October 19, 2017

The Honorable John Barrasso
Chairman, Committee on Environment & Public Works

The Honorable Tom Carper
Ranking Member, Committee on Environment & Public Works

The Honorable Greg Walden
Chairman, Committee on Energy & Commerce

The Honorable Frank Pallone, Jr.
Ranking Member, Committee on Energy & Commerce

The Honorable Chuck Grassley
Chairman, Committee on the Judiciary

The Honorable Dianne Feinstein
Ranking Member, Committee on the Judiciary

The Honorable Bob Goodlatte
Chairman, Committee on the Judiciary

The Honorable John Conyers, Jr.
Ranking Member, Committee on the Judiciary

Re: EPA's Implementation of TSCA and the Scope of Risk Evaluations for the First Ten Chemicals

Dear Chairmen Barasso, Goodlatte, Grassley, and Walden, and Ranking Members Carper, Conyers, Feinstein, and Pallone:

We are writing to urge you to exercise your oversight authority over the Environmental Protection Agency's (EPA) implementation of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act and to counsel EPA to rectify immediately its legally indefensible interpretation of the act, which it adopted in its final framework rule establishing "Procedures for Chemical Risk Evaluation under TSCA."[1]

Individuals across the United States encounter hundreds of chemical substances every day and often simultaneously—in common household and hygiene products, in our food and drinking water, and in our air. Some of these chemicals present serious risks to our health and the environment, and a heightened risk of harm for children, pregnant women, the elderly, and individuals with compromised immune systems. To this day, we are largely unprotected from chemical exposures, even those chemicals widely known to be lethal and for which there is no safe level. Fortunately, the 2016 amendments to TSCA offer a truly meaningful opportunity to address this problem head-on by directing EPA to establish a comprehensive framework for evaluating chemicals and regulating those that pose unreasonable health and environmental risks.

[1] Final Rule, 82 Fed. Reg. 33,726 (July 20, 2017).

To genuinely protect people from adverse health effects due to toxic chemical exposures, EPA must take people as they find them. In other words, the agency must consider all exposures and then determine the risk of additional exposure before deciding what action, if any, is necessary to reduce or eliminate that risk. But EPA ignored this principle in its final risk evaluation rule. Instead, the agency announced that it will exclude certain ongoing uses and disposals of chemical substances from its risk evaluations, resting its decision on an erroneous and unlawful interpretation of the term "conditions of use." EPA has since relied on this legally flawed interpretation to limit the scope of the risk evaluations for the first ten chemicals it has identified for review.

For example, one of the ten chemicals on EPA's initial list is carbon tetrachloride. This chemical once had numerous uses, including in production of refrigeration fluids and propellants for aerosol cans, as a pesticide, as a cleaning fluid and degreaser, in fire extinguishers, and in spot removers.[2] Although many uses of the chemical have been banned, it remains in use for certain industrial applications and production is expected to increase in coming years.[3] Exposure to carbon tetrachloride can occur from breathing in contaminated air near facilities that manufacture or use it, or near waste disposal sites, and from drinking, bathing in, or cooking with water contaminated by the substance.

Exposure to carbon tetrachloride can cause serious health complications. Even at low levels of exposure over a brief time, it can cause an enlarged liver, damage the kidneys, and cause wastes to build up in the bloodstream. Acute exposure to high levels of the chemical can cause harm to the nervous system and brain function, and in severe cases, can lead to coma or death. Scientists have so far been unable to determine conclusively whether carbon tetrachloride causes cancer due to other chemical exposures occurring simultaneously. However, based on existing studies, EPA and the International Agency for Research on Cancer (IARC) consider it a probable human carcinogen. The National Toxicology Program (NTP) agrees and classifies it as reasonably anticipated to be a carcinogen.

