Environmental Defense Fund

Comments on "Updates to New Chemicals Regulations Under the Toxic Substances Control Act"

Docket ID: EPA-HQ-OPPT-2022-0902; 88 Fed. Reg. 34100 (May 26, 2023)

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EPA has a major opportunity to improve the New Chemicals Program by crafting regulations that ensure EPA conducts robust, transparent, and objective reviews of all new chemicals that will fully protect human health and the environment, including for those people at greatest potential risk. In its proposed rule, "Updates to New Chemicals Regulations Under the Toxic Substances Control Act," EPA has put forth some limited changes that, if finalized, represent improvements. However, EPA's proposal falls significantly short of implementing the fundamental changes needed to ensure the safety of any new chemicals allowed onto the market.

EPA states that it has three goals for its proposal: to align its new chemicals regulations with Congress' 2016 reform of the Toxic Substances Control Act ("TSCA"); to improve the efficiency of its new chemicals reviews; and to update the regulations based on the Agency's existing policies and its experience with implementing the New Chemicals Program. In EDF's view, there are numerous additional TSCA goals that should inform this important rulemaking, including providing for meaningful public involvement, ensuring transparency, restoring public trust in the TSCA New Chemicals Program, and – consistent with the primary purpose of TSCA – ensuring that chemicals do not present unreasonable risks to people or the environment.

But even viewed from EPA's relatively narrow perspective, the proposal ("Proposed Rule") falls short of each of the Agency's stated goals. EPA recognizes that Congress, with its major amendments to TSCA in 2016, made fundamental changes to the Agency's new chemicals obligations.[1] However, many of Congress' key reforms to the law are not reflected in the Agency's proposed regulations. Second, the proposed regulations would codify inefficient processes, such as EPA's proposed plan to finalize regulations that continue the practice of sharing its new chemical risk findings with the submitters seeking approval, and then allowing the companies to submit information late in the process to refute the findings.

And as for EPA's third stated purpose for this rulemaking – to employ its experience in implementing the New Chemicals program to update the regulations – there is a serious disconnect between the slight changes EPA proposes to certain procedures and the scope and

[1] EPA, "Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)," 88 Fed. Reg. 34100, 34102-03, May 26, 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0001.

nature of the problems faced by the New Chemicals Program. We have seen a severe decline in public confidence in the objectivity and scientific rigor of decisions made under the program. In our view, this is in part traceable to how the program has long been structured, which has included practices that make the program vulnerable to undue industry access and influence. These problems are made even worse in times of damaging interference by political appointees, when EPA leadership changes and prioritizes industry interests over public interests – as we saw vividly under the previous administration. Despite these significant concerns and challenges, EPA has now proposed, perhaps unintentionally, to codify one-sided, industry-favoring practices. For example, EPA proposes to reopen its orders regulating new chemicals upon receipt of new information only from the companies who profit from the chemicals, and not from members of the public or any other stakeholder. EPA's description of how such new information would be used only includes the possibility of weakening or revoking its regulations of the chemicals, rather than strengthening health and environmental protections.

EDF describes in detail in these comments why and how, instead of finalizing such problematic proposals, EPA can and should take this opportunity to rebuild a new chemicals program that truly serves the public's interests even in the face of possible future efforts to do otherwise.[2]

[2] EPA should obtain public comment on a significantly broader set of regulatory proposals than is included in the Proposed Rule, and then finalize a more comprehensive rule.

Summary of Points

Section I: EPA's Proposed Rule Will Perpetuate Industry's Undue Influence Over New Chemical Reviews and Will Not Halt EPA's Resource-Draining "Rework" To Address Industry Complaints.

Key problems

- The New Chemicals Program is severely hampered by delays and resource drains due to "rework" of assessments and determinations largely resulting from late submissions of information by industry.
- As EPA has recognized, companies sometimes submit information during the new chemicals review process to challenge EPA's risk determinations.

Needed changes

- EPA should align its new chemicals reviews with TSCA by preventing industry interference in its assessment and management of risks.
- EPA should prevent industry interference in EPA's reviews of new chemicals by barring unilateral industry access to draft risk findings, assessments, determinations, or proposed regulatory actions:
    - During the course of its reviews, EPA has shared with submitters its draft risk findings and, sometimes, assessments and allowed them to challenge the outcomes.
    - The sharing of draft risk findings or documents has no basis in TSCA, and the practice invites undue industry influence, as well as creating unnecessary "rework" for the Agency.
    - EPA should explicitly disavow this practice and codify its decision to no longer share draft risk findings or documents with industry during the course of risk reviews of new chemicals.
- EPA should add additional information submission requirements to its proposal.
- EPA should mandate consequences for companies that submit information during the new chemicals review process that they knew, or that was reasonably ascertainable, at the beginning.
- EPA should treat the submission of new information during the new chemicals review period as a new submission.

Section II: EPA's Regulations Must Do Far More to Increase Transparency, Public Access to Information, and Public Participation in the New Chemicals Program.

Key Problem

- EPA's proposed rule does little to codify regulatory provisions to increase the transparency and accountability of, and public engagement in, the New Chemicals Program, and to rebuild public trust.

Needed changes

- EPA should expand its pre-screen process to exclude confidential business information (CBI) claims that are ineligible or do not meet basic TSCA requirements.

- EPA must post all received notices to the Federal Register as required by TSCA.
- EPA should codify TSCA's requirement to post new chemical notices to the Federal Register within five days of receipt.
- EPA should codify its ChemView publication procedures to ensure timely public access to new chemical information.
- EPA's regulations should provide a timely, formal public comment opportunity on new chemical applications received.

<u>Section III</u>: EPA Must Provide For Possible Revisions to Its Regulatory Orders Based on Information Submitted by the Public and Information that Warrants Strengthening Regulation.

Key problems

- EPA appears to contemplate and codifies a role only for the chemical company submitter to provide information to EPA after EPA has issued an order. EPA proposes regulatory text that omits reference to information about a chemical developed or submitted by any other party, including scientific researchers, health advocates, workers, unions, other governmental agencies, or any member of the public.
- EPA's proposed language only indicates that submitted information could lead to the weakening of an order. It fails to include the possibility that additional information could warrant strengthening of protections against potential unreasonable risk.

Needed changes

- EPA's regulations must make clear that EPA will consider information from all stakeholders – not just from company submitters – and also that such information may warrant strengthening the order to ensure protection of human health and the environment.

<u>Section IV</u>: EPA Should Fully Align Its New Chemicals Regulations with Congress' Mandates in Amended TSCA and Describe How It Will Implement the Key Reforms.

Key Problem

- EPA has not fully met its stated purpose of aligning its regulations with Congress' requirements in reformed TSCA. In purporting to codify the requirements of TSCA, the Agency has been troublingly selective.

Needed changes

- EPA's regulations need to address information insufficiency and testing.
- EPA's reviews of new chemicals and significant new uses need to evaluate reasonably foreseen conditions of use.
- EPA's reviews of new chemicals and significant new uses need to assess risk to vulnerable subpopulations.
- EPA needs to provide public notice of and access to "not likely" determinations.
- EPA's regulations need to include requirements relating to significant new use rules (SNURs).

- EPA's regulations need to include additional requirements relating to new chemical exemptions.

Section V: No PFAS Should Be Eligible for the Low Volume and Low Release/Exposure Exemptions, Including All Such Previously Granted PFAS Exemptions.

- EPA is correct to make PFAS categorically ineligible for low volume and low release/exposure exemptions.
- EPA should categorically revoke existing PFAS low volume and low release/exposure exemptions.
- EPA should adopt the OECD PFAS definition.
- EPA should consider excluding other potential high-risk chemical categories from eligibility for low volume and low release/exposure exemptions.

Section VI: EPA Should Make All PBT Chemicals Ineligible for the Low Volume and Low Release/Exposure Exemptions.

- EPA has not proposed to codify its 1999 PBT policy, despite claiming to do so. EPA should make all PBT chemicals categorically ineligible for low volume and low release/exposure exemptions, in addition to other new chemical exemptions, consistent with the agency's PBT policy.
- EPA should codify the actual 1999 PBT policy.
- EPA should consider making persistent, mobile, and toxic (PMT) chemicals ineligible for new chemical notice exemptions, in addition to PBTs.[3]

[3] On April 5, 2022, EDF submitted to the Agency an outline titled "Areas of needed reform in regulations governing EPA's New Chemicals Program, Including 40 C.F.R. Sections 720, 721 and 723" (This outline is available in the docket for this rulemaking, at https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0023). While the body of these new comments delve in greater depth into most aspects of what we included in our outline, we incorporate all of our outline as part of these comments.

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I. THE PROPOSED RULE WILL PERPETUATE INDUSTRY'S UNDUE INFLUENCE OVER NEW CHEMICAL REVIEWS AND WILL NOT HALT EPA'S RESOURCE-DRAINING "REWORK" TO ADDRESS INDUSTRY COMPLAINTS

Chemical companies have long been permitted to engage in back and forth with EPA about the Agency's review of their new chemicals. This back and forth during the new chemical review process, and the resulting additional work for the Agency (which EPA calls "rework"), have been the cause of significant problems. These problems include substantial delays and resource drains, described vividly by EPA; the potential to draw undue agency attention to company submitters' concerns to the exclusion of the public's concerns; the appearance of or actual conflicts of interest; a lack of transparency and ability for the public to have confidence in the program's procedures and decisions; and the subjection of EPA scientists and program managers to pressure and distraction from their mission to thoroughly review the safety of new chemicals. At the same time that the chemical companies have prolonged the review of new chemicals through the late submission of information and back-and-forth engagement, the companies and their trade associations have complained frequently that EPA's reviews are not being completed in 90 calendar days.

There may well be instances in which EPA needs clarifying information from submitters, and the Agency's inquiry then results in some communication with companies. However, the industry has taken advantage of EPA's allowance for industry to communicate with the Agency during its reviews of their new chemicals to gain undue access and influence over the new chemicals review process. EPA itself recognizes that companies may be submitting information that was available to the companies, but not included in their original new chemical submissions, and then engages in back and forth with the Agency, in an effort to change EPA's determination of their new chemicals' risks.[4]

TSCA requires companies to provide required information at the time of the new chemical notice submission ("new chemical submission" or "new chemical application"). The information that chemical companies often provide EPA well after initiation of the new chemical review period – i.e., not as part of the original submission – frequently concerns information well known to the company about its own process, such as its engineering controls, environmental releases, and operating days per year for batch processes.[5] In an attempt to be responsive to the companies submitting the new chemical applications, and to allow and incorporate such late information, EPA has inadvertently supported non-compliance with the basic requirements of TSCA section 5(d) that submitters provide in their submissions all relevant information known to or reasonably ascertainable by them.

Below, we describe the steps that EPA should take to deal with these and other structural issues in the New Chemicals Program, which would substantially improve the program's efficiency,

[4] See subsection B, below.

[5] EPA, "Analysis of Engineering Information Submitted for TSCA Section 5 New Chemical Submissions," https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf.

bring the program in line with Congress' reforms, and promote health and environment-protective decisions on new chemicals.

A. The New Chemicals Program is Severely Hampered by Delays and Resource Drains Due to "Rework" of Assessments and Determinations

EPA has recognized the significant problems posed by industry submitting information after initiation of the new chemicals review process, which engenders what the Agency calls "rework."[6]

> Intake, review, and inclusion of new data and information takes time. When additional information is submitted, EPA reviews it in order to determine whether it is relevant, adequately documented, and well-supported and whether the Agency needs to revise its risk assessment to incorporate it. Revision(s) to risk assessments (known as 'rework') take additional time, causing delays in the new chemical review for the submitter as well as other companies whose new chemical reviews are also delayed.[7]

In 2022, EPA analyzed nearly 100 new chemical reviews and found that, due to industry actions, risk assessments "may be **reworked anywhere from one to five times**, with each rework being the result of an additional information submission, and that the reworks could add at least several months to the case review."[8] The Agency determined that companies submitted such additional information late (as it could and should have been submitted with the new chemical application), resulting in rework in approximately 30 percent of all new chemical submissions.[9]

EPA further found that "in many cases, the same types of information were submitted multiple times by a submitter because they were not accepted by EPA due to a lack of supporting data or documentation" which "can result in several rounds of EPA review and rework."[10] Indeed,

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[6] One definition that EPA provides of "rework" is "intake, review, and revision(s) to risk assessments when additional information is submitted" by companies seeking a new chemical review. EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework (Webinar 2)," October 18, 2022, https://www.epa.gov/system/files/documents/2022-10/TSCA%20Engineering%20Outreach%20Webinar%20-%20Info%20Evaluation%20Consideration%202022-10-12%20508.pdf, at 3.

[7] EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework," https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.

[8] EPA, "Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions," https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf, at 3 (emphasis in original).

[9] *Id*. at 4.

[10] EPA, "TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues," July 22, 2022,

concludes the Agency, "the frequency and amount of information submitted after EPA has started its evaluation causes substantial rework and delays in completing the analysis."[11]

In other words, EPA deals with a large number of new chemical cases where it is burdened with the task of reviewing information that was known to or reasonably ascertainable by companies at the time they submitted their new chemical applications, but that the companies did not include. If warranted, EPA must then redo the risk assessment and risk management analyses and prepare new documents based on companies' belated provision of information that they were required to but failed to include when they submitted their new chemical application request.

It is important to note that these burdens are being placed on an EPA division that is already under a notably tight timeframe for completing its reviews. New chemical reviews under TSCA must generally be completed within 90 days (with possible extensions up to an aggregate of 90 days[12]) for "premanufacture notices," and even shorter periods for exemption applications (30-45 days). And the chemical industry, despite being a major cause of delays, puts pressure on the Agency, continuously complaining that EPA is not wrapping up all of its reviews within 90 days.

B. As EPA Has Recognized, Companies Sometimes Submit Information During the New Chemicals Review Process to Challenge EPA's Risk Determinations

In addition, and particularly troublingly, EPA reports that companies at times submit additional information, triggering rework, in order "to refute EPA's initial risk determination."[13] Indeed, there is ample evidence that industry has used the opportunity that EPA provides during the new chemicals review process for companies to revise and add to their submissions, and to engage in

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https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology%20and%20Results.pdf, at 8-9.

[11] *Id.* at 8. *See also* EPA, "Economic Analysis for the Proposed Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act," page 1-3, May 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0035 ("[S]ubmitters may provide new information in response to EPA's initial risk assessment. Submitters have typically been allowed to provide additional information after the time of the initial submission. As a result, submitters may attempt to mitigate the risk in EPA's initial risk assessment by removing a new use or decreasing a production volume. When EPA receives such late information, it may require EPA to repeat the assessments with the new information. The submission of late information results in inefficient use of EPA resources and can jeopardize EPA's ability to conclude its review and make its determination within the review period outlined in the statute").

[12] 15 U.S.C. § 2604(c) ("TSCA section 5(c)").

