to adjust to the statutory changes.

EPA claimed that the backlog was temporary, and on August 7, 2017, Administrator Pruitt reported that the backlog had been effectively eliminated.[9] Specifically, he noted that when he was confirmed, "over 600 new chemicals were 'stuck' in the EPA review process" and that the caseload was back at the baseline for the Agency, which typically numbers around 300 cases.[10] Moreover, Administrator Pruitt noted that EPA is committed to a "more predictable and transparent process for making safety determinations through a commitment to following operating principles; continuously improving; and, increasing the transparency in the decision-making for new chemical safety determinations."[11]

According to EPA's January 9, 2018 update on the review process, however, the number of cases under review has since increased to a total of 453 cases under review – 379 with EPA and 74 with submitters.[12] While this number is significantly lower than the amount cited when Administrator Pruitt was confirmed, the Chamber believes that EPA should continue to strive to meet the 90-day goal in a timelier and more effective fashion, as intended by Congress.

III. EPA is Not Adhering to Congressional Intent when Administering the New Chemicals Review Program

Many companies that submit PMNs or exemption notices are experiencing delays that significantly and adversely affect all points in the stream of commerce, using processes that go

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[7] 15 U.S.C. § 2604(a)(4)(A).
[8] Pat Rizzuto, *Rate of EPA Chemical Regulation Ramps Up Since Toxics Law Update*, BLOOMBERG BNA (May 17, 2017), *available at* https://www.bna.com/rate-epa-chemical-n73014451140/ (Statement of American Chemistry Council President Cal Dooley that "the backlog of new chemicals awaiting the agency's approval had doubled from 331 to 658 since the passage of the amended law").
[9] *See* U.S. Envtl. Prot. Agency, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 8, 2017), *available at* https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.
[10] *Id.*
[11] *Id.*
[12] *See* U.S. Envtl. Prot. Agency, Statistics for the New Chemicals Review Program under TSCA (Jan. 9, 2018), *available at* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats.

against congressional intent. For example, EPA has asked companies to waive the time limit without providing additional information as to what specific information is needed to finish the review process, either through a significant new use rule (SNUR) or section 5(e) Consent Order, which in turn places a burden on the submitter to comply with the law and can extend the review period for a PMN well past the original 90-day window. EPA should instead use the 90-day extension provision provided for in the statute.[13] This would at least allow the submitter to commence manufacturing without hindering economic development as EPA completes the review process.

Further, EPA has chosen to interpret "reasonably foreseeable" as "reasonably possible" rather than the more limited "probable" standard previously set forth by the Agency.[14] As a result, EPA has increasingly used SNURs as a means of limiting applications of a chemical, no matter how outlandish they may be. The usage of a SNUR allows the review period for a chemical to remain open until the SNUR is published. As such, the New Chemicals Review Program has taken a step back from the more streamlined and expedited approach that Congress intended.

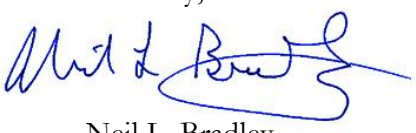
The delays and limited transparency in the review process are further indicative of EPA's overly-conservative approach to hazard and exposure assessments. Under section 5, Congress only intended that EPA find that a substance is "not likely to present" unreasonable risk, rather than the "does not present" an unreasonable risk finding set forth in section 6.[15] This lower bar should allow for an efficient review process, rather than a protracted one.

The new guidance documents certainly aid submitters as to what information should be included in a PMN, but the Chamber believes additional clarity would be beneficial to all parties involved in the New Chemicals Review Program. The Chamber believes it is imperative that these deficiencies are corrected so that the New Chemicals Review Program operates in a more efficient and effective manner.

IV. Conclusion

The Chamber appreciates the opportunity to comment on this important matter, as it is imperative that EPA develop an efficient, high-quality, and science-based New Chemicals Review Program in accordance with TSCA. If you have questions regarding these comments, please contact me at (202) 463-5533 or at environment@uschamber.com.

Sincerely,



Neil L. Bradley

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[13] 15 U.S.C. at § 2604(c).
[14] *See, e.g.*, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,730-31 (July 20, 2017).
[15] *Compare* 15 U.S.C. § 2604(a)(3)(C) *with* 15 U.S.C. § 2605(a).