In recognition of the various risks posed by exposure to the chemical, several existing EPA regulations set limits on carbon tetrachloride in the air, in hazardous waste, and in drinking water. CPSC, OSHA, FDA, and DOE have also adopted standards restricting the use of the chemical due to its toxicity.[4] Yet even with these regulations and with a ban on many uses, the CDC's National Report on Human Exposure to Environmental Chemicals (NHANES) indicates that carbon tetrachloride has appeared in blood samples collected from U.S. adults as recently as 2001-2002, reflecting recent exposure.[5]

Despite the potential health and environmental risk that carbon tetrachloride poses from ongoing uses—even though it is no longer manufactured, processed, or distributed for those uses—and from past and associated future disposals, EPA intends to exclude such uses and disposals from its risk evaluation, citing to its interpretation of "conditions of use" in its final procedural rule.[6] Excluding certain uses and disposals from risk evaluation can result in a gross understatement of risk. Consequently, EPA's current interpretation not

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[2] ATSDR, ToxFAQs: Carbon Tetrachloride (Aug. 2005), https://www.atsdr.cdc.gov/toxfaqs/tfacts30.pdf.

[3] Letter from Safer Chemicals, Healthy Families et al. to the U.S. Environmental Protection Agency, Scope of Risk Evaluation for TSCA Work Plan Chemical: Carbon Tetrachloride (Mar. 15, 2017), http://saferchemicals.org/sc/wp-content/uploads/2017/04/saferchemicals.org_ctc_comment_schf_ehsc_hbn.pdf.

[4] ENVTL. PROT. AGENCY, DOC. NO. EPA-740-R1-7010, SCOPE OF THE RISK EVALUATION FOR CARBON TETRACHLORIDE APPX. A (2017), https://www.epa.gov/sites/production/files/2017-06/documents/ccl4_scope_06-22-17.pdf.

[5] U.S. DEP'T OF HEALTH & HUMAN SERVS., CNTRS. FOR DISEASE CONTROL & PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: UPDATED TABLES, JANUARY 2017, VOLUME ONE 566 (2017), https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Jan2017.pdf.

[6] ENVTL. PROT. AGENCY, DOC. NO. EPA-740-R1-7010, SCOPE OF THE RISK EVALUATION FOR CARBON TETRACHLORIDE 9 (2017), https://www.epa.gov/sites/production/files/2017-06/documents/ccl4_scope_06-22-17.pdf.

only threatens to undermine the bipartisan reforms to TSCA, it also threatens the public's health and the environment.

As members of House and Senate committees with oversight over EPA and TSCA implementation, and as sponsors, co-sponsors, and supporters of the 2016 TSCA amendments, you are instrumental to ensuring that EPA's implementation of TSCA reflects congressional intent to safeguard the public's health and the environment from unreasonable chemical risks. Petitions have recently been filed challenging EPA's final prioritization and risk evaluation rules.[7] We ask you to urge EPA to take immediate corrective action by returning to the correct interpretation set forth in the proposed risk evaluation rule and by correcting the scoping documents for the first ten chemicals under review. The interpretation from EPA's proposal is firmly grounded in the language of the amendments to TSCA and its legislative history and better serves the statute's purpose of protecting our health and environment from the unreasonable risks posed by toxic chemicals.

Background

In accordance with the 2016 TSCA amendments, EPA has issued new rules that establish agency procedures for (i) prioritizing chemicals for risk evaluation and (ii) for conducting risk evaluations. If EPA finds from its evaluation that a chemical presents an unreasonable risk, the agency must issue a risk management rule to protect public health and the environment from harm.