[13] EPA, "TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework, Kickoff Meeting," July 27, 2022, https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Kick%20Off%20Meeting%20Materials.pdf, at 4.

back and forth with the Agency, in an attempt to influence scientific and regulatory decisions in which they have a strong vested financial interest.[14]

Such a regime imposes real costs on the Agency. In its supplemental proposal for fees for the administration of TSCA, EPA explicitly highlighted the "costs incurred by EPA for multiple rounds of revision to the risk assessment due to late submission of information or rebuttals by companies" and the resulting "multiple rounds of risk management actions, redactions and posting of final reports to meet transparency commitments while safeguarding CBI."[15] Each time that EPA receives late information from companies, or has to engage in back-and-forth with submitters over the revisions to the risk assessment or risk management, the Agency expends additional resources beyond what is already required to conduct a new chemical evaluation. Ironically, companies in the industry, their hired law and consulting firms, and especially their trade associations, frequently complain publicly and to members of Congress about EPA's inability to complete new chemical reviews within 90 days when, in fact, it is the chemical companies' back-and-forth actions, and their late provision of information that should have been provided to EPA at the beginning, that are often the source of the delays.[16]

In addition to the costs placed on the Agency, for EPA to allow industry to review and challenge its new chemicals risk determinations and any risk management measures it intends to impose is to give wide and unilateral access to EPA's decisionmaking to the very participants who stand to gain or lose financially from EPA's decisions about their chemicals.[17] Exacerbated by a lack of transparency and the complete exclusion of the public from the process, this practice leads to erosion of public trust in the quality and independence of EPA's reviews of new chemicals.

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[14] *See* EDF, "Loosening Industry's Grip on the New Chemicals Program," September 22, 2021, https://blogs.edf.org/health/2021/09/22/loosening-industrys-grip-on-epas-new-chemicals-program/; Sharon Lerner, "EPA Exposed," *Intercept* series, July 2, 2021-August 1, 2022, https://theintercept.com/series/epa-exposed/.

[15] "Fees for the Administration of the Toxic Substances Control Act (TSCA)," 87 Fed. Reg. 68647, 68651 (Nov. 16, 2022), https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0072.

[16] As a recent example of industry's attempt to put pressure on EPA without acknowledging its key role in delays, *see* the American Chemistry Council's "Tracking Progress: ACC Launches Tool to Signal Concerns with EPA's Approach to TSCA New Chemical Reviews," June 20, 2023, https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2023/tracking-progress-acc-launches-tool-to-signal-concerns-with-epa-s-approach-to-tsca-new-chemical-reviews.

[17] Even if such exclusive access does not always lead to changes in the outcome (i.e., EPA generally considers but is not required to accept the validity of and use the provided information, particularly when the information is not supported or otherwise substantiated), it gives at least the appearance of undue influence because this one interested (and potentially conflicted) party is permitted to provide additional information that it deems to be relevant to (and hopes will lead to a more favorable) assessment of potential hazard, exposure and risk.

C. EPA Should Align its New Chemicals Reviews with TSCA by Preventing Industry Interference in its Assessment and Management of Risks

As described above, EPA has adopted practices not grounded in TSCA that compel it to engage in extensive back and forth with companies over their submissions, and to provide those submitters access to and influence over the new chemicals review process that are opaque, not afforded any other stakeholder, and fail to account for the inherent conflict of interest submitters have with respect to EPA decisions about their new chemicals. Given these pervasive problems, EDF calls for EPA to bring its New Chemicals Program into alignment with TSCA's provisions, including Congress' 2016 reforms to those provisions. EPA's regulations must prevent undue influence by industry during the new chemicals review process.[18] As a start, the finalized new chemicals rule should require industry to submit robust new chemical applications that truly include all relevant information that is known to or reasonably ascertainable by the submitter, and thus do not need to be significantly supplemented during the new chemical review process.

Specifically, EDF urges EPA to finalize a rule that aligns its New Chemicals Program with TSCA. The most straightforward process that best reflects the plain language of the statute would operate in this way:

1) Only if a company's new chemical submission is deemed complete, including all relevant information known to or reasonably ascertainable by the company at the time it submits, as required by TSCA section 5(d)(1),[19] EPA conducts its review of the submission. This should not trigger a back-and-forth process with the company. (EPA has provided ample guidance to companies about what they need to submit – and in the current Proposed Rule has proposed further enhancements that we support – and companies should be expected to use that guidance and regulatory enhancements to prepare new chemical submissions that do not need to be supplemented during the review period.)

2) EPA's risk review and determination are based only on the information that is known or reasonably ascertainable to the submitter and is provided with and at the time of the submission, and any clarifying information requested from the submitter by EPA and submitted as an amendment within the initial time period.

3) Based on EPA's review of that information, EPA makes its statutory determination and, where applicable, takes the appropriate risk management action.

4) The regulatory decisions made by EPA on a new chemical submission are not subject to back and forth with industry. (EPA may choose to codify procedures providing that when EPA notifies submitters of its regulatory decision, submitters have the option to exercise

[18] EDF, "Comments on Fees for the Administration of the Toxic Substances Control Act," Jan. 17, 2023, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0111.

[19] Per the criteria for premanufacture notices as proposed by EPA in proposed 40 C.F.R. § 720.65, along with EDF's suggested additions to that proposed part (see subsection E, below); the criteria for exemptions of § 723.50(e); and the criteria for microorganisms of §§ 725.32 and 725.33.

their right within a short time period to withdraw their submission, per 40 C.F.R. § 720.75(e).)

5) With the exception of test data (described in 40 C.F.R. § 720.50(a)(4)(ii)), if additional or revised information becomes available to the submitter during the review period that the submitter wants EPA to consider in its assessment (whether or not the information was known to or reasonably ascertainable by the submitter at the time of initial notice submission), the submitter shall withdraw the original submission and make a new submission to EPA that includes the additional or revised information.

Codifying the above practice would prevent the current practice – which has no basis in TSCA – of EPA engaging in back-and-forth negotiations with new chemical application submitters and their representatives over EPA's determinations of risk. Instead, EPA must independently review and make decisions on new chemical applications in a manner that is without influence, or the perception of influence, by those companies.

In sum, TSCA's plain language sets forth a clear procedure under which companies submit applications that must meet TSCA requirements, and EPA then reviews each such application, reaches one of several specific determinations, and takes the action applicable to the determination it makes.[20] Following the straightforward process laid out in TSCA would help address the serious problems described above, and recognized by EPA, with the operations of the New Chemicals Program.

D. EPA Should Prevent Industry Interference in EPA's Review of New Chemicals by Barring Unilateral Industry Access to Draft Risk Findings, Assessments, Determinations, or Proposed Regulatory Actions

i. EPA has routinely shared draft risk findings and sometimes assessments with submitters during the course of its new chemicals reviews

EPA gives submitters of new chemical applications exclusive access to the draft risk findings, and in some cases has shared draft risk assessments or related documents.[21]

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[20] *See* 15 U.S.C. §§ 2604(a)(1), (a)(3), (c), (e), (f) (h) ("TSCA sections 5(a)(1), (5)(a)(3), 5(c), 5(e), 5(f), and 5(h)").

[21] Among the examples of these practices:

- EPA's response to a 2019 EDF FOIA request included an email exchange between then-EPA chemicals office head Alexandra Dunn and the chemical industry lawyer Lynn Bergeson. Bergeson writes to complain about EPA redoing its assessments of one of her client's new chemicals. She is concerned that her firm does "not *yet* have the updated hazard and health assessments to know the basis of the disagreement" and that the revised draft risk assessment is "not *yet* forthcoming" (emphases added), and she alerts Ms. Dunn that "we may need to elevate this case." This example illustrates that EPA's draft documents had been shared with the industry law firm, that the firm had a clear expectation that it would be given the updated documents to review.
- Two articles in *The Intercept* reported on whistleblower disclosures made by five EPA scientists in the New Chemicals Program that documented numerous instances of communications between EPA

Not only has the Agency provided draft risk findings to submitters before finalizing the risk assessment, it has allowed the submitter to provide additional information with the intent of leading EPA to modify its assessment. In the preamble to the Proposed Rule, EPA readily acknowledges providing such exclusive opportunities for the submitters to attempt to influence the outcome, stating:

> Currently, after EPA completes its risk assessment of a chemical substance, EPA reaches out to the submitter to explain the findings of the risk assessment and any proposed prohibitions or limitations on the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance. If the submitter disagrees with the potential risks identified in the risk assessment, the submitter may provide additional information intended to demonstrate that risks are lower than EPA estimated.[22]

ii. The sharing of draft risk findings or documents has no basis in TSCA, and the practice invites undue industry influence – as well as creating unnecessary "rework" for the Agency

Such practices are prone to abuse, especially because these draft findings and, in some cases, draft documents are currently made available only to the submitter, and the process operates entirely out of the public's view. Moreover, there is no language in TSCA that seems to authorize or even contemplate this practice.[23] Nowhere does TSCA mention, suggest, encourage, or require that EPA share draft risk findings or documents with industry or seek industry feedback on them before they are finalized. Second, providing draft risk findings or documents to submitters allows the companies to attempt to influence EPA's findings or decisions, but no such opportunity is made available to any other stakeholders, such as public health advocates, unions, and community advocates.[24] This means EPA receives one-sided input from only the industry. Third, engaging only with industry regarding the draft risk findings is contrary to one of TSCA's core policy goals of increasing public access to information about chemicals subject

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staff and companies or law firms representing companies who had submitted new chemical applications in which the staff conveyed and discussed draft risk findings or assessment-related documents. The scientists indicate that these conversations frequently led to changes being made to the documents in response to company complaints. Sharon Lerner, "Whistleblowers expose corruption in EPA chemical safety office," *The Intercept*, July 2, 2021, https://theintercept.com/2021/07/02/epa-chemical-safety-corruption-whistleblowers/; Sharon Learner, "Leaked audio shows pressure to overrule scientists in 'hair-on-fire' cases," *The Intercept*, August 4, 2021, https://theintercept.com/2021/08/04/epa-hair-on-fire-chemicals-leaked-audio/.

[22] 88 Fed. Reg. at 34109.

[23] 15 U.S.C. § 2604 ("TSCA section 5").

[24] In addition, when EPA orally discloses its draft risk assessments to chemical industry submitters – such as by doing so over the phone – there is likely to be no record of the communication that the public may access under FOIA, through ChemView, via a Federal Register Notice, or through any other method, making such back and forth even more problematically opaque and one-sided.

to the statute. Engaging in closed-door conversation with industry and sharing initial findings outside of the public eye is also contrary to Congress' directive to give greater consideration to groups who may be at higher risk from toxic chemicals than the general population.[25] Lack of public access to industry's feedback or other information provided to EPA is also contrary to TSCA's provisions of public access to information such as those requiring EPA to disclose all non-confidential information contained in new chemical submissions.[26]

Further, this practice clearly creates the need for "rework," where industry will submit additional information that EPA must review and may decide needs to be incorporated into its analysis. EPA states that one of the purposes of the Proposed Rule is to reduce rework of risk assessments.[27] It defines rework as redoing all or part of a risk assessment as a result of late submissions of information that delay its review of new chemicals submissions.[28] The Agency's description of its practice of sharing draft risk findings or assessments with submitters – and accepting additional information from submitters (and potentially modifying risk assessments as a result of the additional information) – falls squarely within this definition.[29]

iii. EPA should explicitly disavow this practice and codify its decision to no longer share draft risk findings or documents with industry during the course of risk reviews of new chemicals

EPA has not taken the opportunity to explicitly prohibit this practice going forward. In fact, the Proposed Rule highlights EPA's practice of allowing industry to interfere with new chemical reviews and outcomes by sharing draft risk findings only with industry and not with the public, without stating that this practice will be prohibited. EPA should discontinue this practice for the reasons EDF has provided above, and should codify its decision to cease this practice.

If EPA nevertheless insists that it must convey to submitters the results of its risk assessments and/or share draft findings or any documents, they must be made public at the same time so that all other interested stakeholders may review and comment. Any communication by EPA to a company of its risk findings entails information that the public is entitled to in order to be fully informed about the agency's assessment of and decision on the new chemical, and to ensure public accountability of the new chemical review process. (And if EPA does provide for the

[25] *See* 15 U.S.C. §§ 2602(12) and 2604(a)(3) and ("TSCA sections 3(12) and 5(a)(3)").

[26] 15 U.S.C. §§ 2604(d)(1), 2613 ("TSCA sections 5(d)(1) and 14").

[27] 88 Fed. Reg. at 34102.

[28] 88 Fed. Reg. at 34102.

[29] 88 Fed. Reg. at 34110.

sharing of these materials, its regulations should also provide for the pausing of the new chemical review time period to allow adequate time for public review and comment.[30])

In addition, if EPA proposes to enter into a "consent order" with a chemical company on its new chemical,[31] such an order should not be developed and finalized in a way that excludes public participation. In its final regulations, EPA should codify the following procedure: Immediately upon proposing a consent order, EPA notifies the public in the Federal Register of the proposed order and terms, and provides adequate time for the public to comment on them.[32] Such procedures are, at the minimum, what is necessary to bring any public accountability and transparency to what up to now has been a black box process for reviewing new chemicals under TSCA.

E. EPA Should Add Additional Requirements to the Proposed Requirements to Provide Additional Information in Submissions

EDF fully supports EPA's proposal to clarify and expand on the information on potential uses, exposures, releases, etc. that is a required part of new chemical submissions under TSCA section 5(d). These proposed requirements should reduce the amount of assessment "rework" that the Agency currently conducts and rightfully place the burden on the submitters to provide, at the time of their initial submissions, detailed information that is known or reasonably ascertainable by them. As described below, EDF encourages EPA to propose additional requirements that will enhance EPA's ability to more efficiently and confidently conduct its assessments.

1) EPA is proposing to require that submitters provide "Consumption rates and frequency and duration of use of products or articles incorporating the new chemical substance."[33] EDF believes that it would be useful to EPA to also require submitters to identify the source or basis of the consumption rate/frequency/duration information that they provide in their submission so that EPA can better evaluate the validity of the submitted information. Knowing the data source(s) would also potentially be useful for EPA for assessing potential exposures to other chemicals with similar use patterns.

2) EPA is proposing to require submitters to "designate applicable consumer and commercial product categories using Organisation for Economic Co-operation and Development

[30] As one means to allow sufficient time for comment and for EPA to consider those comments before completing its review, EPA has the authority to unilaterally extend the new chemical review period. 15 U.S.C. § 2604(c) ("TSCA section 5(c)").

[31] We note that TSCA does not provide for consent orders; it provides only for orders issued by EPA to regulate the unreasonable risk posed by a new chemical.

[32] As one means to allow sufficient time for comment and for EPA to consider those comments before the finalization of any such order, EPA has the authority to unilaterally extend the new chemical review period. 15 U.S.C. § 2604(c) ("TSCA section 5(c)").

[33] Proposed 40 C.F.R. § 720.45(f)(1)(vi).

(OECD)-based functional use codes, which would create consistency with TSCA section 8(a) Chemical Data Reporting (CDR) requirements in 40 C.F.R. part 711." Specifically, EPA is proposing to require that "Using the applicable codes listed in Table 1 to paragraph (f)(2), submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial products in which the new chemical substance is intended or known to be used."[34] EDF has two comments/questions about these proposed edits:

- The CDR regulations in 40 C.F.R. § 711.15(b)(4)(ii)(A)(2) provide more guidance than is provided in the 40 C.F.R. part 720 proposed regulatory text on how to utilize the OECD list of applicable functional use codes; specifically, how many use codes should be reported. EDF recommends that, preferably, all applicable codes be reported by the submitter or that this additional text (or comparable text) from the 40 C.F.R. § 711 regulations be incorporated into § 720.45(f)(2):
    - "If more than 10 codes apply to a chemical substance, submitters need only report the 10 codes for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight. If none of the listed consumer and commercial product categories accurately describes the consumer and commercial products in which each reportable chemical substance is used, the category "Other" may be used, and must include a description of the use."
- Presumably, OECD may at some time revise its functional use codes to reflect new products/new technology. EPA should consider whether it can "incorporate by reference" this OECD document so that any future updates to the OECD functional use codes will "automatically" update 40 C.F.R. § 720.45(f).

3) EPA is proposing to require that submitters provide certain information on worker exposures.[35] EDF recommends that EPA revise the wording in 40 C.F.R. § 720.45(g)(3) and 720.45(h)(3) to make clear that the information that must be provided in response to 720.45(g)(3)(ii)-(vii) and 720.45(h)(3)(ii)-(vii) pertains to each worker activity listed in the submission in response to 720.45(g)(3)(i) and 720.45(h)(3)(i). Suggested wording is to add "for each worker activity of the manufacturing/processing/use operations" after the phrase "(3) Worker exposure information." Wording similar to this suggested wording is used in EPA's Points to Consider document.

4) EPA is proposing to require that submitters provide certain information on protective equipment in place.[36] EDF recommends that EPA add the phrase "including specific brand names/model numbers."

5) Although "administrative controls" are probably only seldom identified by submitters as a technique used to mitigate worker exposures, EDF recommends that "Administrative

[34] Proposed 40 C.F.R. § 720.45(f)(2).

[35] Proposed 40 C.F.R. §§ 720.45(g)(3)(i) and 720.45(h)(3)(i).

[36] Proposed 40 C.F.R. §§ 720.45(g)(3)(iii) and 720.45(h)(3)(iii).

controls in place, if any" be added as a requirement to proposed 40 C.F.R. §§ 720.45(g)(3)(iii) and 720.45(h)(3). Thus, all components of the hierarchy of controls would be included in the final regulations.

6) EPA is proposing to require that submitters provide information on the "quantity of the new chemical substance released to the environment after control technology."[37] EDF recommends that submitters also be required to explain the basis/rationale and provide supporting data for the estimates provided. EPA would then have a better basis on which to judge the validity of the estimate. This information would be known or reasonably ascertainable and is similar to what has long been required for Toxics Release Inventory ("TRI") reporting. To assist companies in completing the TRI reporting forms, EPA has developed a table in the TRI instruction manual of various rationales.[38] EPA should incorporate the table of various rationales into the 40 C.F.R. Part 720 regulations.

7) EPA is proposing to require that submitters provide information on "what is used to clean the equipment."[39] EDF recommends that this somewhat vaguely worded phrase be replaced with the following phrase to provide more clarity: "the cleaning method used, including any devices used and any chemical substance used and the physical state of the chemical substance." This suggested wording is based on text from EPA's Points to Consider document.

8) EPA is proposing to require that submitters provide information on the "amount of release per container cleaning."[40] EDF recommends that submitters also be required to explain the basis/rationale for the estimate provided (for example, including a statement such as "estimate based on measured data for the new chemical substance or for similar chemical substances or estimate generated by [name of model]"). EPA would then have a better basis on which to judge the validity of the estimates.

9) The current proposed regulations address fugitive releases to some extent by requiring that the submitter provide "a description of any Leak Detection and Repair program in accordance with 40 C.F.R. parts 60, 61, 63, 65, 264 or 265 (related to the monitoring and management of fugitive releases) the site has implemented."[41] To address stack releases, EDF is recommending that EPA add the language "and the type of air pollution control technologies used at these facilities to treat the stack releases that will contain the new chemical substance, if known" to proposed 40 C.F.R. §§ 720.45(g)(4)(iii) and

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[37] Proposed 40 C.F.R. §§ 720.45(g)(4) and 720.45(h)(4).

[38] *See* EPA, TRI Program: Reporting Forms and Instructions, 6.1 Column B: Basis of Estimate, https://guideme.epa.gov/ords/guideme_ext/f?p=guideme:rfi:::::rfi:4_6_1_2.

[39] Proposed 40 C.F.R. §§ 720.45(g)(4)(i) and 720.45(h)(4)(i).

[40] Proposed 40 C.F.R. §§ 720.45(g)(4)(ii) and 720.45(h)(4)(ii).

[41] Proposed 40 C.F.R. §§ 720.45(g)(4)(iii) and 720.45(h)(4)(iii).

720.45(h)(4)(iii). Although such information may be available to EPA from the Clean Air Act operating permit numbers provided by the submitter, it would require extra effort on EPA's part to find and carry that information over, and may not be obvious from the permit.

10) EPA is proposing to require that submitters provide information on releases to water for facilities with NPDES permits.[42] In addition to the name of the navigable waterway(s) into which the new chemical substance is released, EDF recommends that the submitter also be required to provide the type of wastewater treatment technologies used at these facilities to treat the wastewater that will contain the new chemical substance; the known or expected treatment efficiency of the technology(ies); and the "outfall number" from the NPDES permit corresponding to this release point. Although such information may be available to EPA from the Clean Water Act NPDES permit number(s) provided by the submitter, it would require extra effort on EPA's part to find and carry that information over and may not be obvious from the permit.

11) EPA is proposing to require that submitters provide information on releases to wastewater treatment plants that presumably are not owned by the submitter or potential processors or users of the new chemical substance.[43] Most such facilities would be Publicly Owned Treatment Works (POTWs), which are included in the proposed regulations. Because some privately owned treatment works could receive wastewater, EDF suggests that the phrase "the name(s) of the publicly owned treatment work(s) (POTW)" be modified by adding the phrase "or privately owned treatment works" after "(POTW)." EDF recommends that submitters also provide information on any wastewater pre-treatment technologies employed at the site that are used to remove or degrade any of the new chemical substance from wastewater before discharge to the wastewater treatment plant.

12) EPA is proposing to add a requirement to 40 C.F.R. §§ 720.45(g)(3)(v) and 720.45(h)(3)(v) that submitters provide information on the "Physical form of the new chemical substance to which workers may be exposed and moisture content if physical form is solid." EDF suggests that submitters be required in these sections or in § 720.45(j)(1) to provide information, if known or reasonably ascertainable, on particle size for the neat (i.e., pure) new chemical substance or formulation of the new chemical substance that is in a solid inhalable form and the test method(s) used to develop these data.

13) EPA is proposing to require that any "particle size distribution" be submitted as part of the premanufacture notice ("PMN") form as well as the "particle size distribution analysis."[44] EPA indicates that the term "particle size distribution analysis" refers to the "analysis data used to develop the" (particle size distribution) "value."[45] To avoid any potential misunderstanding of the regulatory text at 40 C.F.R. § 720.45(j)(1), EDF recommends that

[42] Proposed 40 C.F.R. §§ 720.45(g)(4)(iv) and 720.45(h)(4)(iv).

[43] Proposed 40 C.F.R. §§ 720.45(g)(4)(v) and 720.45(h)(4)(v).

[44] Proposed 40 C.F.R. § 720.45(j)(1).

[45] 88 Fed. Reg. at 34107.

the phrase "particle size distribution analysis" be amended to read "particle size distribution analysis (i.e., analysis method and data used to develop the particle size distribution value."

14) EPA is proposing minor edits to 40 C.F.R. § 720.50(a)(4)(ii) concerning required notification of EPA when a test or experiment is completed before the applicable review period ends. If the test or experiment is completed within the last five days of the review period, the submitter must inform its EPA contact "by telephone or email prior to the end of the review period and submit the study, report, or test electronically to EPA via CDX." EPA should clarify in the regulatory text what the deadline is for submitting the study, report, or test electronically.

Modifications to the Submission Procedure

EPA is proposing to add statements with accompanying check boxes to certain screens of the PMN form that indicate that information fields can only be left blank if such information is not known to or reasonably ascertainable by the submitter. If a submitter leaves one of these information fields blank, the submitter would have to check a box on the screen to affirm that the information is not known to or reasonably ascertainable before advancing to the next screen. Additionally, a statement would warn the submitter that if a field that has been left blank is later amended, EPA may declare the original submission incomplete. As an alternative to this check box approach, EPA is considering adding automatic checks in CDX to make certain critical fields mandatory such that the user could not advance to the next screen in the PMN form or submit the form without entering information into the field.

EDF supports the approach preferred by EPA but will also support the alternative approach. Both approaches will better ensure that submitters provide complete and accurate information to EPA in the initial new chemical notification. However, EDF also believes that EPA and the public will have even more confidence that submitters will submit complete and accurate information if EPA amends the Certification Page of PMN Form 7710-25 (which requires the signature of the Authorized Official for the submitter) to include an additional statement (i.e., an additional 4th statement) that clearly states that the Authorized Official certifies that the information fields specified by EPA can only be left blank if such information is not known to or reasonably ascertainable by the submitter and that if a field that has been left blank is later amended, EPA may declare the original submission incomplete.

F. EPA Should Mandate Consequences for Companies that Late Submit Information During the New Chemicals Review Process that They Knew or Could Reasonably Ascertain at the Beginning

EPA has described the many problems associated with late submissions of additional information by industry throughout the review process (see subsection A, above) and there is no reason why EPA should be allowing this "longstanding practice"[46] in the first place. We urge EPA to finalize regulations, consistent with TSCA, that continue to require new chemical applicants to submit all

[46] 88 Fed. Reg. at 34106.

information known or reasonably ascertainable up front,[47] and make clear that EPA will then proceed to review the submission, make a risk determination, and take risk management action if appropriate (see subsection C, above).

EPA states that it intends with its Proposal to ensure that it receives more robust new chemicals submissions that should reduce Agency rework. But instead of taking the opportunity to comprehensively eliminate unnecessary rework, EPA has proposed regulations that would explicitly allow companies to submit late information, during the time that EPA is reviewing their new chemicals, that they should have provided with their new chemical submission. And under the Proposal, these companies would only see a minimal potential consequence: their new chemical review period may be reset to Day 1. Although it is a step in the right direction for EPA to give itself some time to deal with companies' late submissions of information, EPA's proposed regulatory revision is unlikely to substantially deter companies' current behavior – failing to submit required information at the time of the new chemical application and then helping themselves to continuous late submissions thereafter – that so drains the resources of EPA's New Chemicals Program.

A primary problem with EPA's proposed regulation is that even where EPA does determine that the late-submitted information was known to or reasonably ascertainable by the submitters when they submitted their application, EPA only *may* declare those submissions incomplete and restart the review clock. EPA has given no justification for this "may" language.[48] EPA should instead make clear that when any company, during the new chemicals review period, "submits additional or revised information without demonstrating to EPA's satisfaction that the [information] was not known to or reasonably ascertainable by the submitter at the time of the initial notice submission,"[49] the Agency *will* declare the submission incomplete and restart the review period at Day 1. In other words, the Agency should replace its currently-proposed "may"[50] with "will" or "shall."

Second, the Agency should make clear that when companies fail to submit all required information with their new chemical applications that is known to or reasonably ascertainable by them, they are potentially subject to enforcement actions. Failure of a submitter to comply with TSCA section 5(d)(1) constitutes a violation of TSCA pursuant to sections 15(1) and/or (3)(B).[51] Such violations are in turn subject to penalties pursuant to section 16.[52]

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[47] 40 C.F.R. § 720.40(d).

[48] Proposed 40 C.F.R. § 720.65(c)(2).

[49] *Id*.

[50] *Id.*

[51] 15 U.S.C. § 2614

[52] 15 U.S.C. § 2615

Third, EPA should spell out in the final regulations what types of information will be deemed to have been known to or reasonably ascertainable by any new chemical submitter at the time the company submits its application. For example, EPA states in the Proposal that companies reasonably would know, at the time they submit their new chemical applications, "information on basic physical and chemical properties and on anticipated releases or worker exposure at any sites controlled by the submitter" and that "EPA believes that it is extremely unlikely that a submitter would neither know nor be able to reasonably ascertain such information, but could know or ascertain it 20 or 40 or 60 days after the original submission…"[53] This is an example of a category of information that EPA should define in the final regulations as known or reasonably ascertainable to new chemicals submitters at the time of original submission.

G. EPA Should Treat the Submission of New Information During the New Chemicals Review Period as a New Submission

EPA proposes not to restart the review clock at all when companies submit information during the new chemicals review period that "was not known to or reasonably ascertainable by the submitter at the time of the notice submission." This means that even when a company gives such "new" information to EPA mere days before the Agency is required to issue a determination about a new chemical, EPA would be obligated to consider the late information and possibly rework its complete risk assessment, all without any additional time. Second, EDF is concerned that EPA's proposal to treat differently information that is "new" versus known to or reasonably ascertainable by submitters at the time they submitted their new chemical applications could engender disputes and additional back and forth between industry and EPA over which category particular information coming in mid- or late-review falls under. If this occurs, it may drain additional EPA resources despite EPA's intent for its proposal to reduce such burdens.

To address these issues, EPA should finalize regulations making clear that if a company submits new information during the new chemicals review process, such amendment constitutes a new submission.[54] Accordingly, EPA would have the full applicable period to review the information, starting over as for any new chemical submission. Under this procedure, EPA would gain the time that it often needs in any case that it receives new information during the review process; however, unlike in the cases where companies submit information late that was known or reasonably ascertainable to them when they submitted their new chemical applications, these submissions would not be deemed "incomplete," nor would the company be subject to enforcement.

In its economic analysis, EPA estimates that even with its proposed regulations in place, 60 percent of new chemicals applications will still be "amended" after they are submitted, and half

[53] 88 Fed. Reg. at 34111.

[54] EPA may wish to except new information that it receives per the Agency's own request.

of those applications will be amended more than once.[55] EPA should no longer tolerate such wasteful practices, and should put in place procedures that maximize the submissions of complete applications up front so that New Chemicals Program staff may complete their assessments without distraction, interference, and delay.

EDF urges the Agency to make the necessary changes described above, aligning its New Chemicals program with TSCA and dealing with the major problems of industry interference in the new chemicals review process and the significant burden on EPA of reworking its reviews. EPA should codify all these changes in final new chemicals regulations.

II. EPA'S REGULATIONS MUST DO FAR MORE TO INCREASE TRANSPARENCY, PUBLIC ACCESS TO INFORMATION, AND PUBLIC PARTICIPATION IN THE NEW CHEMICALS PROGRAM

EPA should go further in codifying regulatory provisions aimed at rebuilding public trust by increasing the transparency and accountability of, and public engagement in, the New Chemicals Program. The Agency has the increased ability and responsibility under Congress's amendments to TSCA, to take the following actions, which EDF elaborates on below. First, EPA should codify a pre-screen process that incorporates TSCA's confidential business information ("CBI") provisions in order to exclude CBI claims that are inadequately supported or that are for information ineligible for TSCA protection. Second, EPA should post to the Federal Register notices of receipt for all new chemical applications, not just those that are deemed "complete." Third, EPA should codify the statutory requirement that it post notices of receipt to the Federal Register within five days. Fourth, if EPA intends to continue posting new chemical information on ChemView, the Agency needs to codify a requirement that it do so, in order to prevent abrupt changes to agency policy and to preserve public access to key information. Finally, EPA should provide through regulations a comment period on new chemical applications in order to allow the public to provide input on any noticed chemicals of interest before the Agency determines those chemicals' risks.