Although the statute tasks EPA with developing the risk evaluation procedures, it sets forth certain requirements for the agency. EPA must conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."[8] EPA must also ". . . take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance . . . ."[9] Additionally, upon initiating a risk evaluation, EPA must develop scoping documents that describe the "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. . . ."[10]

Across each of these provisions, EPA is directed to conduct its risk evaluations under "the conditions of use." The statute defines this term 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."[11]

In EPA's proposed risk evaluation rule, the agency interpreted "conditions of use," in context of these other provisions, as requiring it to evaluate the risk of *all* known, intended, and reasonably foreseen activities associated with the manufacture, processing, distribution in commerce, use, and disposal of the subject chemical substance.[12]

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[7] *See* Alliance of Nurses for Healthy Environments, et al. v. EPA, Nos. 17-1926 & Consolidated Cases (Fourth Cir., MCP No. 149); Safer Chemicals Healthy Families et al. v. EPA, Nos. 17-72260 & Consolidated Cases (Ninth Cir., MCP No. 148).
[8] 15 U.S.C. §2605(b)(4)(A).
[9] 15 U.S.C. §2605(b)(4)(F)(iv).
[10] 15 U.S.C. §2605(b)(4)(D).
[11] 15 U.S.C. §2602(4).
[12] NPRM, 82 Fed. Reg. 7562, 7565 (Jan. 19, 2017).

However, EPA reversed its interpretation in the final risk evaluation rule, contending that the statute does not require consideration of *all* conditions of use, but rather, allows the agency to exclude certain activities from the definition of conditions of use and also from the scope of the risk evaluation. Specifically, EPA excludes categorically from the definition of conditions of use unsubstantiated or anecdotal statements on the Internet about a particular use, as well as intentional misuses, and all "legacy" uses, associated disposals, and legacy disposals.[13] EPA also claims in the final rule that it may exclude "certain activities that EPA has determined to be conditions of use" from the scope of its risk evaluation.[14] Under this alleged authority, for instance, EPA intends to make a case-by-case determination at the scoping stage as to whether a certain condition of use meets the definition of "reasonably foreseen," although EPA declines to define the term in the final rule.

EPA must consider all conditions of use in risk evaluations and must make a risk determination on the chemical substance, not individual uses.

The plain language of TSCA, as amended, directs EPA to perform risk evaluations of chemical substances over their full life cycles based on all known, intended, and reasonably foreseen manufacturing, processing, distribution, use, and disposal activities. As EPA emphasized in its proposed risk evaluation rule, the statute expressly directs EPA to focus its risk evaluations on the "chemical substance,"[15] rather than individual uses, and to make its risk determination under "*the* conditions of use."[16] Additionally, the statute uses "conditions" in plural form, further supporting the conclusion that EPA must consider all conditions of use, not individual uses.[17]

While the statute grants EPA some authority to determine under what circumstances the substance is known, intended, or reasonably foreseen to be used, EPA cannot exclude known, intended, or reasonably foreseen uses from its risk evaluation once it has identified those uses.[18] Rather, the agency must make a risk determination on the chemical substance as a whole,[19] and only then take action to address a chemical substance that it has determined presents an unreasonable risk to health or the environment.[20]

In EPA's final rule, however, it tosses aside its initial interpretation in favor of one that gives it unbridled discretion to limit the definition of "conditions of use" and exclude certain uses and disposals from its risk evaluations. Under this new and unsupported interpretation, EPA claims it has authority to determine the circumstances that constitute a condition of use on a case-by-case basis.[21] EPA then goes on to list "certain activities that

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[13] Final Rule, 82 Fed. Reg. 33726, 33729-30 (July 20, 2017).
[14] Final Rule, 82 Fed. Reg. 33726, 33729 (July 20, 2017) (pointing to §6(b)(4)(D) as support).
[15] 15 U.S.C. §2605(a); §2605(b)(4)(A); §2605(i). It is also noteworthy that EPA, in its final prioritization rule, asserts that it must consider all conditions of use in making prioritization decisions because the statute says "to make prioritization determinations on a 'chemical substance' . . . not on 'uses.'" Final Rule, 82 Fed. Reg. 33753, 33755 (July 20, 2017). Given the similar focus on the "chemical substance" and not individual uses in §6(b)(4)(a) on risk evaluations, it is unclear why EPA declined to adopt this reasoning in its final risk evaluation rule.
[16] NPRM, 82 Fed. Reg. 7562, 7565 (Jan. 19, 2017); 15 U.S.C. 2605(b)(4)(A).
[17] Contrary to the final risk evaluation rule, EPA makes this argument in its final prioritization rule. Final Rule, 82 Fed. Reg. 33753, 33755 (July 20, 2017).
[18] *See* Comments from the Natural Resources Defense Council on Proposed Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, at 9, n. 29 (Mar. 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0066 ("While EPA must apply the definition of 'conditions of use' to specific circumstances, the Agency lacks discretion to determine that an activity that otherwise meets the definition can be disregarded.").
[19] 15 U.S.C. §2605(b)(4)(A).
[20] 15 U.S.C. §2605(a); §2605(i).
[21] Final Rule, 82 Fed. Reg. 33726, 33729 (July 20, 2017). *But see* EPA's final prioritization rule, in which the agency argues the phrase "the conditions of use" is evidence that Congress "intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a more inclusive