A. EPA Should Expand Its Pre-Screen Process to Exclude Confidential Business Information ("CBI") Claims that Are Ineligible or Do Not Meet Basic TSCA Requirements

While we appreciate EPA's proposal to codify the new chemicals pre-screen process that EPA conducts before moving forward to risk assessment, we are concerned that EPA has excluded nearly all of TSCA's CBI requirements from that process.

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[55] EPA, "Economic Analysis for the Proposed Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act," page 3-6, May 2023, https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0035. Moreover, each amendment involves "10 technical hours and 2 managerial hours" of EPA staff time. *Id.* Based on EPA's estimate of annual number of submissions, under EPA's current proposal, EPA would still be spending over 2,400 technical hours and 480 managerial hours each year dealing with companies' late submissions of information. *Id.* at page 3-6 and page 5-4.

The only reference to confidential information requirements EPA proposes to include is that a submission is not complete if: "[t]he submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 720.80(b)(2)."[56] While that provision is certainly warranted and should be retained in the final regulations, there is no basis for EPA to include only this CBI-related requirement among all of those specified in TSCA.

EPA needs to expand its pre-screen to include all basic requirements and limitations for CBI claims specified in TSCA. Claims for ineligible information or claims that do not meet TSCA's basic CBI requirements should be disallowed from the outset. They neither need nor warrant the full review of CBI claims described in TSCA section 14(g)(1). Absent a robust pre-screen for clearly problematic CBI claims in new chemical notices, EPA would both fail to align its regulations with TSCA as amended in 2016, and would deny the public timely access to new chemical notices redacted only to the extent allowed under TSCA. Failure to expand EPA's pre-screen of CBI claims would perpetuate the many instances EDF and others have identified in which notices and associated documents made available to the public are improperly "sanitized."[57] In contrast, screening out unwarranted CBI claims during the pre-screen would be more transparent, more effective, and more efficient for the Agency. Forcing the public to wait until the Agency goes through a full CBI review pursuant to TSCA section 14(g) would be inconsistent with TSCA's clear delineation of certain exclusions from eligibility for CBI protection and up-front requirements that must be met when first asserting a CBI claim.[58]

Specifically, the final regulations need to identify as erroneous or incomplete any submission that asserts any CBI claim: (1) that does not meet TSCA's basic requirements for assertion, and where required, substantiation, of CBI claims, as specified under TSCA sections 14(c)(1)(A) and (B), (c)(3) and (c)(5);[59] (2) for information that is ineligible for protection from disclosure

[56] Proposed 40 CFR § 720.65(c)(1)(vii).

[57] See EDF's blog highlighting numerous instances of deficient or entirely lacking substantiations for CBI claims in new chemicals submissions. Richard Denison, PhD, "No justification: Substantiations for rampant new chemical CBI claims are deficient or lacking altogether," February 16, 2018, https://blogs.edf.org/health/2018/02/16/no-justification-substantiations-for-rampant-new-chemical-cbi-claims-are-deficient-or-lacking-altogether/. *See also* Amended Complaint, *Environmental Defense Fund v. EPA*, 1:20-cv-00762 (D.D.C. March 18, 2020) PP 136-37 (highlighting 90 instances in which PMNs were released to the public without substantiation documents for the CBI claims that were asserted).

[58] TSCA Section 14(c)(3) requires a submitter asserting a CBI claim to substantiate the claim in order to assert it (where substantiation is required). 15 U.S.C. § 2613(c)(3).

[59] Such claims include unwarranted or erroneous assertions by the submitter that particular information in the new chemical application falls under one of the exemptions from substantiation requirements for information identified in TSCA Section 14(c)(2). EDF has identified numerous examples of PMNs whose submitters erroneously asserted that particular information they were claiming to be confidential fell under provisions of Section 14(c)(2); further, in many of these cases, the information so asserted constitutes health and safety information, such as information about occupational exposure or environmental release, that is ineligible for protection from disclosure in the first place.

pursuant to TSCA section 14(b);[60] (3) for specific chemical identity that fails to include a sufficiently descriptive generic name that meets the requirements of TSCA section 14(c)(2); and (4) for specific use of the chemical that fails to include a sufficiently descriptive generic use description that: (a) EPA is required to include in its notice of receipt published in the Federal Register pursuant to TSCA section 5(d)(2)(B), and (b) is consistent with TSCA section 14(b)(3)(B)'s designation of general chemical use information as ineligible for protection from disclosure under TSCA.[61]

We recognize that the Agency codified a different approach to addressing what it calls "deficient" CBI claims in its recent CBI rulemaking, which we advocated strongly against in our public comments on the rule.[62] Under EPA's newly created process at 40 C.F.R. § 703.50(e), "any applicable review period for the underlying submission will be suspended until either the deficiency is corrected or the 10 business days elapse without such correction." As discussed in more detail in section 16 of our CBI comments:

- While the regulations do state that certain errors or omissions by claimants (for example, failure to provide a public copy of a submission asserting a CBI claim) renders a submission "deficient," identification of that deficiency does not result in rejection of the submission or claim, let alone public access to the information, at that point, if ever.
- Instead, it triggers a wholly new procedure in 40 C.F.R. § 703.5(e)(2) under which EPA will only place a hold on the submission to allow the company to address the deficiency; even if the company fails to do so, EPA will merely proceed with a review of the deficient claim and even then equivocally states only that the Agency "***may*** deny the CBI claim(s)."

We urge EPA to modify its suspension approach, which provides virtually no incentive for companies to avoid making "deficient" claims and only serves to delay if not ultimately deny the public access to information to which it is entitled. If EPA adopts the approach we describe above, at least these and other "deficient" CBI claims will be identified up front and the review clock on the new chemical will not start ticking until the deficiency is remedied.

Finally, EPA's proposed regulations apply only to premanufacture notices ("PMNs"), significant new use notifications ("SNUNs") and microbial commercial activity notices ("MCANs"), as they reside in Part 720. The same pre-screen procedures – modified to address our comments above – need also to be applied to exemption applications, and hence should be replicated in Part 723.

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[60] With respect to health and safety studies or associated information described in TSCA section 14(b)(2), EPA should disallow any CBI claim asserted for information that does not fall under the exceptions provided in that provision.

[61] These factors should be added to the proposed rule at 40 C.F.R. § 720.65(b)(1) and (c)(1).

[62] EDF, Comments on "Proposed Rule: Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)," EPA-HQ-OPPT-2021-0419 (July 11, 2022), 45-48 https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0419-0026.

B. EPA Must Post All Received Notices to the Federal Register as Required by TSCA

EDF opposes EPA's proposal to narrow the types of notices it will post to the Federal Register from any "notice" to any "complete notice." Under EPA's proposed pre-screen procedures, there may be one or more versions of a notice on a given new chemical that are deemed erroneous or incomplete before EPA receives a version of the notice EPA deems complete and ready for review. Thus, under the proposed pre-screen process, there may be multiple notice versions associated with the same new chemical. If EPA were only to post the notice of receipt of the complete notice, this would prevent the public from being able to follow the new chemical notice from its origin. The public would be unable to determine whether the notice was initially deemed erroneous or incomplete, the reason for such determinations, and what changed to make the notice complete. Ensuring that this pre-screening process is a transparent and accountable process is important.

Unlike EPA's proposed process, EPA's current process for posting notices of receipt of new chemical notices to the Federal Register records each such submission and indicates when a version of a notice received is an original notice or an amended or revised version of the original notice. Notice amendments are marked by an "A" following the PMN or SNUN number and a version number is included to indicate the sequential number of the amendment. Moreover, through ChemView, EPA posts each amendment and often provides a useful summary sentence describing the reason for the amendment.

EPA should not abandon its years-long practice of clearly communicating its receipt of new chemical notice amendments to the public. The posting of both original and subsequent amendment notices is critical for the public to be able to meaningfully understand, follow, and engage in the new chemicals review process at EPA. We recognize that the Agency is resource-constrained but given that EPA has for years already been identifying receipt of amended notices in the Federal Register, maintaining this practice would not add additional work for the Agency.

In addition to these practical reasons, only posting "complete notices" to the Federal Register as proposed in 40 C.F.R. § 720.70 is not in accordance with TSCA section 5(d)(2). TSCA section 5(d)(2) states that "not later than five days… after the date of the receipt of ***a notice*** under subsection (a)… the Administrator shall publish in the Federal Register a notice…" (emphasis added).[63] Similarly unambiguous language is used in TSCA section 5(d)(3) pertaining to the monthly listings EPA is required to publish in the Federal Register.[64] TSCA makes clear EPA's obligation to post each notice received, regardless of whether it contains errors or is incomplete. Thus, 40 C.F.R. § 720.70 needs to be consistent with the plain language of TSCA section 5(d)(2).

We urge the Agency to maintain the existing language at 40 C.F.R. § 720.70(a) rather than amend the regulation to only notice in the Federal Register "complete notices" as proposed.

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[63] 15 U.S.C. § 2604(d)(2) ("TSCA section 5(d)(2)").

[64] 15 U.S.C. § 2604(d)(3) ("TSCA section 5(d)(3)").

C. EPA Should Codify TSCA's Requirement to Post New Chemical Notices to the Federal Register Within Five Days of Receipt

In addition to maintaining its regulation stating that the Agency will post notice of receipt of any notice it receives in the Federal Register, EPA should codify a requirement that the notice be posted within five days. First, this is statutorily mandated.[65] Congress has delegated to EPA the authority to implement the requirements of TSCA within the bounds that Congress has set forth.[66] EPA's proposal to ignore the plain language of the statute goes outside of the bounds of any discretion Congress has set for the Agency. Second, EPA's statement in the preamble to the Proposed Rule that it generally posts a notice of receipt of PMNs to ChemView within five days is insufficient.[67] The qualifying language that EPA "generally" posts within five days indicates that it does not always do so. Nor does EPA's reference in the preamble to its practice of posting to ChemView, rather than in the regulatory text itself, provide any guarantee that the Agency will continue to do so.[68] Leaving the practice uncodified makes it possible for the Agency to change course in the future without providing any notice, comment opportunity, or ability to legally challenge such a change in the Agency's practice. Third, even if the publication schedule of the Federal Register means that a submitted notice may not always necessarily be published within the five-day window, EPA should at the minimum codify a requirement that the Agency will send the publication notice to the Federal Register within at most five days of receipt.[69]

D. EPA Should Codify its ChemView Publication Procedures to Ensure Timely Public Access to New Chemical Information

EPA justifies its proposal to remove the requirement in 40 C.F.R. § 720.70(b)(3) to "include a list of data submitted with the PMN in accordance with 40 C.F.R. § 720.50(a)" by pointing to its use of ChemView, the Agency's primary database for new and existing chemical information under TSCA. EPA claims that its transparency goals can be "better achieved through other more efficient and effective mechanisms that negate the need to publish that information [at 40 C.F.R. § 720.50(a)] in the Federal Register."[70] EPA further states that it currently "makes the PMN

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[65] 15 U.S.C. § 2604(d)(2) ("TSCA section 5(d)(2)").

[66] 15 U.S.C. § 2601(c) ("TSCA section 2(c)").

[67] 88 Fed. Reg. at 34105.

[68] *Id*.

[69] TSCA explicitly requires publication in the Federal Register within five business days. 15 U.S. C. § 2604(d)(2). EPA's current practice violates this statutory provision, and the Agency does not propose any codification of the provision (rather, EPA merely states in the preamble that it "generally" posts information to Chemview within five days). Assuming EPA acts on its stated intention not to codify the TSCA Federal Register requirements, EDF recommends this regulatory provision in order at least to help ensure public access to information as soon as possible.

[70] 88 Fed. Reg. at 34105.

itself, including test data submitted with it, available on ChemView (subject to confidentiality claims) generally within 5 workdays of receipt."[71]

As avid users of ChemView, EDF greatly appreciates EPA's current practice of relatively promptly posting new chemical notice information to the database as a supplement to information it publishes in the Federal Register. While some significant limitations and challenges remain, ChemView has evolved to be an important resource to interested stakeholders seeking to engage in the New Chemicals Program at EPA. Given the importance of this data resource, we are greatly concerned that EPA has not proposed to codify its ChemView posting procedures and practices in this rulemaking, even as it proposes to remove from its regulations statutory and regulatory information access requirements for its Federal Register notices. To the extent EPA intends to rely on ChemView, and to ensure that ChemView remains a useful resource to the Agency and the public, EPA should codify in detail its commitments to timely publish new chemical information, including all information it is currently required to provide under TSCA or its existing regulations, but is proposing to remove from the regulations, including its reliance on ChemView for these purposes.[72]

In codifying its ChemView procedures and practices, EPA should ensure the public has timely access (within a few days at most, to allow the public time to comment – see subsection E, below), for all new chemical applications (including exemption applications),[73] to the following information:[74]

- the date of receipt of each application;
- the identity of the applicant, unless claimed CBI in a manner that complies with all applicable TSCA requirements for such claims;
- the identity of the substance or, if claimed CBI, a generic name that conforms with EPA guidance;[75]

[71] *Id*.

[72] EDF again notes that TSCA explicitly requires publication of notices in the Federal Register, so the Agency's Proposed Rule would violate the statutory requirements. 15 U.S.C. § 2604(d)(2). Assuming EPA acts on its stated intention not to codify the TSCA Federal Register requirements, EDF recommends these regulations in order at least to help ensure that EPA provides improved public access to this critical information.

[73] These include premanufacture notices ("PMNs") as well as applications for various exemptions from the PMN review process, including low-volume exemptions ("LVEs"), low-release/exposure exemptions ("LoREXs"), byproduct exemptions, and polymer exemptions. Some of the listed categories of information are currently being publicly provided by EPA for PMNs. EPA should codify a requirement to provide public access to all the categories of information for all new chemical applications.

[74] In the proposal, EPA does note its posting of PMNs to ChemView, but does not codify in its regulations even a requirement that it do so. It proposes to cease publishing in the Federal Register a list of the data received with a PMN. EPA argues its practice of posting to ChemView is sufficient, but again fails to codify any requirement in the regulations that ensures it will continue to do so.

[75] EPA's description of its pre-screen does not mention any review of generic names as to their adequacy.

- the specific chemical use of the substance or, if claimed CBI, a generic use description that conforms with EPA guidance;[76]
- whether the chemical falls within any of the Agency's new chemical categories;
- the public files, including all attachments to the application (and all versions of the application and attachments);[77]
- for exemption applications, whether EPA has granted or denied an exemption for the same chemical or very similar chemicals in the past; and
- all correspondence between EPA and submitters.

In addition, upon completion of its review of a new chemical notice or application, EPA should promptly make public the final risk assessments and standardized reports it developed during the review, any associated determinations and findings it reached, and any orders it issues. The public should also be given prompt access to each new chemical's initial risk assessments and associated documents, as well as any revised versions developed over the course of the review.

With respect to EPA decisions on exemption applications, the conditions applicable to EPA's approval of any application should also be made public, as well as any associated determinations and findings EPA reaches. EPA should specifically indicate the rationale behind "conditional" interim decisions, and for any exemption decision that changes from an initial "conditional denial" to a final "grant," EPA should explain why and how the status changed.

This information should be coded in fields, along with dates the information was posted, to enable ready identification of newly added information and export and analysis of new chemical data. Moreover, EPA should make the necessary changes to ChemView to ensure that a new chemical's journey and timeline from first submission as a new chemical to an existing chemical can be followed. EPA needs to ensure that PMN numbers and similar tracking numbers for other applications (e.g., Low Volume Exemptions ("LVE") numbers) are tied to Chemical Abstract Service ("CAS") numbers (consistent with TSCA section 14), unique identifiers, and other appropriate identifiers. This can be facilitated by combining PMN/CAS ChemView entries into one entry per chemical, which will help to keep all relevant documents on a given chemical (PMN, consent order, significant new use rule ("SNUR"), test data, etc.) in one place.

Alternatively, if EPA will not codify in its regulations procedures detailing what information must be posted to ChemView and when, the Agency should not delete existing 40 C.F.R. § 720.70(b)(3) and should instead expand upon it to encompass and require Federal Register publication of all of the above information. Subsection 720.70(b)(3) is the only codified requirement regarding what information must be provided to the public when EPA gives notice that it has received a PMN. As explained above, unless EPA codifies in its regulations a policy

[76] EPA's description of its pre-screen does not mention any review of generic use descriptions as to their adequacy.

[77] It is unclear whether EPA's intention is still to post amended versions of PMNs to ChemView, assuming it implements its proposal to reset the review clock if an amended version is submitted. EPA should codify that it will continue to do so, for the reasons EDF discusses above in subsection B, about the need to post all notices of receipt of PMNs, not just "complete" ones.

and required procedures that it will use to provide public access to this critical information, EPA could potentially stop doing so at any time. Codification of such requirements is needed to fulfill one of the core policy goals of TSCA – ensuring public access to robust information on chemicals and their potential or actual risks.

E. EPA's Regulations Should Provide a Timely, Formal Public Comment Opportunity on New Chemical Applications Received

Providing the public with timely notices of receipt of, and timely access to, new chemical applications (discussed in the preceding subsections) is necessary but not sufficient to ensure the public has a meaningful opportunity to provide input to EPA regarding the new chemicals or significant new uses industry seeks to commercialize. EPA should also codify procedures to establish a formal public comment opportunity on new chemical applications. These procedures should provide sufficient time for the public to access and review the available information on a new chemical and prepare and submit comments when they so choose. The procedures also need to ensure EPA has ample time to review and consider any public comments received in the course of its own review of a new chemical before making any determination.

Timely publication of notices of receipt in the Federal Register is vital because such Federal Register notices are the only viable means by which EPA can establish a formal notice-and-comment process, which includes an ability for members of the public to post their comments to a formal public docket and an assurance that EPA receives and considers those comments before making any regulatory decisions about a new chemical.

We recognize that EPA currently provides a 30-day comment period in the Federal Register notices it publishes listing certain new chemical applications it received in a given month.[78] However, such listings frequently are not timely published (despite efforts by EPA in recent years to speed up the process), and typically appear many weeks after the review periods for some of the listed new chemicals applications have begun. For example, the listing for May 2023 was not published until June 21, 2023.[79] That listing included a number of new chemical applications first received by EPA early in May, and at least one received in late April. Assuming EPA initiated its review upon receipt of those applications, the public first learned of them six weeks or more after the start of the 90-day (13-week) review period. By the time EPA received any public comments, as few as four weeks of any timely-initiated review period (assuming there was no extension or suspension of the period) would have remained, leaving scant if any time for EPA to consider comments received.

In establishing a requirement in TSCA section 5(d)(2) that EPA publish notice in the Federal Register of its receipt of a new chemical notice within five days, Congress sought to ensure the public is promptly informed when a new chemical application is submitted. This five-day period

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[78] *See*, for example, EPA, "Certain New Chemicals; Receipt and Status Information for June 2023," 88 Fed. Reg. 46157, July 19, 2023, https://www.federalregister.gov/documents/2023/07/19/2023-15301/certain-new-chemicals-receipt-and-status-information-for-june-2023.

[79] EPA, "Certain New Chemicals; Receipt and Status Information for May 2023," 88 Fed. Reg. 40257, June 21, 2023, https://www.govinfo.gov/content/pkg/FR-2023-06-21/pdf/2023-13165.pdf.

is noticeably short compared to other deadlines Congress imposes upon EPA, such as the 90-day period that the Agency is generally provided to review most new chemical applications. This stark difference in timing is clearly intentional. It is strongly to be inferred that Congress set that admittedly short window to ensure that the public could provide its input well before the Agency is required to make a decision on a given new chemical.

Meaningful public review and comment also requires public access to the new chemical application itself (including attachments). We appreciate EPA's efforts to strive to make such materials available via ChemView within five days, but have discussed several serious limitations concerns about this approach in subsection D, above. Assurance of prompt public access is critical here, which makes it all the more important that EPA's reliance on ChemView be codified and include strict timelines.

But while ChemView postings are essential, they do not themselves establish a formal public comment opportunity. And while EDF and others have taken advantage of the informal comment opportunities EPA currently provides in its monthly Federal Register listings, even that insufficiently timely process could be discontinued at any time.

EPA should codify in its regulations a process and timeline to ensure a timely, formal opportunity sufficient for the public to develop and submit meaningful comments on new chemical applications in which it has an interest, one that also leaves sufficient time for EPA to fully consider any comments it receives. For this reason, EPA's regulations need to specify that EPA will not make final determinations on any chemical subject to public comment until after the close of the comment period.

III. EPA MUST PROVIDE FOR POSSIBLE REVISIONS TO ITS REGULATORY ORDERS BASED ON INFORMATION SUBMITTED BY THE PUBLIC AND INFORMATION THAT WARRANTS STRENGTHENING REGULATION

EPA has proposed a troubling addition to its new chemical "determinations" provisions. Specifically, EPA proposes to add regulatory language stating that after it issues an order under TSCA sections 5(e) or 5(f):

> EPA may modify or revoke the prohibitions and limitations in [the orders] after the applicable review period has ended if the submitter submits to EPA additional testing, studies, reports, or other information that EPA determines, upon review, demonstrate that such prohibitions or limitations are no longer necessary to protect against an unreasonable risk of injury to health or the environment.[80]

This proposed provision is troubling for two main reasons. First, EPA appears to contemplate and codify a role only for the chemical company submitter. EPA's proposal provides that if the company, which has a financial interest in manufacturing the chemical subject to the order, comes to the Agency with additional information, EPA will consider that information. While EPA certainly needs to consider information the company develops and submits, including from

[80] Proposed 40 C.F.R. §§ 720.75(d)(3) and 725.170(d)(3).

any testing EPA has required in the order, its proposed provision is too narrow. Specifically, EPA proposes regulatory text discussing only the consideration of information about that chemical developed or submitted by the company, and not by any other party, including scientific researchers, health advocates, workers, unions, other governmental agencies, or any member of the public at all.

Second, the proposed language indicates *only* the *weakening* of the Agency's regulation of the risky chemical. The provision fails to include the possibility that additional information, including information required to be developed by the order, could warrant *strengthening* of protections against potential unreasonable risk, i.e., increasing protection against harms to people or the environment from chemicals that are subject to section 5 orders. Indeed, numerous orders issued by EPA require companies to conduct testing on their new chemicals. In the cases that such testing shows the chemicals to pose additional, potential unreasonable risk to people or the environment beyond those EPA had identified in the risk assessments underlying the original orders, TSCA requires EPA to impose additional regulations sufficient to address those risks. EPA's regulations should require, not preclude, such actions.

In finalizing regulatory language about possible modifications to section 5 orders, EPA must make clear that EPA will consider information from all stakeholders – not just chemical company submitters – and also that such information may warrant strengthening the order to ensure protection of human health and the environment. Therefore, EPA should revise its currently one-sided proposed 40 C.F.R. § 720.75(d)(3) (and, as applied to MCANs, proposed § 725.170(d)(3)) to make clear the Agency will consider new information from all parties and take actions necessary to protect human health and the environment.[81]

EPA has the authority to modify an existing order to make it more protective of public health or the environment. TSCA itself indicates EPA has the authority to modify orders to make them more stringent or protective: Section 21[82] refers to a petition to amend an order issued under section 5(e) or 5(f). Clearly, for Congress to have authorized section 21 petitions to amend orders, Congress intended that they could be modified by EPA. As section 21 petitions would not be filed until after the close of the applicable review period under section 5 of TSCA, and most certainly not resolved until after the end of the review period, Congress clearly anticipated modifications to section 5 orders occurring after the time period for issuing initial section 5 orders. Congress added the reference to section 5(f) in 2016 when it passed the Lautenberg Act, thereby confirming Congress' view in the context of its statutory revisions to section 5.

EPA's authority to revise orders to make them more stringent is consistent with agencies' general inherent authority to reconsider and modify earlier decisions. Courts have repeatedly

[81] Such necessary actions may include revising orders based on new risk information developed over time on categories of chemicals, such as PFAS.

[82] 15 U.S.C. § 2620.

recognized that agencies have that authority in the absence of specific statutory limitations.[83] TSCA does not bar reconsideration of orders; indeed, as described above, it contemplates the revision of section 5 orders by EPA.

The Agency has already taken this more even-handed approach in its standardized "consent order" language, such as:

> EPA may, at any time, upon the receipt or evaluation of any information, new or existing, determine that these New Chemical Substances presents or may present an unreasonable risk of injury to health or the environment, and may issue a rule to regulate the substance or modify this Order to address any risks.[84]

Such language, both recognizing the reality that EPA receives new information indicating unreasonable risk and EPA's authority and duty to address it, should be included in the final regulations.

We note that many section 5 orders, particularly older orders, exist that are not explicit about EPA's ability to reopen the orders based on risk, while at the same time providing a one-sided opening only to weaken the order's restrictions. Therefore, we urge EPA to make clear in its final regulations that whether or not certain "reopener" language appears in its section 5 orders, EPA may reopen those orders at any time based on new information relevant to risk and take any and all needed and appropriate action in response. The ability for EPA to reopen orders does not depend on whether the agency happened to include such language when it issued the order. As explained above, EPA clearly has the legal authority to modify section 5 orders, including "consent orders," regardless of whether there is express language recognizing that authority. Moreover, an attempt to argue that EPA could agree with a private party not to exercise its statutory authority to protect public health and the environment by eliminating unreasonable risks would run afoul of constitutional doctrines of separation of powers.

EDF also urges the Agency to specify in its regulations under what circumstances orders are to be revised based on test results or other new information,[85] and the process used to do so, including providing for public notice and an opportunity to comment.

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[83] *See Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008); *Macktal v. Chao*, 286 F.3d 822, 825-26 (5th Cir. 2002) (collecting cases).

[84] EPA, TSCA Section 5 Order for a New Chemical Substance for Chevron U.S.A. Inc., at 13 (Aug. 25, 2022), https://www.documentcloud.org/documents/23607053-sl-sanitized_consent_order_p_21_0144c.

[85] For example, where the new information alters risk levels sufficiently to warrant changing a level of release allowed under the order, or where the new information identifies a significant potential risk from an activity allowed under the order that should now be restricted.

IV. EPA SHOULD FULLY ALIGN ITS NEW CHEMICALS REGULATIONS WITH CONGRESS' MANDATES IN AMENDED TSCA AND DESCRIBE HOW IT WILL IMPLEMENT THE KEY REFORMS

Congress clearly required, in its 2016 reform of TSCA, that manufacture of a new chemical will not begin until EPA makes a determination on a new chemical application and takes the required Section 5 action on the determination. Congress's change to the law, which previously allowed manufacture of new chemicals even in the absence of EPA's review, represented a bedrock reform to new chemicals review and regulation. As EPA notes, the current regulations are inconsistent with this change, and EDF supports the Agency's proposed modification to 40 C.F.R. § 720.75(d) to align the regulations with this key Congressional reform. EDF also supports EPA's proposed incorporation of the five possible determinations and associated actions, one of which EPA must take in response to each new chemical application (specifically, a PMN, SNUN, and MCAN), at 40 C.F.R. § 720.75(d).

However, EPA has not fully met its stated purpose of aligning its regulations with Congress' requirements in reformed TSCA. In purporting to codify the requirements of TSCA, the Agency has been troublingly selective. We urge EPA to fully bring the regulations into conformance with the 2016 amendments by including the following in the final regulations.[86]

A. EPA's Regulations Need to Address Information Insufficiency and Testing

EPA should clearly spell out in the regulations its authority both to limit or prohibit the manufacture, processing, distribution in commerce, use and disposal of a new chemical substance and to require testing of the new chemical when it finds that information about the chemical is insufficient. One of the key reforms made to TSCA in 2016 was to establish "insufficient information" as a stand-alone finding about a new chemical, which, when made, by itself triggers mandatory regulation of the substance.[87] This was an important change from TSCA as originally enacted, under which information insufficiency could only lead to regulation if EPA also found that the new chemical "may present" unreasonable risk or is produced in large amounts and expected to lead to large environmental releases or human exposures. Under amended TSCA, EPA is to make separate findings as to information sufficiency and potential risk or high release/exposure; if either finding is made, EPA must then issue an order regulating the new chemical.

EPA briefly notes in the preamble to the Proposed Rule that, after a finding of insufficient information, the Agency "may" issue a section 5(e) order requiring testing to be conducted. And it proposes at 40 C.F.R. § 720.75(d)(2)(ii) only that when it makes such a finding, "EPA may issue an order under section 5(e) of the Act that requires certain testing to be conducted and presented to EPA after the applicable review period has concluded." This proposed language

[86] EPA states that its proposal, among other purposes, is "intended to align the regulatory text with the amendments to TSCA's new chemicals review provisions" contained in reformed TSCA. 88 Fed. Reg. at 34100.

[87] 15 U.S.C. § 2604(e)(1)(A)(i) ("TSCA section 5(e)(1)(A)(i)").

raises several concerns. First, the Agency does not discuss – let alone codify in the proposed regulations – that it expects frequently to make determinations of insufficient information. Many new chemicals lack sufficient information for EPA to make the "may present an unreasonable risk" finding or the substantial release or exposure findings. Second, EPA nowhere states that when it does find information is insufficient, it will require testing. EPA has not explained how it would, absent such testing, address the identified insufficiencies.

Nor does the Agency explain how it would go about making insufficient information determinations, such as by including a description in the regulations of what criteria EPA will consider to decide whether available information is sufficient or insufficient. As one example, EPA cannot estimate risk when available information is insufficient to establish a point of departure ("POD"), needed to estimate a risk value. In the final regulations, EPA should include such criteria.[88]

In addition, the Agency should spell out what it will do upon making an insufficient information determination. When EPA issues such an order under TSCA section 5(e), it should include testing requirements to address any data gaps EPA identifies. Such testing should address and be sufficient to resolve any uncertainties in the risk analysis due to the use of analog substances or assumptions and confirm or negate the appropriateness of the use of such analogs or assumptions.