may generally not be considered to be conditions of use," which it argues it identified based on the "legislative history, statutory structure and other evidence of Congressional intent."[22]

This interpretation not only ignores the well-reasoned arguments the agency itself made in the proposed rule, but it also erroneously reads an absence of language giving it discretion to exclude certain activities from the definition of conditions of use as granting that discretion. The absence of such language was intentional, as Congress sought to ensure that the agency evaluated chemical substances over their whole life cycle. Moreover, the express language and structure of the amended statute indicate that Congress intended for EPA to do a robust risk evaluation. To be sure, Congress had contemplated the possibility that EPA may need to exclude certain uses from a risk management rule at the rulemaking stage, and thus, included provisions to this effect in the risk management provisions.[23] No similar provisions on exclusions or exemptions are found in the provisions on risk evaluations, evidencing an intent by Congress to preclude EPA from excluding certain activities until after it has completed the risk evaluation and made a risk determination.

Notably, EPA also argues in the final rule preamble that excluding certain activities and conditions of use from risk evaluations will help "ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines."[24] Not only does EPA fail to explain why it cannot meet its statutory deadlines under its original interpretation,[25] but it also bases its decision to exclude certain uses on resource considerations, which violates the prohibition on considering costs and other non-risk factors in risk evaluations.

Moreover, as EPA emphasized in its proposed rule, "reading the statute as authorizing it to base its unreasonable risk determination on 'merely a subset of individual uses' could result in a finding of no unreasonable risk based on an evaluation of one use even if the chemical has 10 known uses."[26] In other words, applying EPA's procedures for risk evaluation makes it practically impossible for the agency to ensure it conducts comprehensive and quality scientific assessments or aggregate exposure assessments. Incomplete risk evaluations could lead EPA to determine incorrectly that a chemical does not present an unreasonable risk when it in fact does, or alternatively, EPA could determine that a chemical presents an unreasonable risk, but because of the understated risk, its risk management rule may not address the risk sufficiently as the statute requires.

Chemical exposures may occur at any stage of a chemical's life cycle—at manufacturing, processing, distribution, use, or disposal—or exposure may occur from a combination of these activities. For EPA to manage unreasonable risk posed by a chemical, EPA must first

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approach to chemical substance management." Final Rule, 82 Fed. Reg. 33753, 33755 (July 20, 2017). Yet EPA ignores this argument in its final risk evaluation rule and provides no justification for doing so.

[22] Final Rule, 82 Fed. Reg. 33726, 33729 (July 20, 2017). EPA claims that an interpretation giving it this broad discretion to exclude certain activities will help ensure "it always includes an evaluation of the conditions of use that raise greatest potential for risk." EPA points to a statement by Senator Vitter in the legislative history, which repeats this point. Final Rule, 82 Fed. Reg. 33726, 33728 (July 20, 2017) (citing Cong. Rec., S 3511, S3519-20 (June 7, 2016)), https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf. However, Vitter's statement fails to provide any additional clarification on the scope of EPA's discretionary authority. Also, the Senate Democratic negotiators on the bill submitted their intent on certain elements of the statute into the Congressional Record, which conflicts with Vitter's statement. In explaining EPA's authority to evaluate risks from mixtures, they explicitly write: "The definition of 'conditions of use' . . . plainly covers *all uses of a chemical substance* . . . ." Cong. Rec. S3511, S3516 (June 7, 2016) (emphasis added).