Finally, unless EPA concludes that there will be no exposure to the chemical, the order should bar commercialization of the chemical until the testing is completed and reviewed by EPA, and the Agency factors the results into a new determination. EPA's proposed language at 40 C.F.R. § 720.75(d)(2)(ii) should be modified to state clearly that EPA can, and in some cases will, require testing to be conducted up front, before allowing commercialization.

All of the above requirements should be spelled out in EPA's final regulations.

B. EPA's Reviews of New Chemical and Significant New Uses Need to Evaluate Reasonably Foreseen Conditions of Use

EPA should include in the final regulations Congress' key 2016 reform of TSCA requiring EPA to evaluate reasonably foreseen as well as intended conditions of use when reviewing a new chemical or a significant new use. The regulations should include the following:

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[88] EPA needs to develop specific criteria – based on risk and not on cost or other non-risk factors – for: (1) making information sufficiency determinations; (2) deciding what testing is needed to address identified insufficiencies; (3) deciding when test results are to be submitted; and (4) deciding what conditions are to apply while required testing is being conducted, which may include a ban on commercialization pending completion of the testing and assessment of the results. The categories of testing that the criteria need to address include:

- upfront testing, i.e., required before or as a condition of commencement, to address either information insufficiencies or significant hazard concerns;
- triggered testing, i.e., due before certain conditions are met or can be exceeded; and
- pended testing, which should be required before any modification of the order can be considered.

- EPA must conduct an *upfront* evaluation of reasonably foreseen conditions of use in combination with intended conditions of use (TSCA sections 3(4) and 5(a)(3)).[89]
- EPA must take a broad, inclusive approach to identifying reasonably foreseen conditions of use. TSCA's definition of "conditions of use" (TSCA section 3(4)), into which "reasonably foreseen" is integrated, is itself broad and inclusive, expressly including "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." This definition encompasses the full lifecycle of the chemical, requiring EPA to adopt a broad approach to identifying conditions of use, including those that are reasonably foreseen as intended or already known to occur.
- EPA should identify information and factors that at a minimum must be considered in determining reasonably foreseen conditions of use, and evaluate them in combination with intended conditions of use. These should include:
    - any known, intended and/or reasonably foreseen conditions of use of new chemical structural analogs;
    - the potential for expanded or changed use patterns, such as consumer use of a chemical initially intended only for industrial use;
    - production volume increases, with a focus on aggregate production across multiple sites/manufacturers (aggregate production volume increases are reasonably foreseen and must be accounted for);
    - deviations from intended conditions of use, e.g., releases or higher than intended releases to water, air, or other media;[90]
    - potential domestic production of a chemical whose manufacturer only intends to import the substance (raising potential for domestic worker exposure and releases from manufacturing/ processing sites);
    - any potential uses identified in patent searches;
    - any known uses of the PMN substance in other countries; and
    - attributes of the chemical itself – particularly physical-chemical attributes – in order to determine, for example, how readily it will move through or build up in the environment and biota or contaminate environmental media, and how

[89] TSCA section 3(4) provides the definition of "conditions of use," which does not provide any basis for separately (temporally or otherwise) considering reasonably foreseen vs. intended conditions of use; both are relevant to understanding the future risk posed by a new chemical once it is on the market, since both may occur during the same period of time or expose the same individuals or groups. 15 U.S.C. § 2602(4). TSCA section 5(a)(3) in turn specifies the requirement to conduct the review and make the determination for the new chemical under its conditions of use. 15 U.S.C. § 2604(a)(3).

[90] Existing SNUR regulations illustrate how EPA already considers deviations from intended conditions of use to identify significant new uses – that same approach could be applied to identify reasonably foreseen conditions of use.

easily the contaminated environment can be remediated (all critical factors to determine the risks from downstream conditions of use).

C. EPA's Reviews of New Chemicals and Significant New Uses Need to Assess Risk to Vulnerable Subpopulations

EPA should address Congress' key TSCA reform requiring EPA to assess whether a new chemical or new use of a chemical poses an unreasonable risk to vulnerable subpopulations.

With respect to workers:

- EPA should integrate into its regulations its key worker protection policies the following:
  - EPA should codify its 2021 policy indicating it will not assume workers use and are adequately protected by personal protective equipment ("PPE") as a basis for dismissing or minimizing identified hazards to workers.[91] EPA should never assume that workers can and will use PPE, and should certainly consider lack of its use to be reasonably foreseen. Nor should EPA ever assume for a new chemical that the hierarchy of controls ("HOC") is in place for workplaces engaged in activities involving that chemical.
  - EPA should codify the HOC. The HOC is a basic tenet of industrial hygiene and is a longstanding foundational element of the Occupational Safety and Health Administration's ("OSHA") workplace safety policy[92] and of the National Institute for Occupational Safety and Health's ("NIOSH") workplace safety guidance.[93]
  - In addition, EPA should not assume that compliance with OSHA regulations will mitigate TSCA unreasonable risks, as the Agency unfortunately continues to do.[94]
- EPA should codify the requirement to assess the risks of a new chemical across its entire lifecycle, recognizing that exposure and risks to vulnerable subpopulations can occur at any stage of the lifecycle of a chemical or products containing a chemical. For example, releases directly from manufacturing facilities or after disposal of products may lead to exposures.

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[91] EPA," Important Updates on EPA's TSCA New Chemicals Program," March 29, 2021, https://www.epa.gov/chemicals-under-tsca/important-updates-epas-tsca-new-chemicals-program.

[92] *See* OSHA, "Chemical Hazards and Toxic Substances: Controlling Exposure," https://www.osha.gov/chemical-hazards/controlling-exposure.

[93] *See* NIOSH, "Workplace Safety & Health Topics: Hierarchy Of Controls," https://www.cdc.gov/niosh/topics/hierarchy/.

[94] For example, see EPA, EPA Sanitized TSCA Section 5 Order for a New Chemical Substance, Premanufacture Notice (PMN) Numbers: P-21-0144-0147, P-21-0148-0150, P-21-0152-0154, P-21-155-0158 and P-21-0160-0163, Submission Dates: 06/07/2021, 06/07/2021, 06/14/2021,06/08/2021, and 06/14/2021. Received 08/23/2022.

With respect to fenceline communities, EPA should routinely assess fenceline community exposures to new chemicals from intended as well as reasonably foreseen conditions of use, via all pathways and routes.

In assessing risks to vulnerable subpopulations, including fenceline communities, EPA needs to account for the potential for such groups to be subject to combined/multiple exposures to provide a more accurate picture of the risks these subpopulations face from the new chemical:

- EPA should combine dermal, inhalation, and oral exposures to the same subpopulation when assessing exposure and risk.
- EPA must evaluate combined exposures from multiple sources/uses, including increased exposure due to:
    - expansion of a chemical's production/uses over time;
    - additional companies manufacturing/processing/using/disposing of a chemical;
        - This includes additional exposures arising from approval of a SNUN, which must be evaluated in combination with those conditions of use in the original PMN;
    - occupational and consumer exposures, as well as general population;
    - increased exposures to fenceline communities;
    - non-TSCA uses of the new chemical ("background exposures");
    - other sources of exposure to the same byproducts or impurities associated with the new chemical (e.g., dioxins) ("background exposures"); and
    - consideration of cumulative exposures to similar chemicals that have the potential to cause the same or similar toxic endpoint.[95]

Finally, EDF appreciates the intent behind EPA's proposed addition of "overburdened communities" to its regulatory definition of "potentially exposed or susceptible subpopulation."[96] The subpopulations listed in TSCA's definition of the term (section 3(12)) are clearly only examples (the list is preceded by "such as"), and EPA has ample authority to expand the list in its regulatory definition. However, we have several concerns about EPA's proposed inclusion of the adjective "overburdened." First, in the list of example subpopulations, only "communities" is modified by any adjective, let alone the adjective "overburdened," which is not defined. All workers warrant consideration as potentially exposed or susceptible, and so should all communities. We do not see any basis to narrow the scope of only this term, which deviates from the parallel construction of the statutory list.

We also believe "overburdened" – especially the "over" part of the adjective – is setting too high a bar. Potential exposure or susceptibility greater than the general population – terms that already apply to each listed example subpopulation – is what the statute says. Would application of this

[95] Workers, fenceline communities, and consumers are often exposed to multiple chemicals that cause similar harms. For example, workers who use diisocyanates are often exposed to multiple diisocyanates, fenceline communities are exposed to multiple PFAS, and consumers can be exposed to multiple flame retardants and plasticizers (e.g., trimellitate esters).

[96] Proposed 40 C.F.R. § 720.3(mm).

additional term require EPA to show more, e.g., that the burden on a community exceeds some threshold? Such a test is not applied to any of the other example subpopulations.

For these reasons, EPA should not use "overburdened" and instead just add "communities" to the list. All of the other examples (infants, etc.) merely describe a group of individuals that may be more susceptible or exposed, so adding the term "communities" is in parallel with the other group listings and should/need not be further qualified.

D. EPA Needs to Provide Public Notice of and Access to "Not Likely" Determinations

EPA has indicated in the preamble of the proposed rule that notice of EPA's issuance of a "not likely" determination is only provided to the submitter of the subject notice, not the public.[97] It is notable that providing such notice to submitters, and only submitters, is not addressed in TSCA. EPA's regulations need to address and provide for timely public access to the "not likely" determination notices provided to submitters, or at least specify a maximum length of time, which should be as short as possible, between EPA reaching such a determination and notifying the submitter and the subsequent public notice. TSCA section 5(g) requires that EPA publish in the Federal Register a public statement of the finding "as soon as practicable before the expiration of such period [presumably, the applicable review period]"; it is not clear that EPA is always doing so. That TSCA provision also notes that publication of the statement is not a prerequisite to commencement of manufacture by the submitter. EPA should codify the timing requirement for public notice; TSCA provides no basis for submitters to know the outcome of EPA's review before the public is informed.

E. EPA's Regulations Need to Include Requirements Relating to Significant New Use Rules ("SNURs")

EPA should codify several new provisions and make changes to existing provisions to align them with the 2016 reforms made to TSCA.

First, EPA should codify Congress' 2016 requirement that a significant new use rule ("SNUR") must be promulgated following issuance of a section 5(e) or section 5(f) order, or that EPA must publish an explanation of why a SNUR is not needed.[98] The regulations should also specify a deadline for the finalization of the SNUR, which should be as soon after issuance of the order as possible.

Second, EPA should modify its existing regulation at 40 C.F.R. § 721.160(b)(1) to add "reasonably foreseen conditions of use" to those that EPA may include in SNURs as significant new uses. For a number of years, EPA has often considered reasonably foreseen uses in issuing

[97] 88 Fed. Reg. at 34104.

[98] 15 U.S.C. § 2604(f)(4) ("TSCA section 5(f)(4)").

new chemical SNURs,[99] such as when EPA includes "use in a consumer product" or "particle size less than 1 micron" as a significant new use, even when the use was not included in the premanufacture notice, before the 2016 reforms to TSCA EPA was not mandated to do this. EPA should codify that practice, which is consistent with the requirements of amended TSCA.

EPA should also codify a requirement that when reviewing a significant new use notice ("SNUN"), EPA must consider reasonably foreseen conditions of use related to the intended condition(s) of use that are notified by the submitter of the SNUN, particularly given there may be reasonably foreseen uses in addition to those identified when EPA promulgated the SNUR.

Third, EPA cannot rely on its issuance of a SNUR (or its intent to issue a SNUR) as a basis for issuing a "not likely" determination. This illegal and unhealth-protective practice was routine under the previous administration, and EDF provided detailed legal, scientific, and policy critiques of it.[100] In March 2021, EPA announced it would cease this practice.[101] However, this policy decision needs to be incorporated into EPA's new chemicals regulations lest it be able to be reversed in the future without notice or potentially without recourse. EPA should codify a prohibition on any reliance on SNURs as a basis to issue "not likely" determinations even for chemicals or new uses that EPA finds may present unreasonable risk.

Finally, we urge EPA to make some significant modifications to its current provisions that generally exempt articles from coverage under SNURs (including TSCA Section 5(a)(5), added by the 2016 amendments):

1. EPA should revoke the exemption applicable to processing or import of a chemical as part of an article (40 C.F.R. § 721.45(f)) from its SNUR regulations.
    - While EPA currently has authority to revoke the exemption on a case-by-case basis, and has done so in a number of SNURs, the presumption behind the exemption is flawed: "that people and the environment will generally not be exposed to substances in articles."[102]

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[99] EPA has also considered reasonably foreseen uses when issuing SNURs for existing chemicals, including so-called "dead-chemical" SNURs. *See*, for example, EPA, "Significant New Use Rules on Certain Chemical Substances (22-1.5e)," 87 Fed. Reg. 74072, December 2, 2022, https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0847.

[100] *See*, for example, EDF, "Comments on Updated Working Approach To Making New Chemical Determinations Under the Toxic Substances Control Act (TSCA)," EPA–HQ–OPPT–2019–0684, February 18, 2020, sections 3.B and 3.C, https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0684-0013.

[101] *See* EPA, "Important Updates on EPA's TSCA New Chemicals Program," March 29, 2021, https://www.epa.gov/chemicals-under-tsca/important-updates-epas-tsca-new-chemicals-program.

[102] EPA, "Significant New Uses of Chemical Substances; Certain Chemicals," 49 Fed. Reg. 35011, 35014, Sept. 5, 1984, https://www.govinfo.gov/content/pkg/FR-1984-09-05/pdf/FR-1984-09-05.pdf.

- EPA itself has noted that our knowledge of the potential for chemical exposures from articles has evolved greatly since the exemption was created (in 1984) and that the rationale the agency provided for it at that time was "minimal."[103]
- The legislative history of TSCA Section 5(a)(5), added by the 2016 amendments, makes clear the provision was not intended to set a high bar for EPA to require notification of processing or import of a chemical as part of an article, and that EPA needs to have clear authority to review – and regulate as necessary – such processing or import.

2. In deciding whether to require notification for articles, EPA need not and should not differentiate among categories or types of articles based on how the chemical substances are contained in the articles.
    - Nothing in TSCA Section 5(a)(5) compels or necessitates EPA to do so. It only requires EPA to affirmatively find a "reasonable potential for exposure to the chemical substance from the article."
    - The Trump EPA's 2020 PFAS SNUR inappropriately narrowed the category of PFAS-containing articles subject to the SNUR from that originally proposed in 2015 to include only those where PFAS is present in a surface coating, ignoring evidence in the record demonstrating potential for exposure to PFAS when present in an article other than in a surface coating.
    - The 2015 proposal appropriately acknowledged that exposure may result at downstream stages of the lifecycle due to "aging, wear, and disposal of products containing them," processes that would act to expose and release chemicals present in articles in ways other than just in coatings on their surfaces.
3. When subjecting a chemical to a SNUR, EPA should generally require notification of the processing or import of the chemical as part of an article, barring a compelling rationale and evidence bases for not doing so.
    - The purpose of a SNUR is to provide EPA with an opportunity to review a significant new use if there a change in the magnitude, type and duration of exposure and determine whether there is a potential unreasonable risk from such a use, and if so, to regulate the use.
    - EPA should not pre-judge whether there is in fact significant exposure (as opposed to merely a reasonable potential for exposure) to a chemical from an article by excluding such a use from a SNUR; to do so would mean EPA could not obtain and review information on:
        - the precise nature of the article and its lifecycle,
        - the form and manner in which the chemical is added to and present in the article, and
        - how the product is handled during all stages of its lifecycle, including potential exposures and risks from recycling and disposal as well as

[103] EPA, "Benzidine-Based Chemical Substances; Di-n-pentyl Phthalate (DnPP); and Alkanes, C12-13, Chloro; Significant New Use Rule," 79 Fed. Reg. 77898, Dec. 29, 2014, https://www.govinfo.gov/content/pkg/FR-2014-12-29/pdf/2014-29887.pdf.

production and use, and to vulnerable subpopulations including workers and fenceline communities.

EPA does not generally have such information, and the very purpose of a SNUR is for EPA to be able to get that information through the notification and review requirements.

- Similarly and for the same reasons, EPA should not set a *de minimis* threshold level of a subject chemical in an article that would trigger notification because it cannot determine prior to obtaining information whether the exposures are truly *de minimis*.

4. Should EPA nevertheless decide to retain the revocable article exemption in the current regulation (40 C.F.R. § 721.45(f)), it should explicitly incorporate the factors discussed above to ensure that the exemption will be revoked whenever warranted and that the bar for doing so is low, and will be consistent with TSCA's requirement that EPA merely find there is a "reasonable potential for exposure" to a chemical from an article to require notification. Specifically, EPA should make clear in its regulation that it will, in determining whether the exemption should apply:
    - not pre-judge whether there is in fact significant exposure to a chemical from an article or set a *de minimis* threshold level of a subject chemical that would trigger notification;
    - not differentiate among categories or types of articles based on how the chemical substances are contained in the articles (e.g., assume there will not be exposure other than from surface coatings);
    - consider the entire lifecycle of the chemical and article, including downstream activities and processes that could lead to the release of and exposure to the chemical; and
    - consider potential exposures of and risks to vulnerable subpopulations, including fenceline communities and workers.

F. EPA's Regulations Need to Include Additional Requirements Relating to New Chemical Exemptions

EDF supports EPA's regulatory amendments that require EPA's approval of certain new chemical exemption applications before companies can begin to manufacture the subject chemicals.[104] (This is in line with TSCA sections 5(h)(1), (4), and (5), which give EPA the authority to grant exemptions from only certain of the requirements of section 5(a), and therefore to apply other section 5(a) requirements to exemption applications, including the requirement for EPA to review and make a determination on the new chemical before manufacture.) However, EPA only applies this amendment to low volume and low release and exposure exemption applications; EPA should extend this requirement to all new chemical exemption applications, including those for the test marketing exemption, the byproduct exemption, and any additional exemption the Agency provides under TSCA section 5(h)(4). EPA should also include a

[104] *See* Proposed 40 C.F.R. § 732.50(g)(2).

requirement in the final regulations that EPA provide public notice of its determinations and actions, not just notification to the company submitters.

V. NO PFAS SHOULD BE ELIGIBLE FOR THE LOW VOLUME AND LOW RELEASE/EXPOSURE EXEMPTIONS

A. EPA is Correct to Make PFAS Categorically Ineligible for Low Volume and Low Release/Exposure Exemptions

We commend EPA for proposing to make PFAS categorically ineligible for low volume and low environmental releases and human exposure exemptions ("LVE" and "LoREX") under TSCA. This action follows calls in a 2021 petition to EPA sent by us and other organizations to disallow new chemical notice exemptions for PFAS given the chemical class's ubiquitous presence in the environment, animals, and humans, as well as their wide variety of health harms.[105] While EPA had previously suggested in an April 2021 press release that it "generally expects that pending and new LVE submissions for PFAS would be denied,"[106] the codification of ineligibility will improve consistency and efficiency in exemption reviews and increase predictability for interested stakeholders. Further, this is well within EPA's authority. The Agency has discretion to grant exemptions only where the chemical substances will not present an unreasonable risk to human health or the environment.[107] Scientific evidence demonstrates the many risks that PFAS pose to human health and the environment as a category – so the Agency has the statutory authority to make these dangerous chemicals ineligible for the discretionary exemptions.

B. EPA Should Categorically Revoke Existing PFAS Low Volume and Low Release/Exposure Exemptions

While we appreciate EPA's efforts to address PFAS LVEs and LoREXs in this rulemaking, we are disappointed that EPA did go further and categorically revoke these existing exemptions. In our second petition to EPA on this matter, sent in 2022, we and other groups urged EPA to revoke existing exemptions for PFAS given that the weight of the scientific evidence is unequivocal that PFAS, even in very small quantities, pose a risk of cancers, immune system suppression, cardiovascular diseases, as well as human development harms and liver disease in children. Cumulative exposure to PFAS increase the risks to, and disproportionately impact, potentially exposed or susceptible subpopulations such as nursing mothers, women of reproductive age, and communities near where PFAS are manufactured, processed, used, and

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[105] Earthjustice, et al., "Petition to The United States Environmental Protection Agency: To prohibit the use of certain exemptions to the premanufacture notice requirements of the Toxic Substances Control Act for per- and polyfluoroalkyl substances (PFAS)," April 27, 2021, https://earthjustice.org/wp-content/uploads/pfas_pmn_exemptions_petition_04-27-2021.pdf.

[106] EPA, "EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market," April 27, 2021, https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

[107] 15 U.S.C. § 2604(h) ("TSCA section 5(h)").

disposed. Further PFAS bioaccumulate and are extremely persistent, mobile in the environment.[108]

As a result of the well-established harms that PFAS pose to human health and the environment, EPA cannot continue to conclude that PFAS "will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation," which is the finding that is required for an LVE or LoREX application to satisfy TSCA.[109] By continuing to allow the manufacture and use of PFAS that have not undergone the full PMN review process, while simultaneously relying on ineffective voluntary programs that fail to meaningfully limit the manufacture, processing, use, and disposal of PFAS LVEs and LoREXs, EPA is violating TSCA, its own regulations, and the Administrative Procedure Act.

In addition to the arguments laid out in our 2022 petition, EPA itself has made the case for revoking these exemptions, including statements such as the following:

- "Due to the scientific complexities associated with assessing PFAS, and the hazard potential associated with various sub-classes of PFAS, it is challenging to conduct an appropriately robust review of LVE requests for PFAS in the 30 days the regulations allow,"[110]
- "Given the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, an LVE submission for a PFAS is unlikely to be eligible for this kind of exemption under the regulations,"[111] and
- "Under the existing regulations at 40 C.F.R. 723.50(h)(2), at any time after EPA approves an LVE or LoREX notice, EPA can determine that manufacture of the new chemical substance does not meet the exemption criteria."[112]

Given that the Agency has demonstrated that PFAS do not meet the LVE or LoREX criteria, EPA must revoke existing PFAS LVEs and LoREXs and require companies that wish to continue manufacturing these substances to submit a PMN for a full safety review, because EPA cannot continue to find that PFAS will not present an unreasonable risk. Doing this would "allow the agency additional time to conduct a more thorough review through the pre-manufacture notice review process and, as appropriate, put measures in place to mitigate the potential risk of

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[108] Earthjustice, et al., "Petition to The United States Environmental Protection Agency: To revoke the approval of approximately 600 per- and polyfluoroalkyl substances (PFAS) that were granted through low-volume or low-release and low-exposure exemptions to the premanufacture notice requirements of the Toxic Substances Control Act," October 13, 2022, https://earthjustice.org/wp-content/uploads/pfas_revocation_petition_submitted.pdf.

[109] 15 U.S.C. § 2604(h)(4) ("TSCA section 5(h)(4)").

[110] EPA, "EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market," April 27, 2021, https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

[111] *Id.*

[112] 88 Fed. Reg. at 34113.

these chemicals"[113] – a stated goal of EPA's policy changes "to prevent unsafe new PFAS from entering the market."[114]

C. EPA Should Adopt the OECD PFAS Definition

EDF urges EPA to modify its definition of what constitutes a PFAS and adopt a definition that is consistent with that used by other authoritative bodies in the United States and around the world, such as the Organization for Economic Cooperative Development (OECD).[115] The application of the proposed definition to this rulemaking may result in the exclusion of potentially public health relevant PFAS.

Furthermore, given that it is more effective – including cost effective – to assess and mitigate risk from new PFAS *before* they enter the market, it would be appropriate to adopt a more widely recognized definition, such as the OECD PFAS definition, to ensure that all PFAS are ineligible for these exemptions and must go through a comprehensive safety review through the PMN process, rather than assuming that certain PFAS may not pose a risk. Certainly, this is warranted given the history of PFAS and the numerous PFAS approvals EPA has issued for chemicals that have contaminated us and our environment.

D. EPA Should Consider Excluding Other Potential High-risk Chemical Categories from Eligibility for LVE and LoREX

Moving forward, EDF encourages EPA to consider whether other high-risk chemical categories should also be ineligible for LVEs or LoREXs. In the 1982 proposed rule in which EPA proposed to grant a TSCA section 5(h)(4) exemption from the requirements of section 5(a)(1)(A) for companies that manufacture certain new site-limited intermediates in any quantity or certain other new chemical substances in quantities of 10,000 kg or less per year, EPA requested comment on an approach suggested by the Dyes Environmental and Toxicology Organization, Inc (DETO) to exclude from exemption eligibility certain high-risk chemical categories.[116] Under this approach, EPA would identify the list of potential high-risk categories based on chemical structure. Several commenters supported this approach. However, EPA chose not to

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[113] EPA, "EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market," April 27, 2021, https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

[114] *Id.*

[115] OECD, "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance," 2021, https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=en.

[116] EPA, "Premanufacture Notification; Proposed Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000 Kg or Less Per Year; Proposed Rule," 47 Fed. Reg. 33896, August 4, 1982, https://archives.federalregister.gov/issue_slice/1982/8/4/33856-33919.pdf#page=41.

finalize this approach, stating that it would be resource intensive.[117] EDF recommends that EPA consider this approach as part of a supplemental proposed rule or a future rulemaking. Given EPA's experience in reviewing thousands of PMNs, LVEs, and LoREXs since 1985, it should be much less resource intensive to identify potentially high-risk categories of chemicals than it was 40 years ago. The existence of these categories will provide more transparency for the regulated community and other stakeholders. Further, it would be more in keeping with the statutory standard of section 5(h)(4), which limits exemptions to new chemical substances that will not present an unreasonable risk.

VI. EPA SHOULD MAKE ALL PBT CHEMICALS INELIGIBLE FOR THE LOW VOLUME AND LOW RELEASE/EXPOSURE EXEMPTIONS

EDF supports excluding PBT chemicals from eligibility for TSCA section 5(h)(4) exemptions. However, EPA's proposal must be modified: all PBTs should be excluded from eligibility from section 5(h)(4) exemptions, not just the subset of PBTs to which EPA refers. PBT chemicals are of special concern because of their ability to build up in the environment and in people and other organisms. Even small releases of these longer-lived toxic chemicals that can bioaccumulate have the potential to presents risks to human health and the environment. Given this concern about PBTs, in 1999 EPA issued a TSCA section 5 policy statement, "Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances: Policy (1999 PBT Policy)," that identified persistence and bioaccumulation criteria for two tiers of PBTs, a testing strategy for both tiers of PBT chemicals, and the evaluation process for both tiers of new PBT chemical substances.[118]

In this Federal Register notice, EPA stated that "[t]his policy statement is important in our new chemical assessment and TSCA regulatory programs, and represents the first formal statement of national policy regarding new chemical ''persistent organic pollutants.'' Under our domestic program, the policy statement provides guidance criteria for persistence, bioaccumulation, and toxicity for new chemicals and advises the industry about our regulatory approach for chemicals meeting the criteria."[119]

A. EPA Should Codify the Actual 1999 PBT Policy

In choosing to exclude from eligibility for the LVE and LoREX only a subset of what the 1999 PBT Policy identifies as PBTs, EPA incorrectly states that it is codifying this policy. EPA further mischaracterizes the policy as generic and states it is also codifying its "long-standing practice"

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[117] EPA, "Premanufacture Notification; Proposed Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000 Kg or Less Per Year; Final Rule," 50 Fed. Reg. 16477, April 26, 1985, https://www.govinfo.gov/content/pkg/FR-1985-04-26/pdf/FR-1985-04-26.pdf.

[118] EPA, "Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances," 64 Fed. Reg. 60196, November 4, 1999, https://www.govinfo.gov/content/pkg/FR-1999-11-04/pdf/99-28888.pdf.

[119] *Id.* at 60196

that considers PBTs "with anticipated environmental releases and potentially unreasonable exposures." What EPA characterizes as its "long-standing practice" is neither a continuously "long-standing practice" nor consistent with the 1999 PBT Policy.[120]

In pointing to the Agency's 1999 PBT Policy, EPA has mischaracterized it by stating that it provides only "generic guidance regarding how it determines the PBT status of chemical substances" and that "the policies and science used to ascribe discrete scores (i.e., 1–3) to the persistence, bioaccumulative potential, and toxicity of a particular chemical substance are based on the available data and made on a case-by-case basis."[121] In contrast to EPA's claim, even a cursory glance at the 1999 PBT Policy makes clear that EPA did not provide "generic guidance" on how EPA identified PBT chemicals. Rather, it provides clear, explicit, and discrete criteria for identifying chemicals that are persistent and bioaccumulative, as well as very persistent and very bioaccumulative (vPvB) toxic chemicals. The Agency's criteria for identifying PBT and vPvBT chemicals underwent notice and comment rulemaking, and as explained in EPA's response to comments, the criteria for the higher tier PBTs are consistent with the criteria of the Stockholm Convention on Persistent Organic Pollutants.[122] The criteria for the lower tier PBTs are consistent with the criteria adopted by other international authoritative bodies.[123]

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[120] Indeed, from 2014 to 2017, any LVE exemption application that was identified as meeting the criteria of the 1999 PBT policy was required to be raised to the-then EPA Chemical Control Division director. (This procedure was reflected in a 2017 New Chemical Program SOP.) Essentially all were denied because they were PBTs. There was no determination of "potentially unreasonable exposures." Thus, the statement that this was a "long-standing practice" is factually incorrect.

[121] 88 Fed. Reg. at 34115.

[122] EPA, "Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances," 64 Fed. Reg. 60196, November 4, 1999, https://www.govinfo.gov/content/pkg/FR-1999-11-04/pdf/99-28888.pdf. "The proposed TSCA PBT category has been provided to the Criteria Expert Group (CEG) established at the first session of the Intergovernmental Negotiating Committee (INC) for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants, in accordance with the mandate given by the Governing Council of the United Nations Environment Programme (UNEP) in paragraph 9 of its decision 19/13 C (http://irptc.unep.ch/pops/gcpops¥e.html). The CEG is an open ended technical working group with a mandate to present to the INC proposals for science-based criteria and a … Note that the CEG, at the October 26–30, 1998 Bangkok meeting described in Unit II.B. of this document, developed indicative numeric values as bracketed criteria text which included persistence of 2 vs. 6 months in water and log Kow of 4 vs. 5 (equivalent to a BCF of approximately 1,000 vs. 5,000, respectively).