[23] 15 U.S.C. §2605(a)(2)(B) and §2605(g).

[24] Final Rule, 82 Fed. Reg. 33726, 33728 (July 20, 2017). In the proposed rule, EPA had acknowledged that it may be challenging to meet its statutory deadlines if it considers all conditions of use, but determined that it would be able to satisfy them.

[25] NPRM, 82 Fed. Reg. 7562, 7566 (Jan. 19, 2017).

[26] NPRM, 82 Fed. Reg. 7562, 7565-66 (Jan. 19, 2017).

understand those potential risks. Excluding whole categories of activities and conditions of use from risk evaluations could result in EPA leaving out of its evaluation numerous unreasonably risky uses and disposal activities.

EPA cannot exclude ongoing uses and disposals from the definition of "conditions of use" or from the scope of risk evaluations.

In EPA's final risk evaluation rule, the agency relies on its flawed interpretation of "conditions of use" to exclude legacy uses, associated disposal, and legacy disposal from the definition. As support for broadly excluding these uses and disposals, EPA claims that it reads the statute as requiring it to "focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (*i.e.*, is prospective or on-going [*sic*])."[27] Accordingly, EPA claims that the statute mandates that it not look back to evaluate the risks associated with ongoing legacy uses, associated disposal, and legacy disposal. In other words, EPA asserts that it must not evaluate the risks of uses or disposals—even ongoing or reasonably foreseeable future uses or disposals—associated with manufacturing, processing, or distribution activities that occurred in the past and are not continuing in the present.

This interpretation directly conflicts with the statutory construction of "conditions of use," which explicitly mandates that EPA consider uses and disposals of chemical substances in risk evaluations, and in no way limits that consideration to only uses and disposals extending from future manufacture, processing, or distribution.[28] And nothing in this definition indicates that EPA is to give more weight to manufacturing, processing, and distribution activities than to uses and disposals.

Nonetheless, EPA chooses to disregard the statutory construction of the definition as a whole and looks instead to the phrase "to be" in the definition, which it claims, "suggests that the term is focused prospectively."[29] However, neither the statute nor the legislative history ever give mention to this phrase or remotely suggest an intent for TSCA §6 to have only a prospective focus.[30]

EPA also argues that TSCA is a statute for the regulation of chemicals "in commerce," and as such, risk evaluations must focus solely on the ongoing or future manufacture, processing, and distribution of the subject chemical substance, and must only look at uses and disposals that flow from these three activities.[31] EPA refers to asbestos to illustrate this point. However, just because a chemical is no longer manufactured, processed, or distributed does not mean it has exited the stream of commerce. Much of the asbestos currently present in the United States was previously installed insulation and is no longer manufactured, processed, or distributed for that use, yet asbestos is still being "used" and "disposed of" in the United States. And there are active industries performing asbestos abatement and disposal, meaning legacy uses and associated disposals are "in commerce." As several Asbestos EPA Accredited Professionals explain in comments to EPA, "the 'use' of the material does not end at the time of installation. For many of these materials, the 'use' only *begins* at installation."[32]

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[27] Final Rule, 82 Fed. Reg. 33726, 33739 (July 20, 2017).
[28] The findings, policy, and intent provisions of TSCA also refer to the need for EPA to have authority to address exposure risks associated with the use and disposal of a chemical substance. 15 U.S.C. §2601.
[29] Final Rule, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[30] All the legislative history reveals is that a Senate amendment had removed the phrase "to be" and a final House amendment added it back in without any discussion on the record. H. Comm. Rept. 114-176, https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf; Cong. Rec. H2989 (May 24, 2016), https://www.congress.gov/crec/2016/05/24/CREC-2016-05-24-pt1-PgH2989-2.pdf.
[31] Final Rule, 82 Fed. Reg. 33726, 33730 (July 20, 2017).
[32] Letter from Carlos Texidor, Fuss & O'Neill EnviroScience, LLC to Mr. Robert Courtnage (Mar. 9, 2017), https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2016-0736-0019&attachmentNumber=1&contentType=pdf.