[123] *Id.* at 60199. "As outlined in EPA's recent proposal to lower the reporting thresholds for PBT chemicals that are subject to reporting under section 313 of EPCRA (64 FR 688; January 5, 1999), similar values have been proposed by several authorities, including the Ontario, Canada Ministry of Environment and Energy (MOEE) for its Candidate Substances List for Bans or Phaseouts (MOEE, 1992, see Unit VI.10.); the Canadian initiative for Accelerated Reduction/Elimination of Toxics (ARET) (ARET, 1995 and ARET, 1994, see Unit VI.11. and 12.); the International Joint Commission (IJC)'s Great Lakes Water Quality Agreement (GLWQA) (IJC, 1993, see Unit VI.13.); and the United Nations Economic Commission for Europe Convention on Long-Range Transboundary Air Pollution (UNECE LRTAP),

The "specific identification criteria" and associated processes for use in evaluating new chemical PBT substances EPA adopted are shown in the following excerpt (see Fig. 1 below) from the 1999 PBT Policy.[124] None of the specific criteria in the 1999 PBT Policy refers to "unreasonable exposures." The 1999 PBT Policy considers and establishes criteria for the persistence and bioaccumulation of the new chemical, not criteria for exposure. EPA also fails to note that the 1999 PBT Policy discusses the specific types of testing that would be considered for both tiers of PBT chemicals and the regulatory approaches for these two tiers of PBT chemicals.

which did adopt 2 months as the persistence criterion of record for water (UNECELRTAP, 1998, see Unit VI.14.)."

[124] EPA, "Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances," 64 Fed. Reg. 60196, November 4, 1999, https://www.govinfo.gov/content/pkg/FR-1999-11-04/pdf/99-28888.pdf.

Fig. 1 Criteria from EPA's 1999 PBT Policy

IV. Final TSCA New Chemicals Program Policy for PBT Chemical Substances

A. Evaluation Criteria and Process for New PBT Chemical Substances

EPA is adopting the following specific identification criteria and associated process for use in evaluating new chemical substances.

NEW CHEMICALS PROGRAM PBT CATEGORY CRITERIA AND PROCESS

	TSCA Section 5(e) Action	
	5(e) Order Pending Testing/Significant New Use Rule (SNUR)[1]	5(e) Ban Pending Testing[2]
Persistence (transformation half-life).	> 2 months	> 6 months
Bioaccumulation (Fish BCF or BAF)[3].	≥ 1,000	≥ 5,000
Toxicity	Develop toxicity data where necessary[4].	Develop toxicity data where necessary[4]

[1]Exposure/release controls included in order; testing required.
[2]Deny commercialization; testing results may justify removing chemical from "high risk concern".
[3]Chemicals must also meet criteria for MW (< 1000) and cross-sectional diameter (< 20Å , or < 20×10^{-8} cm).
[4]Based upon various factors, including concerns for persistence, bioaccumulation, other physical/chemical factors, and toxicity based on existing data.

Further, EPA states that "the policies and science used to ascribe discrete scores (*i.e.*, 1–3) to the persistence, bioaccumulative potential, and toxicity of a particular chemical substance are based on the available data and made on a case-by-case basis." While of course EPA considers each new chemical and any available data on a case-by-case basis, that does not negate the PBT policy criteria. Further, EPA's internal rankings (using 1, 2 and 3) of persistence and bioaccumulation are simple numerical rankings based on the criteria specified in the 1999 PBT Policy. They are not unique. The use of these numerical rankings is not specific to persistence and bioaccumulation. EPA also uses 1, 2, and 3 to rank human health toxicity and ecotoxicity.

The PBT policy is a TSCA section 5(e) regulatory and testing strategy. It does not include any exemptions, indicating EPA's intent to assess PBT chemicals under section 5(e). The PBT policy consists of two primary components: regulation under a section 5(e) consent order and testing requirements (trigger or ban pending testing, depending on the extent of persistence and bioaccumulation). Neither of these core components of the PBT policy are included in EPA's new chemicals proposal for PBTs.

To codify the 1999 PBT Policy, EPA should make all PBT chemicals categorically ineligible for LVEs and LoREX, in addition to other exemptions, consistent with the Agency's 1999 PBT Policy. All PBTs should be ineligible for new chemical notice exemptions, regardless of intended releases and preliminary estimated exposures.

B. EPA Has Not Proposed to Codify its 1999 PBT Policy, Despite Claiming to Do So

EPA claims to be codifying its 1999 PBT Policy in this rulemaking[125] but has in fact proposed regulatory text that is inconsistent with the Agency's PBT policy, and has omitted additional amendments needed to meaningfully codify the policy. Under the guise of codifying the 1999 PBT Policy, it is actually codifying internal procedures that are inconsistent with the 1999 PBT Policy.

For one, EPA is introducing a new concept of "unreasonable exposure" that does not appear in the 1999 PBT Policy. The 1999 PBT Policy covers all PBTs as defined by discrete persistence and bioaccumulation levels. In contrast, EPA's proposed amendments do not apply to "all PBT chemicals" as EPA claimed in its press release,[126] but rather only to those that have "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." These exposure criteria are not mentioned in the Agency's 1999 PBT Policy. As such, it appears EPA created the concept of "unreasonable exposure" to narrow the scope of PBT chemicals subject to this rulemaking, without providing an accompanying definition or explanation.

Additionally, EPA has not proposed to make PBT chemicals ineligible for all new chemical notice exemptions as its policy indicates. EPA's 1999 PBT Policy demonstrates the Agency's intent to review PBT chemicals under section 5(e), given their status as chemicals of special concern. Indeed, exemptions for PBTs are not mentioned once in the Agency 1999 PBT Policy.

EPA has also failed to propose amendments to the PMN regulations that would implement the bulk of the policy; namely, its PMN regulatory and testing scheme for new PBT chemicals. The policy outlines regulatory and testing requirements based on discrete physical-chemical property cut-off values. Neither regulation under section 5(e) nor testing, based on the criteria established

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[125] EPA, "Biden-Harris Administration Proposes Reforms to New Chemical Review Process to Protect Public Health, Promote Efficiency and Consistency," May 16, 2023, https://www.epa.gov/newsreleases/biden-harris-administration-proposes-reforms-new-chemical-review-process-protect.

[126] *Id.*

in the 1999 PBT Policy, are included in this proposed new chemical rulemaking. Additional amendments to the PMN regulations 40 C.F.R. 720 are necessary to effectively codify the regulatory and testing regime for PBT chemicals set forth in the Agency's 1999 PBT Policy.

Given the specificity of the persistence and bioaccumulation criteria, the types of testing for persistence and bioaccumulation that would likely be required, the comments and responses on the PBT criteria and the policy's regulatory and testing requirements for the different subsets of PBTs, it is incorrect to suggest that the PBT policy provides only "generic guidance" for identifying PBT chemicals.

We are concerned about the inconsistencies between what EPA has proposed and the Agency's 1999 PBT Policy. Because of these inconsistences, omissions, and mischaracterizations, we argue that EPA has not proposed to codify its 1999 PBT Policy, despite claiming to do so. Rather, under the guise of codifying the 1999 PBT Policy, the Agency is actually codifying internal procedures that are inconsistent with the 1999 PBT Policy.

The Supreme Court has stated that an agency that changes its policy must "display awareness that it is changing position" and "show that there are good reasons for the new policy."[127] Further, an "[u]nexplained inconsistency" in agency policy can be "a reason for holding an interpretation to be an arbitrary and capricious change from agency practice,"[128] and "an arbitrary and capricious regulation of this sort is itself unlawful."[129] In order to protect its rule, EPA should acknowledge that its past practice has not conformed with the 1999 PBT Policy, and should codify its 1999 PBT Policy with the proposals EDF includes below.

C. EPA Should Make all PBT Chemicals Categorically Ineligible for Low Volume and Low Release/Exposure exemptions, in Addition to Other New Chemical Exemptions, Consistent with the Agency's PBT Policy

In this new chemical rulemaking, EPA proposed to make any "PBT chemical substance with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms" ineligible for LVEs and LoREXs.

While EDF appreciates EPA's efforts to address PBT chemicals in the context of new chemical notice exemptions, we are disappointed that EPA has only proposed to address a subset of the relevant exemptions – LVEs and LoREXs – and has created problematic criteria limiting which PBTs will be ineligible for these exemptions.

As introduced above, EPA has proposed to narrow the universe of PBT chemicals ineligible for LVEs and LoREXs from all PBT chemicals to any "PBT chemical substance with anticipated

[127] *FCC. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[128] *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U.S. 967, 981-982 (2005).

[129] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016).

environmental releases and potentially unreasonable exposures to humans or environmental organisms." The proposed exposure criteria for ineligible PBT chemicals are inconsistent with both the Agency's 1999 PBT Policy, as discussed in more detail above, as well as EPA's May 2023 press release on the rulemaking. EPA states in its press release for the rulemaking that its proposed amendments to existing LVE and LoREX regulations would "ensure that *all* PBT chemicals are also ineligible for these exemptions" (emphasis added).[130] Despite this claim, the proposed amendments do not apply to "all PBT chemicals," but rather only to those that have "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms."[131]

In addition to these inconsistencies, it is unclear what EPA means by the term "unreasonable exposure." The term is not defined in the Proposed Rule, nor does it appear in the Agency's 1999 PBT Policy, scientific risk assessment literature, or media universe. It appears that EPA created this new term for purposes of narrowing the universe of PBT chemicals subject to this rulemaking without providing a clear definition of the term in the preamble or proposed regulatory text at 40 C.F.R. § 723.50(b). Given that the term is not defined, it is also unclear how "unreasonable exposure" differs from "unreasonable risk" under TSCA. EDF questions whether it is possible for the Agency to make a determination regarding potential releases and "unreasonable exposures" without first conducting an exposure and risk assessment. A determination of "unreasonable exposure" seems to necessitate a comparison of estimated exposures to a reference dose for the chemical, which represents an assessment of unreasonable risk. Finally, it is unclear how the newly created concept of "unreasonable exposures" interacts with the low volume and exposure requirements of the exemptions subject to this rulemaking.

There are additional reasons beyond policy inconsistencies and unclear terminology that argue against EPA's proposed exposure criteria for PBT LVE and LoREX ineligibility. First, EPA's exposure models typically used in the TSCA New Chemicals Program do not capture persistence and bioaccumulation well and are not well-suited for the review of PBT chemicals. EPA has more complex models, such as EXAMS and others, that can be used for this purpose. These are not typically used in the TSCA New Chemicals Program. Second, careful attention must be given to ensuring a comprehensive assessment of releases and exposures given the problematic nature of PBT chemicals at even very low levels in the environment and products. This may include an assessment of production processes, engineering controls, wastewater treatment removal efficiencies, disposal release, and more. It is unclear how EPA expects to, or whether it even can, conduct this type of comprehensive release and exposure assessment for new PBT LVEs and LoREXs in the expedited 30-day review period for these exemptions.

For the reasons discussed above, and to ensure consistency with the Agency's 1999 PBT Policy and previous statements, EDF strongly recommends that EPA remove all references to anticipated environmental releases and "unreasonable exposures" and instead categorically make

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[130] EPA, "Biden-Harris Administration Proposes Reforms to New Chemical Review Process to Protect Public Health, Promote Efficiency and Consistency," May 16, 2023, https://www.epa.gov/newsreleases/biden-harris-administration-proposes-reforms-new-chemical-review-process-protect.

[131] Proposed 40 C.F.R. § 723.50(d)(2)(ii).

all PBT chemicals ineligible for LVE and LoREXs exemptions. EPA clearly demonstrates in the preamble to this rulemaking that PBT chemicals are of special concern and meet the criteria of 40 C.F.R. § 723.50(d) for low volume and low release/exposure exemption ineligibility (i.e., serious acute or chronic effects or significant environmental effects). We urge EPA to make the entire PBT chemical category ineligible for these exemptions given the characteristics of these chemicals and the potential threat of even very small levels of release/exposure.

While we strongly recommend against it, if EPA were to move forward with any determination of "unreasonable exposure," we remind the Agency that under TSCA it must consider all intended and reasonably foreseen conditions of use across a chemical's lifecycle, and should do so in aggregate rather than in isolation. Evaluating exposure across a chemical's lifecycle is critical, especially for PBT chemicals given their ability to persist in the environment and bioaccumulate in humans and biota.

D. EPA Should Consider Making Persistent, Mobile, and Toxic (PMT) Chemicals Ineligible for New Chemical Notice Exemptions, in Addition to PBTs

Moving forward, EPA should consider whether persistent, mobile, and toxic chemicals (PMTs) should also be ineligible for LVEs, LoREXs, and other TSCA exemptions given the threat these chemicals pose to water resources.[132] The mobility of these substances "refers to the fact that they can travel long distances with water, even in the subsurface and thus are able to spread over large spatial and temporal scales."[133] Additionally, "many PMT/vPvM [very persistent, very mobile] substances are extremely difficult to remove from water resources especially when waste water is recycled for drinking water purposes," leading to increases in exposure with continuing emissions.[134]

Significant advancements in the scientific assessment and regulation of persistent, mobile, and toxic (PMT) chemicals have taken place in recent years. For example, the European Commission in its 2020 Chemical Strategy for Sustainability committed to: (1) "propose new hazard classes and criteria in the CLP [(Classification, Labeling and Packaging)] Regulation" to fully address

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[132] In 2019, the German Environment Agency developed criteria for identifying persistent, mobile and toxic (PMT) substances and very persistent and very mobile (vPvM) substances under EU Regulation REACH (EC) No 1907/2006. EPA should consult this resource as it works to systematically address PMT chemicals under TSCA. https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2019-11-29_texte_127-2019_protecting-sources-drinking-water-pmt.pdf

[133] Hale, S. E., Neumann, M., & Schliebner, I. (2022). Getting in control of persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances to protect water resources: strategies from diverse perspectives. *Environmental Sciences Europe, 34*, 22. https://doi.org/10.1186/s12302-022-00604-4.

[134] *Id.*

persistency and mobility[135] and (2) introduce "persistent, mobile and toxic and very persistent and very mobile [vPvM] substances as categories of substances of very high concern" under European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).[136] Moreover, a recent scientific analysis of substances determined to be PMT or vPvM under REACH regulation concluded that "PMT/vPvM substances cause an equivalent level of concern as PBT/vPvB substances and as such should be regulated [as substances of very high concern] under Article 57 in REACH."[137]

Given growing attention on the potential risks from PMTs and evidence that these chemicals present an equivalent level of concern as PBTs, EPA should consider designating PMT chemicals in addition to PBT chemicals as ineligible for new chemical review exemptions.

[135] In April 2023, the European Commissions amended CLP Regulation by adding PMT and vPvM chemicals as a new hazard class, among others. ECHA, "New hazard classes 2023," 2023, https://echa.europa.eu/new-hazard-classes-2023.

[136] European Commission. Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, Brussels, 14.10.2020 COM(2020) 667 final. https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0003.02/DOC_1&format=PDF, at 13.

[137] Hale, S. E., Arp, H. P. H., Schliebner, I. & Neumann, M. (2020). Persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances pose an equivalent level of concern to persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances under REACH. *Environmental Sciences Europe, 32*, 155. https://doi.org/10.1186/s12302-020-00440-4.