Moreover, continuing uses, disposals, and environmental releases may present significant health and environmental risks. In the case of asbestos, for example, "building 'users' are at risk of asbestos exposure from installed legacy asbestos-containing materials caused by vibration, air erosion, water damage and inadvertent or accidental physical contact by citizens and tradesmen."[33] Another excellent example is carbon tetrachloride, as we noted at the outset of this letter.

As further support for its interpretation, however, EPA asserts that it lacks authority "to directly regulate non-commercial use, meaning that [it] would not have an effective tool to address risks found to arise from uses in consumer settings if there were no on-going [*sic*] commercial manufacture, processing or distribution."[34] But for purposes of a risk evaluation, the statute directs EPA only to assess whether the chemical substance presents an unreasonable risk of injury to human health or the environment. If a chemical is still present in the U.S., evaluating its ongoing risk is a legitimate goal intended to protect people and the environment moving forward. EPA is not regulating at the risk evaluation stage, and the availability of risk management options is irrelevant to its risk-based determination. It is also a violation of the statute's prohibition on considering non-risk factors in evaluations. Moreover, under §6(a), one of the risk management actions EPA can impose is proper disposal, meaning the agency can regulate disposal of a chemical substance even if it is no longer manufactured, processed, or distributed. And even if EPA does ultimately lack authority to regulate, Congress set out procedures for EPA to consult with another agency that has adequate regulatory authority under TSCA §9. If no agency has adequate authority, Congress may wish to pass new legislation so that EPA or another agency can address unreasonable risks.

EPA's final argument is that "even if these activities were not excluded from the definition of conditions of use, EPA generally expects that it would exercise its discretion under section 6(b)(4)(D) to exclude them from the scope of risk evaluations."[35] Although EPA does not clearly explain this in the preamble, it suggests that it would argue legacy uses, associated disposal, and legacy disposal are not "reasonably foreseen." Of course, if EPA already knows of a legacy use, its ongoing use is reasonably foreseeable, as well as the fact it has already been or will at some future time be disposed of.

Conclusion

For the many reasons we have outlined, we believe EPA's decision to exclude certain ongoing uses and disposals, both from the definition of conditions of use and from the scope of risk evaluations, rests on an erroneous and unlawful interpretation of amended TSCA. In interpreting the amended TSCA, EPA seems to have bent over backwards and beyond to avoid restricting the use of dangerous chemicals, thus seeking to defeat plain congressional intent by means of executive fiat. EPA's interpretation is not supported by the text of the law; it is a usurpation of congressional power; and it endangers the American people.

Given that many chemicals remain prevalent across the country and will continue to be used and disposed of for many years to come, EPA must not neglect to include ongoing uses and associated disposals from risk evaluations. To fulfill the law's purpose and maximize health and environmental protections, EPA must evaluate all potential sources of exposure and exposure pathways presented by a chemical substance over its full life cycle. This includes all known, intended, and reasonably foreseeable manufacturing, processing, distribution, uses, and disposal activities.

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[33] *Id.*
[34] Final Rule, 82 Fed. Reg. 33726, 33730, 33739 (July 20, 2017).
[35] Final Rule, 82 Fed. Reg. 33726, 33730 (July 20, 2017).

The health of our families, children, and future generations, as well as the health of our environment, cannot endure the harm posed by unregulated toxic substances any longer. It is imperative for EPA to utilize its renewed authority under amended TSCA to maximize protections for public health and the environment.

Sincerely,

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cc: Scott Pruitt; EPA Administrator
The Honorable Tom Udall